

**STATE OF WASHINGTON  
DEPARTMENT OF HEALTH  
ADJUDICATIVE SERVICE UNIT**

In Re: Certificate of Need Application )	
of: )	Docket No. 03-11-C-2005CN
)	
KIRKLAND DIALYSIS, LLC., )	FINDINGS OF FACT,
)	CONCLUSIONS OF LAW
Applicant. )	AND FINAL ORDER
)	
_____ )	

**APPEARANCES:**

Applicant, Kirkland Dialysis, LLC., by  
Bennett Bigelow & Leedom, P.S., per  
Stephen I. Pentz, Attorney at Law

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

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

**PRESIDING OFFICER:** John F. Kuntz, Health Law Judge

The Presiding Officer, through authority delegated to him by the Secretary of Health, conducted a hearing on March 9 – 10, 2004, in Tumwater, Washington. Kirkland Dialysis applied to establish a kidney dialysis facility and the Certificate of Need Program (the Program) denied the application. Kirkland Dialysis appealed. Program decision affirmed.

**PROCEDURAL HISTORY**

On March 26, 2003, Kirkland Dialysis applied for a certificate of need to establish a new dialysis facility in Bellevue, Washington, consisting of 12 in-center and 1 training

FINDINGS OF FACT,  
CONCLUSIONS OF LAW  
AND FINAL ORDER

kidney dialysis stations. On November 4, 2003, the Program denied the application on the grounds that it did not show need existed for a new kidney dialysis facility in east King County. Kirkland Dialysis appealed the Program's decision denying its application on November 19, 2003. DaVita applied for, and was granted, intervention on a limited basis on March 1, 2004. Prehearing Order No. 1.

The hearing was conducted on March 9 – 10, 2004.<sup>1</sup> In addition to the application record (Exhibit P-1) the Program offered two additional exhibits:

Exhibit P-2: A copy of a map of King County, Washington showing the east King County service area.

Exhibit P-3: A copy of a chart showing the application and processing schedule for kidney dialysis applications filed by Bellevue Dialysis, Kirkland Dialysis and Lake Washington.

The Program's exhibits were admitted. Kirkland Dialysis offered Exhibits A-73, A-74 and a new exhibit (an October 30, 2003 letter from Janis Sigman to Fali Sadhva and Syndey Hansen). See Prehearing Order No. 1; Exhibit 78. The Kirkland Dialysis exhibits were admitted.

The parties submitted post-hearing briefs in lieu of closing argument. Posthearing Order No. 2. The date for issuance and service of the final order pursuant to RCW 34.05.461(8) was extended. Posthearing Order No. 3. The hearing record was closed July 26, 2004.

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<sup>1</sup> A third hearing day was convened on March 11, 2004, but the parties did not introduce any other witnesses and the additional hearing time was cancelled. Posthearing Order No. 1.

## ARGUMENTS OF THE PARTIES

### Kirkland Dialysis Arguments

In support of its position Kirkland Dialysis argued:

- The appropriate end stage renal dialysis service area (service area) was King County, but it would also draw some southeast Snohomish County patients. AR at 8, 10, 15, 20, and 22.<sup>2</sup>
- Approximately twenty patients would seek to transfer to the new Kirkland Dialysis facility within the first several months of operation. AR at 11.
- King County was the appropriate service area because Dr. Tung, the nephrologist being proposed as the facility's medical director, cared for patients living in all quadrants of the county and some of those patients expressed an interest in seeking treatment at the Kirkland Dialysis facility. AR at 15.
- In addition to being a well respected nephrologist, Dr. Tung was one of the only Chinese-speaking treatment providers in King County. AR at 15.
- Under WAC 246-310-010, the service area definition must be an individual county. The Program calculated need existed for additional kidney dialysis stations in King County for the 2007 project year. AR at 301 – 302. Kirkland Dialysis was prepared to meet that need.
- Focusing on a county-wide need service area to calculate need for new dialysis stations was consistent with the WAC 246-310-280 need methodology criteria. Unlike other certificate of need regulations which did specifically provide for sub-areas (see WAC 246-310-270), the regulation here did not do so.
- Even if the WAC 246-310-010 service area definition did anticipate a service area other than an individual county documented by patient origin, the documented service area cannot be smaller than an individual county because the service area definition did not specifically provide for sub-areas (see WAC 246-310-270).
- Even if the Program could designate a smaller service area, it could not do so in the present case because it failed to document the east King County service area according to patient origin (that is, did not provide zip code information in support of its sub-area definition).

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<sup>2</sup> Pages from Exhibit P-1 are referred to using the application record (AR) page number.

## Program Argument

In support of its position, the Program argued:

- A need for an additional 31 kidney dialysis stations did exist for the 2007 project year in King County. However, the calculation of county-wide need was only the first step in determining the appropriate WAC 246-310-010 service area for analyzing the Kirkland Dialysis application.
- The WAC 246-310-010 service area definition clearly provides for a service area other than an individual county, as long as it was documented by patient origin. This included service areas which were sub-areas of an individual county. The Program determined the appropriate service area was the sub-area of east King County (an area being bordered by the Interstate 5 highway and Lake Washington). 3/9/04 RP at 54 – 55; see Exhibit P-2. When calculating need using the east King County service area, there was a negative need (or a surplus of eight stations) for the 2007 project year.
- Its interpretation of the service area definition should be accorded substantial weight, since the subject matter being interpreted falls within the Program's area of expertise. See *Bellevue Farm Homeowners Assoc. v. State Shoreline Hearing Board*, 100 Wn.App. 341 (2000).
- Previous kidney dialysis facility applications identified service areas that were sub-areas of an individual county, and those applicants calculated need based on those sub-areas. See Exhibits A-73 and A-74.
- The use of the east King County sub-area was appropriate, given the proposed location of the new Kirkland Dialysis facility (Bellevue) and that the majority of patients new to dialysis services typically dialyze at the facility closest to work or home because of convenience. AR at 303. The Program considered these factors relevant based on its experience in analyzing twenty-eight kidney dialysis applications during the period 2001 through October 2003.
- It does not bear the evidentiary burden. The applicant, Kirkland Dialysis, bears the burden of proving its service area was the correct one under evidentiary standard set forth in WAC 246-10-606. Kirkland Dialysis did not do so.
- Even if Kirkland Dialysis was correct in identifying King County as the WAC 246-310-010 service area, for purposes of the WAC 246-310-280(3) methodology calculation, the application should fail because it could not meet the WAC 246-310-280(4) utilization rate criteria. Two of the seven kidney dialysis facilities in the King County service area (Snoqualmie Ridge and Bellevue

Dialysis Center) would not operate at the 80% capacity level if the Program granted the Kirkland Dialysis application.

### **LEGAL ANALYSIS**

In applying for a license the applicant bears the burden of establishing that it meets all of the applicable criteria. WAC 246-10-606. Evidence shall be of the kind on which reasonably prudent persons are accustomed to rely in the conduct of their affairs. RCW 34.05.452(1); WAC 246-10-606.

The Department of Health implements the certificate of need program. RCW 70.38.105. It seeks to control costs by ensuring better utilization of existing health services. Health care providers must obtain a certificate of need to establish health facilities or services. RCW 70.38.105(3); see *St. Joseph Hospital and Health Care Center v. Department of Health*, 125 Wn.2d 733, 736 (1995). Kidney dialysis treatment centers are health care facilities which provide a tertiary health service, a specialized service which requires sufficient patient volume to optimize provider effectiveness, quality of service and improved outcomes of care. RCW 70.38.105(4); RCW 70.38.025(14). Public policy requires the development of health services in a planned orderly fashion, consistent with identified priorities and without unnecessary duplication or fragmentation. RCW 70.38.015(2). Here Kirkland Dialysis (a health care provider) seeks to establish a kidney dialysis treatment facility (a health care facility offering a tertiary health service).

An applicant must comply with the WAC 246-310-280 need methodology requirements, as well as the general requirements found in WAC 246-310-210 through WAC 246-310-240, to receive a certificate of need. WAC 246-310-280(1). Using data

obtained from the Northwest Renal Network (see WAC 246-310-280(2), a mathematical formula known as a methodology is used to calculate whether additional need exists for a given projection year (defined as the third year following the application).

WAC 246-310-280(3). In the present case the projection year is 2007, and the WAC 246-310-280(3) methodology calculation shows a net need will exist for 31 dialysis stations in King County in the 2007 projection year. If the need analysis ended here it would appear Kirkland Dialysis should meet the WAC 246-310-280(3) need requirement.

Before applying the WAC 246-310-280(3) methodology, it is necessary to identify the correct end stage renal dialysis service area (the service area). WAC 246-310-010 defines the service area to mean:

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.

The Program interprets the definition using a two-step approach. It first calculates whether a need exists for additionally kidney dialysis stations<sup>3</sup> in the individual county. It then determines whether another service area documented by patient origin exists and if it the correct service area for calculating need. The term “patient origin” is not defined in chapter 246-310 WAC.

Kirkland Dialysis asserts King County is the appropriate WAC 246-310-010 service area or, in the alternative, a county-sized area documented by patient origin.

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<sup>3</sup> A station is the individual site within the kidney dialysis facility where the patient receives dialysis treatment.

The Program disagrees and asserts the definition allows for an alternative service area, even one smaller than a county, as long as it is documented by patient origin.

Rules of statutory construction apply to administrative rules, particularly when the rule or regulation is adopted pursuant to express legislative authority. *Cannon v. Department of Licensing*, 147 Wn.2d 41, 56 (2002). A court's primary duty in interpreting any statute is to discern and implement the intent of the legislature, and the starting point is the statute's plain language and ordinary meaning. *State v. J.P.*, 149 Wn.2d 444, 450 (2003). Where the plain language is unambiguous (that is, when it admits only of one meaning) then legislative intent is apparent and no statutory interpretation is necessary. *State v. J.P.*, 149 Wn.2d at 450. A statute is not ambiguous simply because arguments regarding distinct interpretations of it are conceivable. See *In re Riley*, 122 Wn.2d 722 (1993). A statute or rule must be construed so that no word, clause or sentence is superfluous, void or insignificant and the language must be given its plain meaning according to English grammar usage. *State v. Raper*, 47 Wn. App. 530, 536 (1987). Words or clauses cannot be added to an unambiguous statute when the legislature does not include the language, and language may not be deleted from an unambiguous statute. *State v. J.P.*, 149 Wn.2d at 450.

As previously stated Kirkland Dialysis argues the Program must interpret the service area definition to be an individual county or at the very least to a county sized area. The WAC 246-310-010 service area definition does not support the Applicant's interpretation, as it would render "superfluous, void or insignificant" that portion of the WAC 246-310-010 definition "or other service area documented by patient origin" or

would require deleting that phrase. Had the definition ended after the language “each individual county” the position taken by Kirkland Dialysis would be persuasive. However it does not. The regulation’s language is unambiguous, as it provides for an alternative service area. A service area can be either an “individual county ...or other service area documented by patient origin.”<sup>4</sup>

Even if the WAC 246-310-010 service area definition was ambiguous, and therefore subject to statutory interpretation, Kirkland Dialysis’s position fails. Language must be given its plain meaning according to English grammar usage. *State v. Raper*, 47 Wn.App 530 (1987). A nonrestrictive clause, which is also called an independent clause, can be removed without changing the essential meaning of the sentence. *The Redbook: A Manual on Legal Style*, section 10.20 (2002) (*The Redbook*).

Nonrestrictive clauses are usually set off from the rest of the sentence by commas. *The Redbook*, section 10.20.

Kirkland Dialysis argues the language “designated by the department as the smallest geographic area for which kidney dialysis station need projections are calculated” restricts the service area definition language which immediately precedes it. DaVita (the Intervenor) argues the clause can be removed from the sentence without changing the essential meaning. The essential meaning of the definition is unchanged if the clause in question is removed. As the clause can be removed without changing the essential meaning, and is set off by commas, DaVita’s argument is more

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<sup>4</sup> The rules of statutory construction also defeats Kirkland Dialysis’ alternative argument that a service area be no smaller than a county. To achieve that interpretation would require the addition of language to give it effect (for example, “each individual county...or other county sized service area documented by patient origin.”)



persuasive. So even if the language of the rule had been ambiguous, and therefore subject to interpretation, that ambiguity would not favor the position taken by Kirkland Dialysis.

Kirkland Dialysis argues the Program failed to define “east King County” and failed to document the service area by patient origin. Kirkland Dialysis argues the analysis did not contain any reference to which zip codes were within the east King County sub-area. 3/09/04 RP at 45. As previously noted “patient origin” or “documented by patient origin” is not defined in chapter 246-310 WAC. There is no regulatory requirement to use zip code information to identify an area or sub-area. The Program points out any determination of patient origin for future patients based on patient zip code information would be impossible here because Kirkland Dialysis has no patients. For that reason it relies on a common sense interpretation of the boundaries of the east King County service area.

Under WAC 246-10-606 an applicant shall establish that its application meets all applicable criteria. Kirkland Dialysis proposed a kidney dialysis service area covering the entire county with methodology calculations showing need for that service area. It also provided information in the event east King County was the appropriate service area. It supplemented that information with methodology calculations to show need in the smaller service area at the Program’s request. The Program reviewed the application and disagreed with the Kirkland Dialysis assertion that the service area was King County. The Program determined east King County was the appropriate service area, given the location Kirkland Dialysis chose for its proposed facility and based on

the Program's previous experience using sub-areas in analyzing kidney dialysis applications in King County. The Program also reviewed the Kirkland Dialysis need methodology calculations, and substituted the 1998 – 2002 historical data rather than the 1997 – 2001 data used in the application. The Program could therefore point to the evidence in the record it used to support its decision and provided the necessary statistical information it used in reaching its decision. See *In Re: Auburn Regional Medical Center*, Docket No. 01-05-C-1052CN (February 20, 2003) at 22 – 23. (The order contains an analysis of the burden of proof versus the burden of persuasion). Kirkland Dialysis provided the evidence it argued met the burden of proof, and the Program pointed to the evidence or information it used to meet its burden of persuasion. The Program met its burden here.

Even if Kirkland Dialysis was correct in its assertion that the Program erred in defining the service area, the application still fails. An applicant must make a threshold showing that need exists under WAC 246-310-280(3). Once the applicant makes its threshold showing, it must also show it meets the WAC 246-310-280(4) criteria:

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.

This translates to a facility showing it meets the 80% utilization rate (the 748.8 dialyses per nontraining station per year) before additional stations may be added. The Program points out there are two King County facilities which count toward existing capacity that are not being utilized at the 80% utilization rate. Because Kirkland Dialysis cannot show

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that all of the relevant King County kidney dialysis facilities meet the 80% utilization rate, its application failed even if it met the need requirement.<sup>5</sup>

Based on a careful review of the record, the Presiding Officer enters the following:

## **I. FINDINGS OF FACT**

1.1 On March 26, 2003, Kirkland Dialysis applied for a certificate of need to establish a new kidney dialysis facility containing 13 stations (12 in-center stations and 1 training station) in Bellevue, King County, Washington.

1.2 Kirkland Dialysis identified the end stage renal dialysis service area as King County and parts of Snohomish County and included all zip codes in King County.

1.3 Kirkland Dialysis identified King County as the service area because Dr. Millie Tung, the Applicant's proposed medical director, cared for patients in all quadrants of King County. In addition to being a well-respected nephrologist, Dr. Tung was one of a limited number of Chinese-speaking treatment providers in the county.

1.4 In determining the number of kidney dialysis stations for the 2007 projection year, the Program initially calculated the WAC 246-310-280 need requirements using King County as the service area and projected a net need of 31 kidney dialysis stations for the 2007 projection year.

1.5 Consistent with its prior interpretation of the WAC 246-310-010 service area definition, the Program correctly analyzed that the correct service area was not the

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<sup>5</sup> The Program's analyst testified that if need could be shown then the WAC 246-310-220 – WAC 246-310-240 criteria would be satisfied. 3/9/04 RP at 116 – 117. This does not relieve Kirkland Dialysis from meeting the WAC 246-310-280(4) criteria.

entire county but a portion of the county. The Program identified the appropriate service area as east King County (an area bordered by the Interstate 5 highway and Lake Washington) based on a number of factors. These factors included experience in analyzing 28 kidney dialysis applications from 2001 through October 2003, the Bellevue location proposed by Kirkland Dialysis, and the fact that most patients new to dialysis choose to dialyze at the facility closest to them.

1.6 Having identified the correct WAC 246-310-010 service area, the Program calculated the number of kidney dialysis stations in the east King County service area for the 2007 projection year under WAC 246-310-280. The Program found a deficit need existed, that is there was a surplus of 8 kidney dialysis stations in the 2007 project year. Because of this surplus of need the Program determined the application was not consistent with the certificate of need review criteria under WAC 246-310-280(3).

1.7 Even though the Kirkland Dialysis application failed to meet the necessary need threshold criteria under WAC 246-310-280(3), the Program analyzed the application to determine whether approving the project would result in a reduction of the 80% market share requirement for any existing facility under WAC 246-310-280(4). The Program determined approval of the application would result in the reduction of the 80% market share requirement for the Snoqualmie Ridge and Bellevue Dialysis Center because these facilities had not yet reached the 80% market share capacity measurement. Sufficient kidney dialysis capacity therefore existed to serve patients in the east King County service area and approval of Kirkland Dialysis application was not consistent with the WAC 246-310-280(4) criteria.

## II. CONCLUSIONS OF LAW

2.1 The Department is responsible to implement the certificate of need program in Washington. RCW 70.38.105(1). Development of kidney dialysis facilities should be accomplished in a planned, orderly fashion and without unnecessary duplication of services. RCW 70.38.015(2). When an applicant is denied a certificate of need, it can appeal the department's denial decision. RCW 34.05.413(2); WAC 246-310-610(1). To be approved a kidney dialysis treatment center must meet the [WAC 246-310-280] standards and the review criteria under WAC 246-310-210, 246-310-220, 246-310-230 and 246-310-240. WAC 246-310-280(1).

2.2 In all cases involving an application for licensure, the applicant shall establish that it meets all applicable criteria. WAC 246-10-606. The burden of proof on the applicant is preponderance of the evidence. WAC 246-10-606. Evidence should be the kind upon which reasonably prudent persons are accustomed to rely in the conduct of their affairs. RCW 34.05.452(1); WAC 246-10-606.

2.3 The WAC 246-310-010 service area definition authorizes the use of other service areas, as long as the area could be documented by patient origin. Kirkland Dialysis did not provide sufficient evidence in its application to support its contention that King County was the service area.

2.4 Kirkland Dialysis argued the Program failed to define "east King County" and failed to document the service area by patient origin, and did not provide any reference to which zip codes were within the east King County sub-area. The terms "patient origin" or "documented by patient origin" are not defined in chapter 246-310

WAC. There is no regulatory requirement to use zip code information to identify an area or sub-area. A determination of patient origin for future patients based on patient zip code information would be impossible here because Kirkland Dialysis had no patients at the time it filed the application. The Program could rely on a common sense interpretation of the boundaries of the east King County sub-area to show where the new patients were likely to come from.

2.5 Based on information contained in the Kirkland Dialysis application, and based upon its experience in analyzing kidney dialysis applications, the Program concluded the WAC 246-310-010 service area was east King County. The Program reasoned this was the appropriate service area because of the proposed location for the Kirkland Dialysis facility (Bellevue) and given that patients new to kidney dialysis commonly choose to dialyze at a location near to their homes or work.

2.6 Additionally, the Program correctly included updated forecast information, obtained from the Northwest Renal Network, in performing the WAC 246-310-280(3) methodology calculations. This updated forecast information was not available to Kirkland Dialysis at the time it filed its application. The Program's updated information showed the existence of additional stations that were not yet operational that increased the existing capacity. This increased capacity affected the net need methodology calculations.

2.7 Even if the Program had erred in identifying the WAC 246-310-010 service area for purposes of its WAC 246-310-280(3) need calculations, Kirkland Dialysis could not show it could meet the WAC 246-310-280(4) criteria. Kirkland Dialysis was

responsible to show that all other King County kidney dialysis facilities would meet the 80% utilization rate under WAC 246-310-280(4) and it could not do so.

2.8 Because Kirkland Dialysis could not show that a need existed for its facility, and could not show that the establishment of its facility will not act to reduce the utilization rate for existing King County facilities, the application to establish a kidney dialysis facility must fail.

### III. ORDER

Based on the foregoing Procedural History, Findings of Fact and Conclusions of Law, the Certificate of Need Program determination (denying the Kirkland Dialysis kidney dialysis facility application) is AFFIRMED.

Dated this \_19<sup>th</sup>\_ day of November, 2004.

\_\_\_\_\_/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:

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

and a copy must be sent to:

Certificate of Need Program  
PO Box 47852  
Olympia, WA 98504-7852

The petition 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).