

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

In Re: Certificate of Need Decision on)	
DaVita Inc. Application to Expand)	Docket No. 06-01-C-2003CN
its Kidney Dialysis Center in)	
Federal Way, Washington, and)	AMENDED FINDINGS OF FACT,
)	CONCLUSIONS OF LAW
DaVita, Inc.,)	AND FINAL ORDER
)	
Petitioner.)	
_____)	

APPEARANCES:

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

Department of Health Certificate of Need 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's (Program) analysis and denial of a certificate of need application for an increase in stations to DaVita's existing kidney dialysis treatment facility in Federal Way. *REMAND.*

RECONSIDERATION

The Program filed a petition for reconsideration of the Findings of Fact, Conclusions of Law and Final Order. After review of the briefs and reconsideration of the evidence, the Presiding Officer modifies the Findings of Fact, Conclusions of Law and Final Order issued as follows.

**AMENDED FINDINGS OF FACT,
CONCLUSIONS OF LAW
AND FINAL ORDER**

ISSUE

Did Program correctly deny DaVita's certificate of need (CN) application pursuant to its market share analysis under WAC 246-310-280(4)?

SUMMARY OF PROCEEDINGS

During the hearing, Program presented the testimony of Program Analyst Karen Nidermayer. DaVita presented the testimony of DaVita Group Director Monica Demitor, DaVita Federal Way Dialysis Center Medical Director Yajuan He, M.D., Ph.D., DaVita Federal Way Facility Administrator Joyce Post, and Health Care Consultant Robert McGuirk.

A complete copy of Program's administrative record (AR) was admitted as Exhibit 1 (1,413 pages). Closing arguments were presented through briefs.

I. FINDINGS OF FACT

1.1 On October 6, 2004, DaVita filed an application to add ten in-center stations to its existing 15 station kidney dialysis facility known as the Federal Way Community Dialysis Center (Federal Way). Such an expansion would result in a total of 25 kidney dialysis stations.

Need for Additional Kidney Dialysis Stations

1.2 On September 27, 2005, Program issued its decision and analysis denying DaVita's application to add stations to its Federal Way facility. Program found that there was a need for additional kidney dialysis stations, but concluded under WAC 246-310-280(4) that DaVita's proposed addition would have an impermissible negative

market impact on a facility in the service area.¹ A market share impact is an estimated number of patients/dialysis treatments an existing facility will lose to the proposed new competing facility or expansion of an existing facility.

Service Area

1.3 South King County is the DaVita Federal Way facility's service area. This service area is also served by DaVita's Kent Kidney Dialysis Center (Kent) and by Northwest Kidney Centers' Auburn Regional Center (Auburn). DaVita's Kent facility has 12 kidney dialysis stations. In May 2005, Program issued the Auburn facility a CN for a seven-station addition to its existing 17 station dialysis facility.² Auburn's seven additional stations were approved but not operational at the time Program analyzed and denied DaVita's application. The Auburn facility is approximately five miles from the Federal Way facility with an estimated seven-minute drive.³ DaVita's Federal Way facility is approximately eleven miles from its Kent facility with an estimated 13-minute drive.⁴

1.4 Even with the seven-station addition at the Auburn facility, there is a growing need for additional kidney dialysis service stations in the south King County service area. Six additional stations are needed in 2006, ten additional stations will be needed in 2007, and 15 stations will be needed in 2008.

¹ Service area is a geographic region appropriate for effective health planning for dialysis services.

² Northwest Kidney Centers submitted its CN application to add stations to its Auburn facility before DaVita filed its application to add stations to its Federal Way Facility.

³ AR 1342

⁴ AR 1341

Impermissible Market Impact

1.5 Program found a need in the south King County service area for additional stations, but Program concluded that DaVita's proposed addition to its Federal Way facility would result in an impermissible⁵ market share impact on the Auburn facility. Program, therefore, denied DaVita's application for additional stations.⁶

1.6 An 80 percent utilization rate is the regulatory threshold identifying an impermissible negative market impact on an existing facility that would stand to lose market share by the approval of DaVita's proposed addition to its Federal Way facility.⁷ Before additional stations are approved for a service area, the existing facilities must be operating at an 80 percent utilization rate.⁸ The 80 percent threshold measures the utilization of three of the four daily kidney dialysis shifts available at kidney dialysis facilities. The last shift ends approximately at midnight. Northwest Renal Network⁹ data is used in the need and market analysis calculations.¹⁰ The Northwest Renal Network's quarterly data reflects one day utilization of a facility, the number of dialysis treatments provided. It is not a monthly or quarterly average.

⁵ The methodology to determine the impermissible market impact is set forth in WAC 246-310-280(4).

⁶ Program concluded that DaVita's proposed expansion would not have an impermissible market impact on DaVita's Kent facility.

⁷ WAC 246-310-280(4) utilization threshold rate for existing facilities is 748.8 dialyses treatments per non-training station per year. This rule is generally described as the 80 percent market share rule.

⁸ Zip code data indicates a large number of patients reside within the same zip code area where DaVita's Federal Way facility is located and in the zip code area directly east of the Federal Way facility. The Auburn facility is located one zip code area west of Federal Way. It is not clear from the record whether these patients dialyze or will dialyze once the Auburn seven additional stations are operational.

AR 1194-6; 1311; 1318-9; 1334-76.

⁹ Northwest Renal Network is independent of Northwest Kidney Center's Auburn Regional Center.

¹⁰ WAC 246-310-280(2).

Annual Utilization Rate

1.7 In determining an annual utilization rate of facilities in the service area, Program relied on quarterly data¹¹ that reflects patient utilization of the facilities on one day in June 2005. In contrast, DaVita relied upon facility utilization data on four days by evaluating quarterly data from four quarters (October 2004 - June 2005). The one day utilization data in June 2005 indicates the Kent facility operated at 93 percent capacity with 67 patients, and the Auburn facility operated at 94 percent capacity with 96 patients.¹² The one-day utilization data in March 2005 indicates that the Kent facility operated at 89 percent and Auburn at 94 percent. The one day utilization data in December 2004 indicates that Kent operated at 76 percent and Auburn at 92 percent. The one day utilization data in October 2004 indicates that Kent operated at 72 percent and Auburn at 97 percent.

1.8 Based upon the one-day utilization data in June 2005, the existing facilities in the service area were operating above the 80 percent threshold. Program adjusted the June 2005 utilization data for the Auburn facility by its approved, but non-operational, seven additional stations.¹³ In evaluating the need for additional dialysis stations in a service area, Program reasonably and routinely considers dialysis stations that are authorized through the issuance of a certificate of need, but not yet constructed or operational. If Program does not count the authorized, non-operational stations in its market analysis, an oversupply of stations may be granted through CN review process.

¹¹ Pursuant to WAC 246-310-180, the parties relied on the Northwest Renal Network quarterly data reports.

¹² AR 1144.

¹³ Auburn's seven station expansion increases the Auburn facility to 24 stations.

1.9 Auburn projected that the utilization rate at its facility will quickly rebound back above 80 percent once the seven additional stations are operational. Auburn projected that it will be operating at 78 percent during its first full year of operation in 2006, 83 percent in 2007, and 89 percent in 2008.¹⁴

1.10 From at least October 2004, DaVita's Federal Way facility utilization rate has exceeded 100 percent and has steadily increased.¹⁵ In June of 2005, DaVita's Federal Way facility utilization rate increased to 117 percent. As a result, DaVita refers its overflow of patients to other facilities in the area, including the Auburn and Kent facilities, as well as facilities outside of the south King County service area. In addition, many Federal Way facility patients dialyze during the fourth shift ending at midnight. Public transportation is rarely available at this hour. As a result, the fourth shift patients and/or their families/friends drive to the facility late at night, which causes problems for some patients. Some dialysis patients experience dementia, exhibiting agitation, and confusion and, therefore, need family or friends to drive them to and from their dialyses session. New patients, who are usually the sickest and most unstable patients, are frequently assigned this late night shift. The sicker patients often have more special needs and a higher transportation rate to the hospital from the facility. Patients' regular nephrologists and other needed medical resources are not always available during the late hours of the fourth shift. Hospital admissions are generally more difficult during

¹⁴ AR 1144. WAC 246-310-280(5) requires that newly approved stations "must reasonably project to be operating" at 80 percent by the third year of operation. Northwest's projections exceed that requirement.

¹⁵ Utilization rates must be calculated pursuant to WAC 246-310-280.

these late hours. These factors create additional hardships for patients and their families.

Market Share Analysis

1.11 Even with the addition of Auburn's seven approved, but non-operational stations, there is a clear need for additional kidney dialysis stations in the south King County service area.¹⁶ On the other hand, the potential impermissible adverse market share impact question¹⁷ is not as easily answered. Program's and DaVita's health care analysts both made errors in their market share analysis.

1.12 Program and DaVita disagreed as to how many "data points" (the number of patients utilizing a facility on one day during a quarter) should be considered in the market share calculations under WAC 246-310-280(4). Program relied upon only one utilization data point that was modified by the addition of seven Auburn non-operational stations. Based upon one data point, Program concluded that the Auburn facility's annual¹⁸ utilization rate was below the 80 percent minimum threshold.¹⁹ A single data point is not a reasonable representation of an annual utilization treatment rate for the Auburn facility. Program did not identify a 12-month period for its market share analysis. Program's analyst projected the utilization rate into the future rather than analyzing the most recent year's utilization data. Multiple quarterly data points

¹⁶ Pursuant to WAC 246-310-210; WAC 246-310-280(2) and (3)

¹⁷ Pursuant to WAC 246-310-280(4)

¹⁸ WAC 246-310-280(4) uses the terms "per year".

¹⁹ Program considered the "current" quarterly data as of the date the Program was analyzing the DaVita's expansion application.

would smooth out the sudden changes from one-time events such as temporary closures for repairs/maintenance that cause short-term utilization drops.

1.13 In contrast, DaVita's analyst identified a 12-month period to evaluate the annual utilization rate, relied upon four quarterly data points, and concluded that the Auburn facility's annual utilization rate was above the 80 percent threshold. But DaVita's analyst failed to adjust three of the four quarterly data points by Auburn's seven approved, but non-operational dialysis stations.

1.14 As a result of errors made by both Program's and DaVita's analysts, it is not clear whether DaVita's proposed Federal Way addition would result in an impermissible adverse impact on the Auburn facility. Therefore, the case must be remanded so Program may recalculate the annual utilization rate and determine whether Auburn's utilization rate would fall below the 80 percent minimum threshold.

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 chapter 70.38 RCW and chapter 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 246-10-606.²⁰ 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 expansion of a kidney dialysis facility is subject to the certificate of need review. RCW 70.38.105(4)(h). An applicant of a kidney dialyses treatment center or expansion must meet the specific kidney dialysis criteria set forth in WAC 246-310-280, in addition to the general review criteria set forth in 246-310-210 (need), WAC 246-310-220 (financial feasibility), WAC 246-310-230 (quality of care), and WAC 246-310-240 (cost containment). Program found that the applicant met these criteria, except the market impact threshold criterion under WAC 246-310-280(4).²¹

Market Share Analysis Pursuant to WAC 246-310-280(4)

2.4 Since there is a recognized growing need for additional kidney dialysis stations in the service area, the only issue is whether Program properly applied the market share impact rule under WAC 246-310-280(4). This rule states that;

²⁰ Chapter 246-10 WAC procedural rules supplement the hearing process statutes and rules in chapter 70.38 RCW and chapter 246-310 WAC.

²¹ WAC 246-310-280 recent amendments do not apply to the case at hand because the effective date of the amendments is January 1, 2007.

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 non-training station per year before additional non-training stations are approved.
(Emphasis added)

WAC 246-310-280(4). The 748.8 figure translates to a facility or treatment center operating at 80 percent capacity before the approval of additional stations. This rule prevents the addition of new stations to a service area when any existing facility is not operating at or above 80 percent.

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

2.6 WAC 246-310-280(4) does not address the inclusion or exclusion of approved, but non-operational stations in the market analysis, but it is reasonable to include approved stations so absurd results are not reached (the approval of more stations than are needed). Chapter 78.38 and Chapter 246-310 WAC do not directly address the inclusion of approved but non-operational stations. Looking at the CN laws as a whole, it is clear that approved, but non-operational, stations should be included to avoid absurd results. In RCW 70.38.115(2), the Legislature provides a non exclusive list of criteria to be considered in the review of CN applications. This list is not exclusive, therefore, does not preclude consideration of dialysis stations that are

approved but not constructed or operational. RCW 70.38.115(2)(a) requires Program to determine the need of the population to be served, and therefore, more stations than are needed should not be approved unless an application falls within one of the need exceptions in WAC 246-310-280(6). WAC 246-310-210 outlines the general need criteria to determine need in such a manner that it would be illogical to exclude authorized and non-operational dialysis stations. WAC 246-310-210(1) states in part:

The population served or to be served has need for the project and other services and facilities of the type proposed are not or will not be sufficiently available or accessible to meet that need. (Emphasis added)

2.7 WAC 246-310-280(4) clearly states that a “per year”, an annual, utilization rate should be determined. Laws should be interpreted so all of its language is given effect with no portion rendered meaningless or superfluous. *State v. Roggenkamp*, 153 Wn. 2d 614, 624 (2004). Program failed to identify a 12-month time period for which it was calculating the “per year” annual utilization rate. WAC 246-310-280(4) does not state that one is to calculate future annual utilization rate. It clearly implies the past annual utilization rate. Under the facts at hand, it is not reasonable to rely on a single data point to determine the utilization rate “per year” under WAC 246-310-280(4).

2.8 Because DaVita’s analyst failed to adjust three of the four data points by Auburn’s approved, but non-operational dialysis stations, DaVita failed to prove by a

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preponderance of evidence that the approval of its application would not result in an impermissible adverse market impact under WAC 246-310-280(4).²²

Exemptions set forth in WAC 246-310-280(6)

2.9 DaVita argues that even if there is an impermissible market impact under WAC 246-310-280(4), the proposed addition to its Federal Way facility should be approved under one of the exceptions set forth in WAC 246-310-280(6).

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 outlined in WAC 246-310-280(2)(3).²³ None of the exceptions outlined in WAC 246-310-280(6) apply to the facts at hand. This 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 non-training 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

²²DaVita cites Program’s 2004 decision that approved an application despite existing facilities operating capacities falling below 80 percent when approved, non-operational stations were counted. *Evaluation of Qualicenter’s Application to Establish a 12-centner Kidney Dialysis Facility to be Known as FMC Downtown Spokane Dialysis*. Program argues that its prior decisions containing errors in the interpretation of the 80 percent rule (WAC 246-310-180(4)) should not be applied to the case at hand.

²³It is not clear why this rule was drafted so it only applies when “need” is not established under methodology set forth in WAC 246-310-280(3).

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

WAC 246-310-280(6). These exceptions do not apply to the facts at hand because there is need for the additional stations. The language clearly states that the exceptions only apply when the approval of additional dialysis stations would result in “more than the number of stations identified as being needed” in the service area.

WAC 246-310-280(6). (Emphasis added)

2.10 Even if DaVita’s proposed expansion would result in more stations than are needed, it is not clear whether the exception in subsection (a) of WAC 246-310-280(6) would apply. Subsection (a) applies when “additional stations are needed to be reasonable close to the people they serve.” WAC 246-310-280(6)(a). Due to a very high utilization rate, some of DaVita’s Federal Way patients and potential patients, are referred to other facilities, and some patients must dialyze during the fourth shift that ends at midnight. The evidence demonstrates that a number of new patients seeking care at DaVita’s Federal Way facility are forced to use the undesirable late night fourth shift or are referred to other facilities. DaVita’s 117 percent utilization, patient referral and fourth shift use, along with the zip code data is sufficient evidence to demonstrate that the facility is “reasonably close to the people they serve.” The remaining exceptions clearly do not apply. Subsection (b) only permits an exception when existing facilities are operating at 100 percent for three of the four patient shifts. This provision would not apply because the Kent and Auburn facilities are operating below the 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 CN application to add ten in-center stations to its existing 15 station kidney dialysis facility in Federal Way is **REMANDED** to Program for further analysis and decision. Program shall identify a 12-month period from which it will determine an annual utilization rate using more than one quarterly data point to recalculate its market share analysis under WAC 246-310-280(4) in a manner that is consistent with this Order. Program shall issue its analysis and decision no later than **April 30, 2007**.

Dated this __13__ day of March 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.

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).

**AMENDED FINDINGS OF FACT,
CONCLUSIONS OF LAW
AND FINAL ORDER**