

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

In Re:)	Master Case No. M2008-118469
)	
Evaluation of Two Certificate of Need)	FINDINGS OF FACT,
Applications Submitted by Central)	CONCLUSIONS OF LAW,
Washington Health Services Association)	AND FINAL ORDER
d/b/a Central Washington Hospital and)	
DaVita, Inc., Proposing to Establish New)	
Dialysis Facilities in Douglas County,)	
)	
Central Washington Hospital,)	
)	
Petitioner.)	
_____)	

APPEARANCES:

Petitioner, Central Washington Health Services Association,
d/b/a Central Washington Hospital (Central), by
Davis Wright Tremaine LLP, per
Brad Fisher and Lisa Rediger Hayward, Attorneys at Law

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

Law Offices of Kimberlee L. Gunning, per
Kimberlee L Gunning, Attorney at Law

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

PRESIDING OFFICER: John F. Kuntz, Review Judge

Central appeals a Program decision denying Central's certificate of need application to establish a 22-station kidney dialysis facility in East Wenatchee, Douglas County, Washington.

FINDINGS OF FACT,
CONCLUSIONS OF LAW
AND FINAL ORDER

SUMMARY OF THE PROCEEDINGS

At the hearing, the Program presented the testimony of Janis Sigman and Bart Eggan. Central presented the testimony of Steven Jacobs, Cheryl Shakelford, and Jody Carona. DaVita presented the testimony of Tracy A. Kasnic, Heather Ashbaugh, and Robert McGuirk.

The Presiding Officer admitted the following exhibits (except where indicated):

Program Exhibits

- Exhibit P-1: Central's Application Record (Central AR).
- Exhibit P-2: DaVita's Application Record (DaVita AR).
- Exhibit P-3: Table 5 – Moveable Equipment Comparison. (This exhibit was created from information contained on pages AR 36, AR 52, 214, and AR 239 of the Central application record). Demonstrative Exhibit – Not Admitted.
- Exhibit P-4: Table 2 – Comparison of Central's Cost per Treatment to DaVita's 2010, 2011, and 2012 9 (This exhibit was created from information contained on pages 71 and AR 258, with judicial notice of information contained in Exhibit P-2). Demonstrative Exhibit – Not Admitted.

DaVita Exhibits

- Exhibit D-1: CWH 000216-19.¹
- Exhibit D-2: CWH 000242-44.
- Exhibit D-3: CWH 000275.
- Exhibit D-4: CWH 000277-79.
- Exhibit D-5: CWH 000283.

¹ CWH refers to pages received by DaVita from Central Washington Hospital during discovery. DaVita identified the exhibits using page numbers without any other description of the exhibit.

- Exhibit D-6: CWH 000714-15.
- Exhibit D-7: CWH 001382A.
- Exhibit D-8: CWH 001386A.
- Exhibit D-9: CWH 001390A.
- Exhibit D-10: CWH 001467A.
- Exhibit D-11: CWH 00158.
- Exhibit D-12: CWH 001632-33.
- Exhibit D-13: CWH 001646-48.
- Exhibit D-14: CWH 001659-60.
- Exhibit D-15: CWH 001669-70.
- Exhibit D-16: CWH 001679-82.
- Exhibit D-17: CWH 001683-84.
- Exhibit D-18: CWH 001690-91.
- Exhibit D-19: CWH 001924A.
- Exhibit D-20: CWH 002176.
- Exhibit D-21: CWH 002174-75.
- Exhibit D-22: Central Washington Hospital Year End Report Cost Center Summary, FYE December 31, 2007.
- Exhibit D-23: Department of Health Certificate of Need Evaluation of DaVita Application Proposing to Establish a New 15-Station Dialysis Center in Douglas County, issued October 29, 2007 (excerpt). Not admitted.²

² Previous certificate of need decisions are not treated as exhibits in certificate of need administrative hearings, but the parties may refer to such previous decisions in their briefs in lieu of closing argument.

- Exhibit D-24: Curriculum Vitae for Bob McGuirk.
- Exhibit DD-25: Central's Actual Hemodialysis Treatments and Patients, 2002-2007. Not Admitted – Demonstrative Only.
- Exhibit DD-26: Central's Pro Forma Targets DaVita Cost per Treatment. Not Admitted – Demonstrative Only.
- Exhibit DD-27: Central Fudges G&A (General and Administrative) Allocation to Beat DaVita Pro Forma. Not Admitted – Demonstrative Only.
- Exhibit DD-28: Analysis of Reported Administrative and General Cost Allocation for Central Dialysis Project. Not Admitted – Demonstrative Only.
- Exhibit DD-29: Central Fudges Salaries Expenses to Beat DaVita Pro Forma. Not Admitted – Demonstrative Only.
- Exhibit DD-30: Central's 15-Station Pro Forma – AR 71 highlighted to show unreliable entries. Not Admitted – Demonstrative Only.
- Exhibit DD-31: Central's 22-Station Pro Forma – AR 258 highlighted to show unreliable entries. Not Admitted – Demonstrative Only.
- Exhibit D-32: Excerpt from Jody Carona Deposition, dated March 18, 2010.

Central Exhibits

- Exhibit C-1: Excerpt from Northwest Kidney Center Application for Certificate of Need Health Care Facility Project (Cover page, page 18, and Appendix 8). Not Admitted.
- Exhibit C-2: Northwest Kidney Center letter dated April 9, 2007, to Mark Thomas, Analyst, Certificate of Need Program, regarding Screening Questions Responses. Not Admitted.
- Exhibit C-3: Evaluation of the Certificate of Need Application Submitted by Northwest Kidney Centers Proposing to

Establish a New 38 Station Dialysis Center in King County Subservice Area #2. Not Admitted.

- Exhibit C-4: Settlement Evaluation of the Certificate of Need Application Submitted on Behalf of Kadlec Medical Center Proposing to Add Fifty-Eight Acute Care Beds to the Hospital, September 29, 2006. Marked for identification, but not offered for admission by Central.
- Exhibit C-5: Pages 10, 55, and 56, from the Evergreen Hospital Medical Center's May 2008 application to add 80 acute care beds to its existing hospital. Not Admitted.
- Exhibit C-6: Reconsideration Evaluation of the Certificate of Need Application Submitted on Behalf of Evergreen Hospital Medical Center Proposing to Add Eighty Acute Care Beds to the Existing Hospital in East King County. Marked for identification, by not offered for admission by Central.
- Exhibit C-7: Evaluation of the Certificate of Need Application Submitted by Franciscan Health System Proposing to Amend the Department's June 27, 2007, "Intent to Issue Certificate of Need." Marked for identification, but not offered for admission by Central.
- Exhibit C-8: Evaluation of the Certificate of Need Application Submitted by Virginia Mason Medical Center Proposing to Establish a Free-Standing Ambulatory Surgery Center in Federal Way. Marked for identification, but not offered for admission by Central.

I. FINDINGS OF FACT

General Findings

1.1 A certificate of need is a non-exclusive license to establish a new health care facility. See *St. Joseph Hospital & Health Care Center v. Department of Health*, 125 Wn.2d 733, 736 (1995); see also RCW 70.38.105(4)(a). The definition of "health care facility" includes a kidney dialysis facility. RCW 70.38.025(6) and

WAC 246-310-010(26). A certificate of need applicant must show or establish that it can meet all of the applicable criteria. WAC 246-10-606. The applicant must show that the proposed project is needed, will foster containment of costs of health care, is financially feasible, and will meet the criteria for structure and process of care. WAC 246-310-200(1). To show that there is a need for a kidney dialysis project, the applicant must also show compliance with the need methodology set forth in WAC 246-310-284. The need methodology is a mathematical calculation that the applicant must complete that shows the projected population growth in the relevant planning area that will require additional kidney dialysis stations to meet that growth. See WAC 246-310-280(4).

1.2 An applicant can obtain information regarding the certificate of need application process from six different sources:

- (1) The application form, which contains the information that the Program has “prescribed and published” as necessary for the specific certificate of need application under review. See WAC 246-310-090(1)(a);
- (2) Chapter 70.38 RCW (Health Planning and Development);
- (3) Chapter 246-310 WAC (Certificate of Need);
- (4) Screening questions that the applicant receives from the Program (that is, clarifying questions the Program asks the applicant following receipt and initial review of the application);
- (5) Past certificate of need application decisions (both Program evaluations of applications and certificate of need adjudicative decisions); and
- (6) Direct information requests made to the Program during the application process.

In the event an applicant makes a direct information request, the Program should make a written record of the request and the Program's written answer to that request. The written record is then placed in the back up documentation section of the application record. While it should make a written record of information requests, the Program does not always do so.³

1.3 Even if the Program does not include a written record of the applicant's information request, nothing prevents the applicant from making the information request a part of the application record. Since the applicant bears the burden of proving it complies with all of the necessary criteria (see WAC 246-10-606), it is in the applicant's best interest to do so. This is especially true because the applicant may need to prove compliance with all necessary criteria at the Program and adjudicative hearing levels.

1.4 The Program's application form contains general questions designed to obtain information (see Sections 1 and 2 of the application form).⁴ The application form also contains questions that mirror the regulations set forth in Chapter 246-310 WAC, for the type of certificate of need application being applied for (see Sections 3 through 6).⁵ The applicant then enters the general or specific information requested by the application form. The applicant may supplement its answers by reference to exhibits or attachments. In fact, much of the detailed information is contained in the exhibits or

³ Answering an applicant's direct information request does not authorize the Program to interpret the statutory and regulatory requirements (including those prescribed and published requirements set forth in its application form under WAC 246-310-090) in a manner that is contrary to law.

⁴ See Central AR 182 – 193 (the amended application).

⁵ See Central AR 194 – 223 (the amended application).

attachments. The standard certificate of need application form (including exhibits or attachments) can consist of anywhere from 500-1,000 pages of material.⁶

1.5 A certificate of need application contains information that is known (past recorded information) and information that is projected (for example, the projected growth in the population of the state of Washington or a specific county). While the past recorded or known information can be measured with some certainty (how many patients in a service area received kidney dialysis treatments), the projected information reflects the applicant's best estimate of what can be done based on past experience (projecting the population growth in a service area and projecting how many of those individual will require kidney dialysis services). The Program verifies some, but not all, of the applicant's information.

1.6 When the Program receives two applications for a certificate of need for the same planning area it engages in a concurrent review.⁷ A concurrent review is a comparative analysis and evaluation of competing or similar projects in order to determine which of the projects best meet the identified needs. RCW 70.38.115(7). For kidney dialysis facilities, the concurrent review process is set forth in WAC 246-310-282.

1.7 Applicants know the Program's concurrent review process creates a competition between kidney dialysis applicants, and that only one of the applicants may be awarded the certificate of need. With the 2007 amendment of the kidney dialysis

⁶ Central's application record was 616 pages in length. DaVita's application record was 1,379 pages in length.

⁷ A planning area means an individual geographic area (generally a county) designated by the department for which kidney dialysis station need projections are calculated. See WAC 246-310-280(8) and (9).

rules, applicants also know that competition is created for tie-breaker points. More specifically, the 2007 kidney dialysis rules create a tie-breaker system between multiple applicants, in the event each of the competing applicants meet the basic certificate of need criteria (WAC 246-310-210 through WAC 246-310-240), and there is only enough projected station need to approve one of the applications submitted in the review cycle. See WAC 246-310-288.

1.8 Given the competitive nature of the concurrent review application process, applicants closely review: (1) prior certificate of need applications in the same service area for guidance on how to maximize the applicant's chances to be awarded a certificate of need; and (2) the "opposing" applicant's certificate of need application in the same application cycle. By doing so, the applicant seeks to maximize its chances (and minimize its opponent's chances) for obtaining the certificate of need.

1.9 The Program's 2007 kidney dialysis rules were drafted to prevent an applicant from "gaming the system" (defined or characterized as a method to prevent applicants from misrepresenting or concealing facts to obtain an advantage over competing applications). While the Program seeks to prevent an applicant from "gaming the system," the competitive process creates the opposite effect. Absent a specific request for information (and given the competition created by the system), an applicant may choose to provide the minimum necessary information to support the application and maximize its chances against competing applications. The applicant's decision may be further colored by the possibility that the competing applicant may appeal the Program's decision to grant the certificate of need.

1.10 Given the amount of information required to obtain a certificate of need, an applicant supplements the application form with supporting documentation. Given the number of applications and the volume of information contained in each application, the Program does not verify all of the material submitted by the applicant.⁸ Because of the volume of information and time constraints, the Program generally reviews the applicant's information using a reasonableness standard.⁹ The Program's reasonableness standard is an assessment whether the information contained in the certificate of need application is similar to information contained in past applications (for example, past kidney dialysis applications). The Program also considers comments provided by the opposing applicant and/or affected and interested persons in assessing the reasonableness of the applicant's application.

1.11 The certificate of need application process provides for a public hearing or opportunity to submit written information regarding the application. The public hearing or written information provides persons (the parties and interested and affected parties) an opportunity to comment on or contest the information contained in the application. It gives the applicant an opportunity to respond to the comments. It does not provide any opportunity to the parties to conduct discovery regarding the information contained in the application record. It is unclear whether the lack of discovery at this stage of the

⁸ The Program does verify the information regarding medical director salaries and lease agreements being submitted by an applicant.

⁹ For example, WAC 246-310-220(2), WAC 246-310-230(2) and (5), and WAC 246-310-240(2)(b).

proceeding contributes to “gaming” the system by applicants (or competitors of the applicants).¹⁰

Kidney Dialysis Certificate of Need Criteria

1.12 The Program substantially revised the kidney dialysis facility rules, which became effective on January 1, 2007 (2007 rules). See WAC 246-310-280 through WAC 246-310-289. The 2007 rules include a separate definition section for kidney dialysis treatment center application terminology and, as previously discussed, a tie-breaker system to decide between competing applicants. See WAC 246-310-280 and WAC 246-310-288. The tie-breaker rules provide that each applicant will be awarded one point for specified criteria (training services; private rooms for isolating patients needing dialysis; permanent bed stations at the facility; evening shift (a shift that begins after 5:00 p.m.); and meeting the projected need. WAC 246-310-288(1). Only one of the competing applicants can be awarded a point for each of the four tie-breaker criteria (economies of scale; historical provider; patient geographical access; and provider choice). WAC 246-310-288(2).

Central Application for Certificate of Need

1.13 In November 2007, there was no kidney dialysis facility in Douglas County, Washington. DaVita and Central each filed a certificate of need application to establish a new kidney dialysis facility in Douglas County to address the county’s need.

¹⁰ For the application system to work properly, both applicants and competitors should fully disclose all relevant information during the public hearing process.

Central initially applied to establish a 15-station facility. DaVita applied to establish a 22-station facility.

1.14 While there was no kidney dialysis facility in Douglas County as of November 2007, Central was, and is, operating a kidney dialysis facility in neighboring Chelan County, Washington. This is approximately six miles away from the proposed facility location Central now proposes to establish in Douglas County, Washington. In fact, Central's facility in Chelan County is drawing 36 of its in-center patients from Douglas County. Central AR 9 and Central AR 194.

1.15 In December 2007, the Program notified DaVita and Central that it would review the applications under the concurrent review process. On December 31, 2007, Central amended its certificate of need application, seeking to establish a 22-station kidney dialysis facility rather than a 15-station facility originally requested.

1.16 On July 31, 2008, the Program approved the DaVita application and denied the Central application. The Program chose to award the certificate of need to DaVita following its evaluation using the tie-breaker process under WAC 246-310-288. On August 26, 2008, Central requested an adjudicative proceeding to contest the Program's decision.¹¹ On October 2, 2009, the Presiding Officer issued an Order on Cross-Motion for Summary Judgment, which ruled that DaVita's application should not be approved. See Prehearing Order No. 12. Following the denial of the DaVita application, the remaining issue at hearing was to determine whether Central should be awarded the kidney dialysis certificate of need for Douglas County.

¹¹ The parties stipulated to DaVita's intervention in the Central appeal.

Planning Area Boundary

1.17 A kidney dialysis applicant must prove that there is a need for the facility. See WAC 246-310-210. Determining whether a facility is needed starts with identifying what is the applicable planning or service area. The planning area is now clearly defined as the county under the WAC 246-310-280(9) definition adopted in 2007 rules.¹²

1.18 However, from December 1996 through December 2006, the “end-stage renal dialysis (ESRD) service area” was defined to mean an individual county *or other service area documented by patient origin*. See WAC 246-310-010 (emphasis added). Prior to January 1, 2007, the Program could treat a portion of Douglas and Chelan Counties as a combined service area. Central AR 17 and Central AR 195.

1.19 With the implementation of the new kidney dialysis rules in 2007, Chelan and Douglas Counties each became a separate service area. Under that analysis, need was determined for each county and not a “service area documented by patient origin.” The change in the planning area boundary definition affected how Central approached its certificate of need application, both in terms of its initial decision to request a 15-station facility and how to best utilize its resources in its request to establish its amended (22-station) application.

Kidney Dialysis Need Methodology

1.20 To show that need existed for a kidney dialysis facility in Douglas County, Central must prove that its application meets the WAC 246-310-210 need criteria, using

¹² King, Snohomish, Pierce, and Spokane counties are the exception, as they have smaller geographic planning area boundaries based on zip code information. See WAC 246-310-280(9).

the WAC 246-310-284 need methodology calculation process. The methodology calculation process measures the annual growth rate of the planning area and divides that number by 3.2, the number of resident in-center patients per station which are necessary for that county. Central's calculation shows there is a need for 22 kidney dialysis stations in Douglas County. Both the Program's and DaVita's calculations confirm this number. As there is no existing kidney dialysis facilities in Douglas County, Central could apply for the entire 22-stations.

1.21 Need also requires that Central prove that all residents of the service area (to include low-income persons, racial and ethnic minorities, women, handicapped persons, other underserved groups, and the elderly) are likely to have adequate access to the proposed health services. Central submitted, as a part of its application, a copy of its Current Patient and Charity Care policy, under which Central would accept any patient for end stage renal disease treatment without regard to race, color, national origin, sex, age, religion, or disability. Central AR 249 – 256. Central's Admission and Charity Care shows that the proposed facility's financial resources include both Medicare and Medicaid revenues.

Financial Feasibility

1.22 Central anticipated its 22-station facility would become operational by the end of May 2009. Under this timeline, 2010 would be the first full calendar year of operation and 2012 would be year three. Based on the number of stations, the number of treatments, the number of patients, and the utilization rate, Central anticipated it

would raise sufficient revenue to profit during all three operating years (2010-2012). See Central AR 539; DaVita AR 1290.

1.23 In its pro forma statement, Central (a nonprofit entity) presented a general and administrative overhead allocation for its project of approximately six percent of overall expenses (that is, the percentage of general and administrative overhead to the total expense amount). AR 258. Central (a nonprofit entity) uses a different accounting method for its general and administrative allocation than a for-profit entity (for example, DaVita's accounting method). The six percent overhead allocation figure, by itself, is not sufficient to prove Central's project would not be profitable.

1.24 To make its application competitive, Central attempted to make the general and administrative overhead expenses as low as possible. This is reflected in email communications between Central employees Steve Jacobs and Cheryl Shackelford. See DaVita Exhibit 5. Central's attempts to keep its general and administrative overhead expenses as low as possible were done to maximize its position under the concurrent review process, and to maximize its opportunity to receive any tie-breaker points under WAC 246-310-288.

1.25 Central identified the capital expenditures for establishing the 22-station facility as \$1,906,343.00 in 2009, growing to \$2,765,715.00 by 2010. Central AR 539 and DaVita AR 1293. The source for the majority of Central's capital expenditure figures are based on the Medicare end-stage renal disease entitlements receipts and the Medicaid reimbursement amounts. These amounts equal 82 percent of its income. There is no evidence that the source of Central's receipts would have any adverse

impact on the remaining 18 percent of reimbursement for services. Neither is there any evidence that reimbursement amounts will have an unreasonable impact on the costs and charges for healthcare services within the service area.

1.26 Central submitted an exhibit as a part of its application which listed the movable equipment. The moveable equipment list that Central included in its amended application identified 22 kidney dialysis machines.¹³ Central AR 239. Central did not submit any detailed information regarding the movable equipment (for example, there is no detailed information whether the kidney dialysis machines were new or used, purchased, transferred, or donated). Central's application did state that it "anticipates sharing staff, equipment, and other resources to ensure both facilities operate cost-efficiently and effectively without duplicating services." See Central AR 204. Central further stated "[w]e do not propose to relocate or eliminate any existing stations or services. We do, however, recognize that we will have excess capacity in Chelan County as a result of this project." Central AR 205.

1.27 The Program's application form does not require that an applicant specify whether a kidney dialysis machine is new or used. The Program did not take any specific steps to verify any of Central's statements regarding the source of the moveable equipment, including the kidney dialysis machines (that is, the Program did not verify if the kidney dialysis machines were new, used, transferred, purchased, or donated). Unlike the Program's practice of asking for proof (documentation or information) regarding the proposed site of the project and whether the applicant has a

¹³ Kidney dialysis machines are also known as hemodialysis machines.

sufficient interest in the proposed site (see Central AR 192-193), the Program did not verify the kidney dialysis machine issue.

1.28 A kidney dialysis machine is a long-lived asset, as it is intended for use for more than one year. In fact, kidney dialysis machines can be used anywhere from five to ten years, depending on the number of hours it is operated per year and the maintenance performed on the machine.

1.29 Central's source of financing for its 22-station is Central's own cash reserves. Central AR 371 – 375. The financial information provided by Central shows that it possesses sufficient cash reserves to finance its proposed Douglas County kidney dialysis project. Central AR 265 – 364.

Structure and Process (Quality) of Care

1.30 Central determined that it would need 8.05 full time equivalent (FTE) employees during the first partial year (2009), which would increase to 14.45 FTE employee positions by the end of the third full year (2012) of operation. Central AR 217 and DaVita AR 1296. Central identified Joseph Anzalone, M.D., and Andy Prasad, M.D., from the Wenatchee Valley Medical Center as possible candidates as medical director for its Douglas County facility. Central submitted its proposed medical director fees (Central AR 227) and draft medical director agreement (Central AR 228-235) as a part of its application. Regarding its other staff requirements, Central anticipated that at least some of the employees that would be needed for the project were already on staff at its Chelan County facility and intended to share the employees with the Douglas County facility.

1.31 Central also intended to use this same approach (using Chelan County facility staff to provide ancillary services (pharmacy, laboratory, and radiology), social services, and dietary support for its patients.

1.32 A kidney dialysis facility applicant must be able to prove that it will conform to the state's licensing requirements. Central's proof that it could conform to the state licensing requirements consists of the Department of Health, Office of Health Care Survey's recent (February 2006) survey of Central's existing end-stage renal disease facility. The February 2006 survey did not reveal any non-compliance issue related to the care and management of that facility. In addition, neither of the candidates identified as a possible medical director for the Douglas County kidney dialysis facility (Dr. Anzalone and Dr. Prasad) had any recorded sanctions with the Medical Quality Assurance Commission. The survey results are also evidence that Central can provide safe and adequate care to the public.

1.33 Central has a history of providing kidney dialysis services to the residents of Washington State based on its operation of the Chelan County kidney dialysis facility. Central AR 39. This is especially true given Central's history of providing kidney dialysis treatment to Douglas County residents at its Chelan County kidney dialysis facility.

1.34 Douglas County currently does not have a kidney dialysis facility, but its projected population growth shows a need for 22-stations. Because there is currently no dialysis stations in Douglas County, Central can provide the projected 22-station need without causing any fragmentation of any existing services (assuming it meets all other certificate of need criteria).

Determination of Cost Containment

1.35 Before it can obtain a certificate of need, Central must consider whether there are any superior alternatives to establishing its new facility. Central considered three different alternatives rather than establishing a new facility, included: (1) doing nothing; (2) downsizing the existing Chelan County units and relocating stations to Douglas County; or (3) continuing with its original 15-station application.¹⁴

A. Central ruled out the option of “doing nothing.” Central had concerns about the certificate of need being awarded to a non-affiliated unit (that is, another kidney dialysis provider). Central believed this option would adversely affect its Chelan County facility. The adverse affect Central was specifically concerned about was the loss of the Douglas County patients that it was currently treating at its Chelan County facility. In addition to the loss of patients, Central viewed this option as creating a negative effect on the other regional service the hospital provided to Chelan and Douglas County residents.

B. Central considered downsizing the kidney dialysis facility it operates in Chelan County. Central contacted the Program about the downsizing option (moving Chelan County kidney dialysis stations and relocating those kidney dialysis stations to the new Douglas County facility). Central AR 222 and Central AR 552. The Program advised Central that if it were to remove stations from the Chelan County facility it would not factor into the Program’s ultimate Douglas

¹⁴ Central’s (or any applicant) application should address a “fourth” option (how its proposed facility was superior to DaVita, its sole competitor in this service area). Given the prior summary judgment ruling, it is unnecessary to consider the fourth option here. See Prehearing Order No. 12.

County facility decision. Based on the Program's statement, Central discarded or ruled out the downsizing option.

C. Central also considered going with its initial 15-station application rather than amending the application to request all 22 stations established under the need methodology calculations. As the need methodology calculations clearly show a need for 22-stations, the Program advised Central that the option of going forward with the 15-station application would not address the identified need in Douglas County. At the time it filed the application, Central was competing with DaVita's application to establish a 22-station facility in Douglas County. Rather than limit its ability to compete with DaVita, Central chose to go forward with a 22-station application, determining it was the most effect cost containment choice (that is, the most superior option).

1.36 Central's kidney dialysis project involves the construction of a stand-alone facility. In order to meet these criteria, Central's application must show that the costs, scope, and methods of construction and energy conservation were reasonable. Central provided a single line drawing, a letter that states it met the required zoning laws, and a statutory warranty deed to prove that it maintained sufficient legal interest in the site of the proposed kidney dialysis facility in Douglas County. Central AR 241, Central 243, and 245-246.

1.37 Central anticipated its capital costs for the 22-station project were \$1,906,343.00 for the first year of operation (the partial year of 2009) and growing to \$2,765,715.00 by the third full year of operation (2012). Central AR 188 and Central

AR 258. Based on the information contained in Central's pro forma statement, the cost per treatment station for the 22-station facility would be \$86,651.95 per station. Central AR 557 and DaVita AR 1308. This was greater than DaVita's cost per station amount (\$84,629.19 per station). The Program had awarded DaVita the cost per station tie-breaker point for that reason. Central AR 558. While the tie-breaker point is no longer important in deciding whether to award a certificate of need to Central, it clearly reflects the competitive nature of the concurrent review process.

II. CONCLUSIONS OF LAW

2.1 The Department of Health is authorized and directed to implement the certificate of need program. RCW 70.38.105(1). The applicant must show that its application meets all of the applicable criteria by a preponderance of the evidence. See WAC 246-10-606. Admissible evidence in certificate of need hearings 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).

2.2 The Presiding Officer is both the agency's fact-finder and final decision maker. *DaVita v. Department of Health*, 137 Wn. App. 174, 184 (2008) (*DaVita*). The Presiding Officer may consider the Program's written analysis in reaching his decision. See WAC 246-310-200(2)(a). The Presiding Officer need not give any particular deference to the Program's analyst. See *DaVita*, 137 Wn. App. at 182-183. This does not mean that the Presiding Officer is free to disregard the Program's decision. *DaVita*, 137 Wn. App. at 184. This is especially true because the appeal process does

not begin the application process anew. *University of Washington v. Department of Health*, 164 Wn.2d 95, 104 (2008).

2.3 Whether a certificate of need may be issued to an applicant shall be based on determinations whether the proposed project:

- (a) Is needed;
- (b) Will foster containment of costs of health care;
- (c) Is financially feasible; and
- (d) Will meet the criteria for structure and process of care identified in WAC 246-310-230.

WAC 246-310-200(1).

2.4 In addition to the above four certificate of need criteria, an applicant for a kidney dialysis certificate of need must comply with the kidney dialysis rules set forth in WAC 246-310-280 through WAC 246-310-289.

Need

2.5 To prove that need exists for a kidney dialysis facility, Central must first meet the criteria in WAC 246-310-210.¹⁵ The criteria are:

- (1) 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.
- (2) All residents of the service area, including low-income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly are likely to have adequate access to the proposed health service or services.

¹⁵ The following sub-criteria are not discussed in this decision because they are not relevant to the Central project. WAC 246-310-210(3), (4), (5), and (6).

2.6 The kidney dialysis need methodology is set forth in WAC 246-310-280(4).

That subsection states:

The number of dialysis stations projected as needed in a planning area shall be determined by using the following methodology:

- (a) Determine the type of regression analysis to be used to project resident in-center station need by calculating the annual growth rate in the planning area using the year-end number of resident in-center patients for each of the previous six consecutive years, concluding with the base year.
 - (i) If the planning area has experienced less than six percent growth in any of the previous five annual changes calculations, use linear regression to project station need; or
 - (ii) If the planning area has experienced six percent or greater growth in each of the previous five annual changes calculations, use nonlinear (exponential) regression to project station need.
- (b) Project the number of resident in-center patients in the projection year using the regression type determined in (a) of this subsection. When performing the regression analysis use the previous five consecutive years of year-end data concluding with the base year. For example, if the base year is 2005, use year-end data for 2001 to 2005 to perform the regression analysis.
- (c) Determine the number of dialysis stations needed to serve resident in-center patients in the planning area in the projection year by dividing the result of (b) of this subsection by the appropriate resident in-center patient per station number from subsection (3) of this section. In order to assure access, fractional numbers are rounded up to the nearest whole number. For example, 5.1 would be rounded up to 6. Rounding to a whole number is only allowed for determining the number of stations needed.
- (d) To determine the net station need for a planning area, subtract the number calculated in (c) of this subsection from the total number of certificate of need approved stations located in the planning area.

WAC 246-310-284(4).

FINDINGS OF FACT,
CONCLUSIONS OF LAW
AND FINAL ORDER

Page 23 of 35

Master Case No. M2008-118469

2.7 Based on Findings of Fact 1.17 through 1.20, Central proved by a preponderance of the evidence that its application met the WAC 246-310-210(1) criteria (incorporating the WAC 246-310-280(4) kidney dialysis need methodology).

2.8 Based on Findings of Fact 1.17 and 1.21, Central proved by a preponderance of the evidence that its application met the WAC 246-310-210(2) criteria.

Financial Feasibility

2.9 To obtain a kidney dialysis certificate of need Central must also show that its project is financially feasible under WAC 246-310-220. That regulation requires a showing that:

- (1) The immediate and long-range capital and operating costs of the project can be met.
- (2) The costs of the project, including any construction costs, will probably not result in an unreasonable impact on the costs and charges for health services.
- (3) The project is appropriately financed.

WAC 246-310-220.

2.10 The parties argue whether Central's application accurately shows what are its immediate and long-range capital and operating costs. Much of the testimony provided in the hearing revolved around how an applicant proves this issue. The testimony addressed a number of issues, including: (1) the method used to depreciate equipment; (2) how to value equipment that has been fully depreciated; (3) how to accurately determine appropriate general and administrative overhead; (4) what

constitutes an accurate pro forma statement; and (5) whether Central donated, shared, or transferred 10 dialysis machines.

2.11 Many of these issues are not specifically defined or established in the statutes or rules, or specifically set out in the application form (the information the Program has “prescribed and published” as necessary to the certificate of need application pursuant to WAC 246-310-090).¹⁶ For example, testimony was received on what constitutes appropriate general and administrative costs. There is no standard that reflects what is the “correct” amount or percentage for general and administrative costs. The standard for a non-profit facility (Central) would differ from a for-profit facility (DaVita). Additionally, key terms (for example, “donation” and “pro forma”) are not defined.

2.12 The Program may consider nationally recognized standard or state professional organization standard to supplement for use in making the required determination. See WAC 246-310-200(2)(a)(ii) and WAC 246-310-200(2)(b). Absent clearly written standards, or clearly specified supplemental standards, the Presiding Officer must rely on the language of the statutes, regulations, and the application form (as currently written) to determine whether Central’s application meets all of the required criteria.

¹⁶ While a certificate of need application form shall be limited to the information necessary to perform a review, the application form shall be varied to the appropriate category of review. WAC 246-310-090(1)(a)(i). The required information *shall include what is necessary to determine whether the proposed project meets the applicable criteria. Id* (emphasis added). If the application form does not clearly include what it required information, it is difficult (if not impossible) for applicants to provide the required information as part of the application process. It is also difficult (if not impossible) for interested and affected parties to evaluate the application during the application process.

2.13 Central argues that it met all of the application criteria before the Program. Even if this is so, once Central appealed the matter, it still has the burden of proving it meets all of the required criteria to the Presiding Officer at hearing. See *DaVita v. Department of Health*, 137 Wn. App. 174, 185 (2007); see also WAC 246-10-606.

2.14 Both the Program and DaVita argue (and Central does not dispute) that an applicant must submit a document called a “pro forma” to demonstrate that the applicant can meet its immediate and long-range capital and operating costs. The term “pro forma” is not defined in chapter 246-310 WAC or in the application form. It can be given a dictionary meaning. *J & S Services, Inc. v. Department of Labor and Industries*, 142 Wn. App. 502 (2007). “Pro forma” is defined as “a matter of form or for the sake of form. Used to describe accounting, financial, and other statements or conclusions *based upon assumed or anticipated facts.*” Black’s Law Dictionary, Sixth Edition (1990) (emphasis added).

2.15 To prove the assumed or anticipated facts that are necessary to prove it meets the immediate and long-range capital and operating costs, Central’s pro forma must accurately portray its capital expenditures under WAC 246-310-280(2):

“Capital expenditures,” as defined by Generally Accepted Accounting Principles (GAAP), are expenditures made to acquire tangible long-lived assets. *Long-lived assets represent property and equipment used in a company’s operations that have an estimated useful life greater than one year. Acquired long-lived assets are recorded at acquisition cost and include all costs incurred necessary to bring the asset to working order.* The definition of capital expenditure includes the following types of expenditures or acquisitions.

- (a) A force account expenditure or acquisition (i.e., an expenditure for a construction project undertaken by a facility as its own contractor).
- (b) The costs of any site planning services (architect or other site planning consultant) including but not limited to studies, surveys, designs, plans, working drawings, specifications, and other activities (including applicant staff payroll and employee benefit costs, consulting and other services which, under GAAP or Financial Accounting Standard Board (FASB) may be chargeable as an operating or nonoperating expense).
- (c) Capital expenditure or acquisition under an operating or financing lease or comparable arrangement, or through donation, which would have required certificate of need review if the capital expenditure or acquisition had been made by purchase.
- (d) Building owner tenant improvements including but not limited to: Asbestos removal, paving, concrete, contractor's general conditions, contractor's overhead and profit, electrical, heating, ventilation and air conditioning systems (HVAC), plumbing, flooring, rough and finished carpentry and millwork and associated labor and materials, and utility fees.
- (e) Capital expenditures includes donation of equipment or facilities to a facility.
- (f) Capital expenditures do not include routine repairs and maintenance costs that do not add to the utility of useful life of the asset.

(Emphasis added).

2.16 Principles of statutory construction apply to administrative rules. See *State Department of Licensing v. Cannon*, 147 Wn.2d 41, 56 (2002). The aim of statutory interpretation is to “discern and implement the intent of the legislature.” *City of Olympia v. Drebeck*, 156 Wn.2d 289, 295 (2006) (internal citation omitted). A provision’s plain meaning may be ascertained by an “examination of the statute in which

the provision at issue is found, as well as related statutes or other provisions of the same act in which the provision is found.” *City of Olympia v. Drebeck*, 156 Wn.2d at 295 (internal citation omitted). An unambiguous statute need not be interpreted or construed. See *Whatcom County v. Bellingham*, 128 Wn.2d 537, 546 (1996).

2.17 Central decided to utilize 10 used dialysis machines (not entire stations) from its existing Chelan County facility to the proposed Douglas County facility to efficiently use the machines. There is no evidence that any applicant (including Central) is prohibited from installing used machines at its new facility. But the 10 dialysis machines clearly meet the definition of a capital expenditure, given that they are assets with a useful life of more than one year. The plain language of WAC 246-310-280(2) requires that Central record the long-lived assets at their acquisition cost and include all costs incurred necessary to bring the assets to working order (excluding any routine repair and maintenance costs that do not add to the utility of the useful life of the asset). See WAC 246-310-280(2) and (2)(e).

2.18 Based on the above ruling, it is immaterial how Central characterizes the 10 kidney dialysis machines (whether donated, transferred or shared). To qualify for the certificate of need, Central’s application must identify such capital expenditures to comply with the requirements under WAC 246-310-280(2). Even if it could share assets (which infers that at some point Central intended to return the “shared” equipment to its Chelan County facility), Central did not provide sufficient evidence at hearing that it intended to return the 10 kidney dialysis machines to their original facility.

2.19 There is no clear statement in Central's application that it intended or intends to install 10 used machines. There is merely a reference in the application that it "anticipates sharing staff, equipment, and other resources to ensure both facilities operate cost-efficiently and effectively without duplicating services." See AR 204. Without knowing more than that, it is unclear whether Central's pro forma can effectively show that it can meet its immediate and long-range capital and operating costs. In point of fact, Central stated it did not include any acquisition cost or costs necessary to bring these assets to working order. The Presiding Officer concludes Central's pro forma statement is inaccurate. An inaccurate pro forma statement means Central cannot prove that it can meet its immediate and long-range capital and operating costs for the project.¹⁷

2.20 In its closing brief, the Program argues that an applicant should not be permitted to misrepresent/conceal the facts to "game the system" in order to gain an advantage. *Certificate of Need Program's Post Hearing Brief*, at 6. In so ruling, the Presiding Officer does not infer that Central took its actions in bad faith or to "game the system." The concurrent review system, by its nature, creates competition between applicants. The Program identified that applicants can review prior applications to determine what approaches the Program will accept or have accepted in submitting a certificate of need application. The approach used by Central was previously used in

¹⁷ Capital expenditure is also important in determining whether an applicant in the concurrent review process qualifies for the economies of scale tie-breaker point. See WAC 246-310-288(2)(a). As this is no longer a concurrent review application situation, there is no need to determine whether Central would have obtained this tie-breaker point.

the Northwest Kidney Centers certificate of need application. See *Central's Opening Post-Hearing Brief*, Exhibit 5. Given the competitive nature of the system and Central's reasonable reliance on the Northwest Kidney Centers evaluation, there is no evidence of "gaming the system" here.¹⁸

2.21 Based on Findings of Fact 1.23 through 1.28, and Conclusions of Law 2.9 through 2.20, Central did not prove by a preponderance of the evidence that its application met the criteria set forth in WAC 246-310-220(1).

2.22 Based on Finding of Fact 1.22, Central proved by a preponderance of the evidence that its application met the criteria set forth in WAC 246-310-220(2).

2.23 Based on Finding of Fact 1.29, Central proved by a preponderance of the evidence that its application met the criteria set forth in WAC 246-310-220(3).

Structure and Process (Quality) of Care

2.24 Central must also show that its project meets the structure and process of care requirements set forth in WAC 246-310-230 to obtain a kidney dialysis certificate of need. That regulation provides:

A determination that a project fosters an acceptable or improved quality of health care shall be based on the following criteria.

- (1) A sufficient supply of qualified staff for the project, including both health personnel and management personnel, are available or can be recruited.

¹⁸ Although not controlling in the decision, the Department's public policy goals of transparency and predictability in the application process can be met by the Program clearly stating in the application form what the applicant must provide and what national/state standards the Program will use in analyzing the application.

- (2) The proposed service(s) will have an appropriate relationship, including organizational relationship, to ancillary and support services, and ancillary and support services will be sufficient to support any health services including the proposed project.
- (3) There is reasonable assurance that the project will be in conformance with applicable state licensing requirements and, if the applicant is or plans to be certified under the medicaid or medicare program, with the applicable conditions of participation of related to those programs.
- (4) The proposed project will promote continuity in the provision of health care, not result in an unwarranted fragmentation of services, and have an appropriate relationship to the service area's existing health care system.
- (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 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 a failure to comply with applicable federal conditions or 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.

2.25 Based on Findings of Fact 1.30 and 1.31, Central proved by a preponderance of the evidence that its application met the WAC 246-310-230(1) criteria.

2.26 Based on Findings of Fact 1.30 and 1.31, Central proved by a preponderance of the evidence that its application met the WAC 246-310-230(2) criteria.

2.27 Based on Findings of Fact 1.32 and 1.33, Central proved by a preponderance of the evidence that its application met the WAC 246-310-230(3) criteria.

2.28 Based on Findings of Fact 1.32 and 1.34, Central proved by a preponderance of the evidence that its application met the WAC 246-310-230(4) criteria.

2.29 Based on Findings of Fact 1.14, 1.32, and 1.33, Central proved by a preponderance of the evidence that its application met the WAC 246-310-230(5) criteria.

Determination of Cost Containment

2.30 To obtain a kidney dialysis certificate of need, Central must also show that it meets the determination of cost containment set forth in WAC 246-310-240. That regulation provides:

A determination that a proposed project will foster cost containment shall be based on the following criteria:

- (1) Superior alternatives, in terms of cost, efficiency, or effectiveness, are not available or practicable.

- (2) In the case of a project involving construction:
 - (a) The costs, scope, and methods of construction and energy conservation are reasonable; and
 - (b) The project will not have an unreasonable impact on the costs and charges to the public of providing health services by other persons.
- (3) The project will involve appropriate improvements or innovations in the financing and delivery of health services which foster cost containment and which promote quality assurance and cost effectiveness.

WAC 246-310-240.

2.31 Based on Findings of Fact 1.23 through 1.28, Findings of Fact 1.35 through 1.37, and Conclusions of Law 2.9 through 2.20, Central has not proved by a preponderance of the evidence that its application met the WAC 246-310-240(1) criteria. Unless it can prove that its long-range capital and operating costs can be met, Central cannot show that it is the superior alternative.

2.32 Based on Findings of Fact 1.23 through 1.28, Findings of Fact 1.35 through 1.37, and Conclusions of Law 2.9 through 2.20, Central has not proved by a preponderance of the evidence that its application met the WAC 246-310-240(2) criteria. Without knowing the costs of the project, Central cannot show that its project will or will not have an unreasonable impact on the costs or charges to the public.

2.33 Based on Finding of Fact 1.29, Central proved by a preponderance of the evidence that its application met the criteria set forth in WAC 246-310-240(3).

III. ORDER

Based on the foregoing Findings of Fact and Conclusions of Law, the certificate of need application to establish a 22-station kidney dialysis facility in Douglas County filed by Central is DENIED.

Dated this 17 day of June, 2010.

_____/s/_____
JOHN F. KUNTZ, Review Judge
Presiding Officer

NOTICE TO PARTIES

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

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

and a copy must be sent to:

Department of Health Certificate of Need Program
P.O. Box 47852
Olympia, WA 98504-7852

This petition must state the specific grounds for reconsideration and what relief is requested. WAC 246-10-704. The petition is denied if the Adjudicative Service Unit does not respond in writing within 20 days of the filing of 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, the above 30-day period does not start until the petition for reconsideration is resolved. RCW 34.05.470(3).

The order is in effect while 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 is "served" the day it is deposited in the United States mail. RCW 34.05.010(19).

For more information, visit our website at <http://www.doh.wa.gov/hearings>