STATE OF WASHINGTON
DEPARTMENT OF HEALTH
ADJUDICATIVE SERVICE UNIT

In Re: Certificate of Need Evaluation of the PUGET SOUND KIDNEY CENTERS APPLICATION PROPOSING TO ESTABLISH A NINE STATION DIALYSIS CENTER IN SKAGIT COUNTY and DAVITA APPLICATION PROPOSING TO ESTABLISH A NINE STATION DIALYSIS CENTER IN SKAGIT COUNTY, DAVITA INC., Petitioner.	Master Case No. M2012-1073 FINDINGS OF FACT, CONCLUSIONS OF LAW, AND FINAL ORDER

APPEARANCES:

Puget Sound Kidney Centers (PSKC), by
Davis Wright Tremaine LLP, per
Brad Fisher and Lisa Rediger Hayward, Attorneys at Law

DaVita, Inc.(DaVita), by
Perkins Coie LLP, per
Brian W. Grimm, Attorney at Law, and

Law Office of James M. Beaulaurier, per
James M. Beaulaurier, 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: Frank Lockhart, Health Law Judge

The Presiding Officer conducted a hearing on April 30 - May 1, 2013, regarding two Certificate of Need (CN) applications to each establish dialysis stations in the same

planning area (Skagit County, Washington), to wit: PSKC's application to establish a nine-station dialysis center in Anacortes, Washington, and DaVita's application to establish a nine-station dialysis center in Burlington, Washington.

ISSUES

A. Does PSKC's CN application to establish a nine-station dialysis facility in Anacortes meet the criteria set forth in WAC 246-310-210, WAC 246-310-220, WAC 246-310-230, and WAC 246-310-240?

B. Does DaVita's CN application to establish a nine-station dialysis facility in Burlington meet the criteria set forth in WAC 246-310-210, WAC 246-310-220, WAC 246-310-230, and WAC 246-310-240?

C. If both applications meet the criteria set forth in WAC 246-310-210, WAC 246-310-220, WAC 246-310-230, and WAC 246-310-240, then which application better meets the criteria set forth in WAC 246-310-288?

PROCEDURAL HISTORY

On November 30, 2011, PSKC applied for a CN to establish a nine-station dialysis facility in Anacortes. PSKC's proposal includes the expense of purchasing land and building the facility at an estimated capital expenditure of $4,053,082.

On that same day, DaVita submitted its application for a CN to establish a nine-station dialysis facility in Burlington. DaVita's proposal envisions renting (and remodeling) an existing building at an estimated capital expenditure of $1,505,575.

On July 20, 2012, after an extensive evaluation, the Program awarded the CN to PSKC. DaVita timely filed a petition for an adjudicative hearing.

SUMMARY OF PROCEEDINGS

At the hearing, the Program presented the testimony of Mark Thomas, CN Analyst. PSKC presented the testimony of: Harold Kelly, President and CEO of PSKC; Kenneth Kouchi, PSKC's Comptroller; and Jody Carona, CN consultant with Health Facilities Planning and Development. DaVita presented the testimony of Anthony Halbeisen, DaVita's Director of Business Development and CN Initiatives; and Frank Fox, CN consultant with Health Trends. Closing arguments were filed by brief pursuant to RCW 34.05.461(7).

The Presiding Officer admitted the following exhibits at hearing:

Program Exhibits

Exhibit S-1: The Application Record.

PSKC Exhibits

Exhibit P-1: The Application Record (Exhibit S-1);

Exhibit P-2: Northwest Renal Network Modality Reports for 12/31/08, 12/31/09, 12/31/10, 6/30/11, and 9/30/11;

Exhibit P-3: 2010 U.S. Census Data showing population and demographic data for Skagit and San Juan Counties, several Skagit County zip codes and Washington State;

Exhibit P-4: ESRD Network Data Regarding Newly Diagnosed Chronic ESRD Patients (ESRD Incidence) and Summary Table;

Exhibit P-5: 2010 National Chronic Kidney Disease Fact Sheet; and

Exhibit P-6: Map showing distance between Skagit Valley Kidney Center and proposed DaVita facility.

DaVita Exhibits

Exhibit D-1: The Application Record (Exhibit S-1);

Exhibit D-2: "Interpretation of WAC 246-310-288 Kidney Disease Treatment Centers – Tie Breakers", Washington State Department of Health, Reports & Guidelines;

Exhibit D-5: Northwest Renal Network report, Washington residents as of 12/31/11 using data as of 2/13/12;

Exhibit D-6: Northwest Renal Network report, Washington residents as of 3/31/12 using data as of 5/14/12;

Exhibit D-7: Curriculum vitae of Frank Fox, Ph.D.;

Exhibit D-8: Map depicting dialysis patients by zip code; and

Exhibit D-9: Aerial map showing Skagit and surrounding counties.

Demonstrative Exhibits

A number of charts and maps were brought to the hearing by the parties with the intent of either offering them as demonstrative exhibits or using them for the first time at the hearing. Certain of those demonstrative exhibits were used at hearing to summarize points in the Application Record. Certain of those demonstrative exhibits were disallowed by the Presiding Officer at hearing because they did not relate to the Application Record or included information outside of the Application Record. The remaining demonstrative exhibits were not used at all at hearing and therefore are *de facto* disallowed. The following were the demonstrative exhibits utilized at hearing.

Program Demonstrative Exhibits

Exhibit S-2: Skagit County Zip Code Map with population figures.

PSKC Demonstrative Exhibits

Exhibit A: Map showing zip codes; and

Exhibit C: Map showing population density.

DaVita Demonstrative Exhibits

Exhibit DD-1: Skagit County Patients by Zip Code Chart;

Exhibit DD-4: Chart showing capital expenditures per station;

Exhibit DD-6: Map showing Anacortes distance rings;

Exhibit DD-7: Map showing Burlington distance rings;

Exhibit DD-8: Graph showing patients by zip codes;

Exhibit DD-9: Graph showing patients by mileage;

Exhibit DD-11: Graph showing population by mileage; and

Exhibit DD-25: Maps showing bus routes.

(Note: All citations to the Application Record herein are in footnote form, citing to the Bates Stamp number, as in "AR 343". All citations to the transcript of the administrative hearing are likewise cited, as in "TR 99".)

I. FINDINGS OF FACT

1.1 PSKC is a private, not-for-profit corporation that operates four dialysis facilities in Snohomish and Island counties. DaVita is a publicly held, for-profit corporation that provides dialysis services in multiple states including Washington. DaVita owns or operates 30 kidney dialysis centers in Washington.

1.2 Both applicants applied for a CN to establish a nine-station dialysis facility in the planning area of Skagit County. Unlike other counties that contain multiple planning areas, Skagit County is one planning area unto itself.[1]

1.3 In order to qualify for a CN, an applicant must show compliance with WAC 246-310 and demonstrate that the proposed project (a) is needed; (b) is financially feasible; (c) will meet certain criteria for structure and process of care; and (d) will foster containment of costs of health care. Both PSKC's and DaVita's applications were reviewed under these criteria in the adjudicative process.

WAC 246-310-210 "Determination of Need"

1.4 Pursuant to WAC 246-310-210, applicants for CNs must demonstrate a need for the proposed services. For kidney disease treatment facilities, the method for projecting the numeric need for dialysis stations is described in WAC 246-310-284. A linear regression analysis is used to calculate future dialysis need based on the historical number of dialysis patients residing in the area and the annual growth rate for the area.

1.5 Using verified population and patient information from the Northwest Renal Network, both PSKC and DaVita arrived at the same result: that by 2014, there would be a need for 36 dialysis stations in the planning area.[2] The Program's

[1] TR 25.

[2] See, AR 22 and AR 307. DaVita's calculations showed the total planning area need by 2014 at 35.08 dialysis stations, but pursuant to WAC 246-310-284(4)(c), calculations are rounded up to the nearest whole number.

calculations verified this need.[3] Subtracting the 27 stations that already exist in the planning area (at Skagit Valley Hospital in Mt. Vernon) leaves a total need for nine additional dialysis stations by 2014. Thus, all the parties confirmed the need for nine additional dialysis stations in the planning area.

1.6 Subsection (1)(b) of WAC 246-310-210 looks at whether existing facilities in the planning area could be utilized to fill the need. However, the only existing dialysis facility in the planning area, Skagit Valley Hospital, is already operating at 80 percent capacity.[4]

1.7 Subsection (2) of WAC 246-310-210 focuses on whether all residents of the service area, including low-income, racial and ethnic minorities, women, handicapped persons, other underserved groups, and the elderly would have adequate access to the proposed projects. A review of the admission policies, charity care policies, and Medicare eligibility certifications and policies of both applicants shows that both PSKC and DaVita would accept patients with end stage renal disease needing chronic hemodialysis without regard for age, race, color, ethnicity, sex or sexual orientation, religious or political beliefs, medical disease, disorder or disability. While the traditional view[5] of this WAC is to focus on the question of "adequate access" by

[3] AR 835, TR 25.

[4] TR 26. Pursuant to WAC 246-310-284(5), CNs for additional dialysis stations may only be granted when the existing facilities in the planning area are operating at 80 percent capacity. Skagit Valley Hospital did not apply for a CN to expand its current service but has "affected person status" in these proceedings pursuant to WAC 246-310-010(2). AR 240.

[5] AR 233.

examining whether there are policy/financial/procedural barriers (as opposed to geographical barriers) to the use of an applicant's dialysis services by historically-disadvantaged groups, there was extensive testimony presented at hearing in this case about the geographical accessibility of the respective proposals. While the issue of geographical location is shaped by certain legal assumptions built into the CN process (see Paragraph 1.23), the Presiding Officer notes the following:

- The nine stations that both applicants are vying for would (once built) represent 25 percent of the dialysis stations in the planning area. The other 75 percent would be located at Skagit Valley Hospital in Mt. Vernon.

- The highest percentage of known dialysis patients is located in the area near Skagit Valley Hospital.[6]

- The proposed DaVita facility in Burlington would be approximately 2.8 miles from Skagit Valley Hospital in Mt. Vernon, while the proposed PSKC facility in Anacortes would be approximately 14 miles from Skagit Valley Hospital.[7] As indicated, Skagit Valley Hospital's 27 dialysis stations are currently operating at 80 percent capacity.[8]

- Mt. Vernon contains two zip codes: 98274 to the west and 98273 to the east. Skagit Valley Hospital in Mt. Vernon is located at the very western edge of zip code 98274. Driving from the Skagit Valley Hospital to Anacortes, one passes through three additional zip code areas: 98273 (which includes Mt. Vernon), 98257 (of which the larger part is slightly closer to Anacortes but whose largest city La Conner is almost equidistant from Burlington and Anacortes), and 98221 (which contains the city of Anacortes).[9]

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[6] See, Demonstrative Exhibit DD-1. There are two zip code areas that touch the city of Mt. Vernon (98273 and 98274). As of the 4th quarter of 2011, there were 65 known dialysis patients in those two zip codes.

[7] AR 126. (Both distances are straight line distances.)

[8] TR 25.

[9] *See,* Demonstrative Exhibit P-A for a zip code map.

- A higher percentage of older citizens live in the Anacortes 98221 zip code area than live in the entire Skagit County area.[10] The adjoining zip code area, 98257, has an even higher percentage of older adults.[11] The combined population of these two zip codes is 21 percent of the population of Skagit County.[12]

- The fact that a higher percentage of older adults live in or near the Anacortes zip codes is significant. More than 20 million adult Americans suffer from Chronic Kidney Disease (CKD), usually caused by diabetes or hypertension. Of those 20 million, almost 45 percent are 65 years or older. Although early CKD may have no symptoms, it is irreversible and progresses to kidney failure known as End Stage Renal Disease (ESRD) which requires dialysis. The incidence of ESRD is greater among adults over 65.[13] Thus, it would be expected that zip codes with more people 65 or older would have a higher need for dialysis on a per capita basis.[14]

- Dialysis patients who do not drive have to either make arrangements for family or friends to drive them to treatment several times a week, or they must take public transportation. There is no Dial-a-Ride service from Anacortes to Mt. Vernon.[15] Additionally, there is not direct bus transportation from Anacortes to Burlington. Riders have to change buses at March's Point, Washington.[16] While this would affect patients living near Burlington trying to get to Anacortes as well, those Burlington area patients would still have the option of more available public transportation to Skagit Valley Hospital in Mt. Vernon.

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[10] For example, almost 50 percent of the 98221 residents are over 50, while only 38 percent of Skagit County residents are over 50. Almost 24 percent of the 98221 residents are 65 or older, while the percentage of Skagit County residents 65 or older is 16 percent. *See* Exhibit P-3 (2010 U.S. Census data).

[11] Of the 98257 residents, almost 55 percent were over 50 and almost 30 percent were 65 years or older. See, Exhibit P-3. The city of La Conner is at the southern section of the 98257 zip code area and in 2011 held more dialysis patients than Anacortes (Demonstrative Exhibit DD-8). La Conner is roughly equidistant (approximately 12 miles) from both Anacortes and Burlington (Demonstrative Exhibit P-G).

[12] Exhibit P-3. However, PSKC's CN consultant testified that the number of residents in proximity to Anacortes was 27 percent of the population of Skagit County. TR 194.

[13] *See*, Exhibit P-5, Center for Disease Control fact sheet on National Chronic Kidney Disease.

[14] It is also reasonable to expect that patients with the most severe cases of ESRD would need more frequent dialysis. Whereas typical patients receive dialysis three times a week, severe cases of ESRD might need five or more sessions a week. *See,* TR 37.

[15] TR 39.

[16] TR 367-8.

1.8 DaVita's proposal for a facility in Burlington is so close physically to the Skagit Valley Hospital facility that it is tantamount to adding 9 dialysis stations to Skagit Valley Hospital. Clearly, the Mt. Vernon–Burlington–Interstate 5 corridor area has the largest grouping of known dialysis patients,[17] but the distance from that area to Anacortes is not that great. Thus, a facility in Anacortes would have an advantage over a Burlington location because those patients closer to Anacortes who did not drive would have easier access to Anacortes, while patients who lived closer to Burlington could still continue to go to Skagit Valley Hospital. However, that advantage does not rise to the level of saying that the underserved groups identified in WAC 246-310-210(2) would not have adequate access to either project.

1.9 Based on the Application Record, the reliability of the underlying population and patient data used by all parties, the application of the proper methodology in projecting need used by all parties, the consistent result in the prediction of a need for nine additional dialysis stations by the year 2014, and the accessibility of care available with both PSKC's and DaVita's proposals, the Presiding Officer finds that Need was properly determined.

WAC 246-310-220 "Financial Feasibility"

1.10 Pursuant to WAC 246-310-220, an applicant for a CN must demonstrate that the project is financially feasible. Specifically, an applicant must demonstrate that the capital and operating costs can be met; that the costs of the project will probably not

[17] *See*, Exhibit P-2.

result in an unreasonable impact on the costs for health services; and that the project can be appropriately financed.

1.11 PSKC's project involves buying land and building its own facility in Anacortes at an estimated capital cost of $4,053,082 whereas DaVita's project involves renting an existing building in Burlington and modifying it, at an estimated capital cost of $1,505,575. A review of each applicant's financial position and pro forma financial statements in their applications demonstrates that both applicants can finance their respective projects from their own cash reserves. The testimony at hearing confirmed that neither party would have difficulty financing their respective projects.[18]

1.12 However, two criteria remain: (1) Can the operating costs be met and (2) will either project have an unreasonable impact on the costs of health services? WAC 246-310-220 does not lay out a single method of evaluating whether operating costs can be met. Therefore the Program has adopted a practice of looking at income and expenses for the 3rd year of operation as an indicator of financial feasibility.

> "[U]sing its experience and expertise the department evaluates if the applicant's pro forma income statements reasonably project that the proposed project is meeting its immediate and long-range capital and operating costs by the end of the third complete year of operation." [19]

This practice is not codified in RCW or WAC. It is simply a method for examining

[18] During the review process, DaVita questioned PSKC's ability to finance their project. However, PSKC's audited 2010 financial statements show assets in excess of 11 million dollars. TR 253. PSKC's Comptroller testified that at the end of 2011, they had over 30 million dollars in assets with no substantial debt. TR 163.

[19] AR 248.

financial feasibility. What is codified in WAC 246-310-284(6), however, is that all new dialysis facilities must be operating at 4.8 patients per station by the end of the third full year of operation.[20] Of course, meeting the requirement of operating at 4.8 patients per station is not a guarantee of meeting or exceeding operating costs. However, both are measures of a facility's financial viability, and in this case, DaVita challenged PSKC's financial feasibility by asserting that PSKC would not be able to meet the 4.8 patient per station requirement.

1.13 The language of WAC 246-310-284(6) is clear: "By the third year of operation, new in-center kidney dialysis stations must *reasonably* project to be operating at (a) 4.8 in-center patients per station ...." (emphasis added). PSKC's projection of 4.8 patients per station by the end of the third year is reasonable, given the growth in the planning area, the population in the zip codes near Anacortes, the clustering of older adults in the Anacortes and La Conner area, and the clearly documented need for nine additional dialysis stations in the planning area.[21] (See Paragraph 1.23 for discussion of how the planning area "need" factors into the 4.8 projection.)

1.14 Both applicants projected that their net revenue would exceed their operating expenses by the third full year of operation. Given the fact that the number of stations is the same, and the projected utilization rates were almost identical, one would

[20] Operating at 4.8 patients per station is equivalent to operating at 80 percent capacity.

[21] AR 203-4 and AR 245-6.

expect their income/expense projections to be similar, but they are not.

THIRD FULL YEAR OF OPERATION[22]

	DaVita	**PSKC**	Difference
Net Revenue	2,732,563	2,042,839	689,724
Total Expense	2,384,980	1,957,952	427,028
Net Profit	347,583	84,887	262,696

While both applicants disparaged the other side's projections,[23] the Presiding Officer finds that both applicants' third year projections, despite the difference in figures, are good faith estimates that fulfill the "reasonable projection" requirement of WAC 246-310-284(5). Thus, the Presiding Officer determines that both applicants can meet their operating costs.

1.15 As for the issue of whether either project would have an unreasonable impact on the costs of health services, as indicated, there was simply insufficient evidence upon which to draw a negative conclusion. Thus, the Presiding Officer finds that both applicants fulfilled the financial feasibility criteria of WAC 246-310-220.

WAC 246-310-230 "Structure and Process of Care"

1.16 The criteria for structure and process of care, spelled out in WAC 246-310-230, includes five areas that must be considered when reviewing a CN Application, to wit: adequate staffing, appropriate organizational structure and

[22] AR 250-251.

[23] PSKC accused DaVita of charging insurance companies more (TR 300-301), implying that DaVita's project would have an unreasonable impact on the cost and charges for health care services, while DaVita accused PSKC of understating its operating costs (TR 390-391) to show 3rd year profitability. However, neither side presented sufficient evidence to substantiate their respective claims.

support, conformity with licensing requirements, continuity of health care, and the provision of safe and adequate care.

1.17 Both applicants certainly have experience in establishing, staffing, and operating dialysis facilities. As indicated, PSKC operates four dialysis facilities in nearby Island and Snohomish counties. As part of its application, PSKC identified both a medical director and a corporate medical director and submitted executed medical and corporate medical director agreements. PSKC also submitted a reasonable staffing plan.[24] PSKC maintains working relationships with hospitals, physicians, and long term care facilities in the planning area, and submitted copies of executed transfer agreements with Island Hospital, Everett Medical Center, and Skagit Valley Hospital.[25] PSKC has a good track record on compliance issues.[26]

1.18 DaVita operates 30 dialysis facilities in Washington and certainly is well experienced in the area of establishing and managing kidney dialysis facilities. As part of its application, DaVita proposed Dr. C.J. Kuan as medical director and submitted a medical director's agreement.[27] Dr. Kuan is currently the medical director for Skagit

[24] DaVita's witness criticized PSKC's pay scale for its employees (TR 391-392) as too low, but the Presiding Officer determines that the FTE plan and pay scale are reasonable. PSKS operates a nearby dialysis facility on Whidbey Island and is familiar with the local labor market.

[25] AR 76-89.

[26] Since January 2008, the Department of Health's Investigations and Inspections Office has conducted seven compliance surveys for PSKC facilities, revealing only minor non-compliance issues that are typical of dialysis facilities. AR 258.

[27] AR 393.

Valley Hospital's dialysis program.[28] The proposed medical director's agreement with Dr. Kuan contains a non-competition clause. One of the sub-criteria of WAC 246-310-230 is that a proposed project does "not result in an unwarranted fragmentation of [health care] services." At hearing, PSKC argued that DaVita's close proximity to Skagit Valley Hospital means that DaVita will "cannibalize Skagit Valley's patient base," and that the hiring of Skagit Valley's dialysis medical director would fragment health care services.[29] While the allegations are troubling, there was insufficient evidence presented to conclude that the hiring of Dr. Kuan would amount to an "unwarranted" fragmentation of health care services.[30] Furthermore, even though it might be true that some of Skagit Valley Hospital's patients might decide to use DaVita's Burlington facility, there was insufficient evidence to conclude that DaVita's proximity to Skagit Valley Hospital would fragment health care services.

1.19 DaVita did not submit any transfer agreements from nearby hospitals, but given DaVita's historical activity in the state, it is reasonable to assume that nearby hospitals and long term care facilities would cooperate with DaVita. DaVita's staffing plans are reasonable.[31] While DaVita has had some safety issues in other states,[32] DaVita has a good track record on compliance issues in Washington.[33]

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[28] TR 304-305.

[29] *See,* TR 19 and TR 302-310.

[30] For example, it may well be that Dr. Kuan's proposed move was agreeable to Skagit Valley Hospital. There was simply insufficient evidence to conclude that Dr. Kuan's proposed move would be disruptive to Skagit Valley Hospital.

[31] AR 821.

1.20 The Presiding Officer finds that both applicants meet the criteria in WAC 246-310-230 for structure and process of care.

WAC 246-310-240 "Cost Containment"

1.21 The final criteria for CN Applications is found in WAC 246-310-240. This WAC is divided into three subsections: Subsection (1) asks if there are "superior alternatives in terms of cost, efficiency, or effectiveness". Subsection (2) looks at the costs of projects involving construction. Subsection (3) asks if a project involves improvements or innovations in the financing or delivery of health services.

1.22 However, the Program did not do an analysis under WAC 246-310-240(1). The Program's method of concurrent review is to analyze the two applications under WAC 246-310-210, 220, and 230. If both applications meet the criteria in those three WACs, then the Program jumps to a "tie-breaker" contest as described in WAC 246-310-288. In terms of the "superior alternative" analysis of WAC 246-310-240(1), the Program only looks at whether each applicant has considered any other alternative to that applicant's own project, not whether one application is superior to the other application. This method of evaluating CNs has been

[32] AR 437-438.

[33] Since January 2008, the Department of Health's Investigations and Inspections Office has conducted 30 compliance surveys for DaVita facilities, revealing only minor non-compliance issues that are typical of dialysis facilities. AR 259.

criticized in numerous other CN cases.[34] WAC 246-310-240(1) requires a comparison and determination of whether concurrent applications may be superior to each other. Only if two applications meet all the criteria in WACs 246-310-210 through 240, and no one application is clearly superior under WAC 246-310-240(1), should the "tie-breakers" of WAC 246-310-288 be applied.

1.23 Discussion: However, a word needs to be said about "superiority." In order to make CN decisions in a logical, consistent manner, the law allows, and the Program employs, certain legal fictions:[35] Legal Fiction Number 1: A CN decision is only based on the information and data available within the "snap-shot in time,"[36] that is, within the time frame of the application period, through the public comments, to when the record is closed. This is an absolutely vital rule to managing CNs because the data never stops pouring in. There is always more up-to-date data. If the Application Record remained open to capture the most recent data, there would never be a point that a CN

[34] *See*, Prehearing Order No 4, (Order Granting Part Motion for Summary Judgment), In Re Certificate of Need on the Applications of Puget Sound Kidney Centers and DaVita, Inc., to Establish Dialysis Centers in the Snohomish County Planning Area No. 1, Master Case No. 2008-118573, pg 21. Theodora Mace, Presiding Officer. *See also*, Prehearing Order No. 6, (Order on Motion for Summary Judgment), In Re Evaluation of Two Certificate of Need Applications Submitted by Central Washington Health Services Association d/b/a/ Central Washington Hospital and DaVita, Inc., Proposing to Establish New Dialysis Facilities in Douglas County, Master Case M2008-118469, pgs. 11-12, John Kuntz, Presiding Officer. *See also,* Findings of Fact, Conclusions of Law, and Final Order, Evaluations Dated February 9, 2012 for the Following Certificate of Need Application Proposing to Add Dialysis Station Capacity to King County Planning Area #4: (1) Northwest Kidney Centers Proposing to Add Five Stations to SeaTac Kidney Center; and (2) DaVita, Inc, Proposing to Establish a Five Station Dialysis Center in Des Moines, Master Case No M2012-360, pgs. 13-15, Frank Lockhart, Presiding Officer.

[35] By definition, and as used here, no pejorative meaning is meant by the term "legal fiction." It is simply an assumption of fact used as a basis for deciding a legal question necessary to dispose of a matter.

[36] *University of Washington Medical Center v. Washington State Dept. of Health*, 164 Wn.2d 95, 103-104 (2008).

could be granted because there's always more recent data available. So there has to be an arbitrary end point beyond which one does not consider more recent data. Legal Fiction Number 2. Each planning area is an island unto itself. In order to make a decision on the available data, the Program has to pretend that no prospective patient who resides in the planning area would leave the planning area to seek treatment in a different planning area. Likewise, it is assumed that no prospective patient from another planning area would come into this planning area to seek treatment. In the instant case, the data indicates that there is a need for nine additional dialysis stations in Skagit County. It is assumed that patients in need in Skagit County, and only those patients in need in Skagit County, will obtain their treatment in Skagit County. For example, there are no dialysis services available on the San Juan Islands in San Juan County. The ferries that serve the San Juan Islands disembark in Anacortes. It is logical to assume that if a dialysis facility is located in Anacortes, that patients from the San Juan Islands would utilize it because it would be their closest dialysis service. However, for the purposes of granting CNs, no adjustment is made to Anacortes' utilization projections for out-of-county patients. As counterintuitive as these legal fictions appear to be, they actually create more statistically reliable results, because the alternative would be to speculate on patient migration, on a mile-by-mile basis, radiating out from every proposed location, a speculation for which there is no detailed or accurate data. Thus, for purposes of granting a CN, it is assumed that once the need for dialysis stations is established, those patients in the planning area will travel to

wherever the stations are, no matter where they are in the planning area. Thus, within this legal fiction, the geographical location of the proposed stations is irrelevant.[37]

1.24 However, this legal fiction is counterbalanced by the "superior alternative" test of WAC 246-310-240(1) which gives to the Program, and ultimately to the Presiding Officer, the ability to apply practical human discernment to the analysis. For example, while geographical location does not matter in the legal fiction, clearly a proposed project that was extremely difficult to get to, would not be superior in terms of travel costs, or efficiency of treatment delivery. Similarly, a proposed project that was easy to get to, but increased health care costs because of the expense of the project, might lose the superiority test to a project that was slightly more inconvenient to get to, but had lower costs. The superior alternative test of WAC 246-310-240(1) allows the Program, and ultimately the Presiding Officer, to look at the totality of both applications, to weigh all the factors, and to, if possible, make a determination if one project is superior to the other. Because this superiority determination of WAC 246-310-240(1) looks at the totality of each application, it actually requires the decision-maker to first look at WAC 246-310-240(2) and (3) to see if any factor regarding construction costs or innovations in health care delivery might cause one project to be superior. If, after weighing all the factors of both applications, no superiority determination is possible,

[37] The two exceptions are (1) under WAC 246-310-210(2), the disadvantaged and elderly must have "adequate access" to the proposed dialysis services, and (2) under the tie-breakers of WAC 246-310-288, the geographical location becomes decisive, because, all other factors being equal, the project that is located furthest from the existing facility wins a tie-breaker point.

then and only then, are the tie-breakers of WAC 246-310-288 applied.[38]

1.25 PSKC's project involves construction which triggers an analysis under WAC 246-310-240(2). The capital expenditure associated with the project is $4,055.071 of which 71 percent is related to construction and site preparation. Based on the application record and the testimony at hearing, the costs and scope of the project are reasonable. There was no evidence that the project would have an unreasonable impact on the costs to the public of providing health services by other persons.

1.26 As for the WAC 246-310-240(3) question of whether either DaVita's or PSKC's project involved innovations in the financing and delivery of health services (the aforementioned factor that, in some cases, could override higher health costs), the answer is no. Both companies are able to provide professional quality treatment. No improvements or innovations in the financing or delivery of health services were demonstrated by either project.

1.27 Returning to the question of WAC 246-310-240(1) superiority, it is clear that both applicants' projects would fulfill the need in the planning area. Both projects can be adequately financed. Both applicants are experienced and capable of staffing and managing their respective projects. Both projects are reasonably projected to meet or exceed their operating expenses by the third full year of operation. Neither project would have an unreasonable impact on the costs of health services, nor would either

[38] *See*, Paragraph 2.9, Conclusions of Law.

project result in unwarranted fragmentation of the delivery of health care services. PKSC's construction costs are reasonable. Neither project demonstrates innovations in the financing or delivery of health care. While PSKC's Anacortes location would be more advantageous to the residents living closer to Anacortes, especially the older residents who do not drive, the Presiding Officer does not find, within the context of WAC 246-310-240, that either application is superior.

WAC 246-310-288 "Tie-Breakers"

1.28 However, within the context of WAC 246-310-288, PSKC's project is *de facto* superior. Because both applications met all the criteria of WAC 246-310-210 through WAC 246-310-240, and because neither application is superior to the other under WAC 246-310-240, the "tie-breaker" of WAC 246-310-288 is applied. Here, because PSKC's project is furthest away[39] from the existing facility (Skagit Valley Hospital), PSKC gets the decisive tie-breaker point. The logic of WAC 246-310-288 is that, if all other factors are equal, the dispersion of dialysis facilities in a planning area is superior to clustering them in one area.

1.29 While the Presiding Officer disagrees with the Program's omitting the superiority analysis under WAC 246-310-240, the fact is that the Program's analysis of WAC 246-310-288 in their evaluation was directly on point.

1.30 An analysis of the WAC 246-310-288 tiebreaker criteria properly awards

[39] The exact requirement of WAC 246-310-288(2)(c) is that one point will be awarded to the facility furthest away from the existing facilities if that facility is at least 3 miles from the existing facility. PSKC qualifies for the point. DaVita, at 2.8 miles from Skagit Valley Hospital, does not qualify for the point.

seven points to PSKC and six points to DaVita. Both parties are awarded five points for meeting the WAC 246-310-288(1)(a-e) criteria of having training services, a private room, a permanent bed station, an evening shift, and meeting the projected need. However, the WAC 246-310-288(2) criteria points can only be awarded to one provider. DaVita receives the economies of scale point for having the lower capital expenditure per station. PSKC receives the point for patient geographical access for being the farthest from the existing facility in Mt. Vernon.[40] PSKC also receives the point for "provider choice" for not already having a facility in the planning area.[41] Thus, applying the criteria of WAC 246-310-288, PSKC is awarded seven tie-breaker points while DaVita only accumulates six points.

1.31 The Presiding Officer finds that both DaVita's and PSKC's applications meets the criteria for CN set forth in WAC 246-310-210, WAC 246-310-220, WAC 246-310-230, and WAC 246-310-240. However, because PSKC wins the majority of the tiebreaker points under WAC 246-310-288, the CN is awarded to PSKC.

II. CONCLUSIONS OF LAW

2.1 The Department of Health is authorized and directed to implement the CN program. RCW 70.38.105(1). Kidney dialysis treatment centers are health care facilities that require a CN. WAC 246-310-284. See also, WAC 246-310-010(26). The

[40] WAC 246-310-288(2)(c) is clear that to receive this point, a facility must be more than three miles from the existing facility. PSKC qualifies for this point. DaVita's close proximity to Skagit Valley Hospital precludes them being awarded this point.

applicant must show or establish that its application meets all of the applicable criteria. WAC 246-10-606. Admissible evidence in CN 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). The standard of proof is preponderance of the evidence. WAC 246-10-606.

2.2 The Presiding Officer (on delegated authority from the Secretary of Health) is the agency's fact-finder and final decision maker. *DaVita v. Department of Health*, 137 Wn. App. 174, 182 (2007) (*DaVita*). The Presiding Officer engages in a de novo review of the record. *See, University of Washington Medical Center v. Department of Health,* 164 Wn.2d 95 (2008) (citing to *DaVita).* The Presiding Officer may consider the Program's written analysis in reaching his decision but is not required to defer to the Program analyst's decision or expertise. *DaVita*, 137 Wn. App. at 182-183.

2.3 In acting as the Department's final decision maker, the Presiding Officer reviewed the application record. The Presiding Officer also reviewed the hearing transcripts and the closing briefs submitted by the parties pursuant to RCW 34.05.461(7). The Presiding Office applied the standards found in WACs 246-310-200 through 246-310-240 in evaluating both parties' applications.

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[41] Exhibit D-2 shows the Program's rationale and policy for awarding the "provider choice" to the applicant that also is awarded the "patient geographical access point". This written policy is also posted on the Program's CN website and is not new information to applicants.

2.4 WAC 246-310-200 sets forth the “bases for findings and actions” on CN Applications, to wit:

> (1) The findings of the department's review of certificate of need applications and the action of the secretary's designee on such applications shall, with the exceptions provided for in WAC 246-310-470 and 246-310-480 be based on determinations as to:
>
> (a) Whether the proposed project is needed;
>
> (b) Whether the proposed project will foster containment of the costs of health care;
>
> (c) Whether the proposed project is financially feasible; and
>
> (d) Whether the proposed project will meet the criteria for structure and process of care identified in WAC 246-310-230.
>
> (2) Criteria contained in this section and in WAC 246-310-210, 246-310-220, 246-310-230, and 246-310-240 shall be used by the department in making the required determinations.

2.5 WAC 246-310-210 defines the “determination of need” in evaluating CN Applications, to wit:

> The determination of need for any project shall be based on the following criteria, except these criteria will not justify exceeding the limitation on increases of nursing home beds provided in WAC 246-310-810.
>
> (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. The assessment of the conformance of a project with this criterion shall include, but need not be limited to, consideration of the following:
>
> . . . .

(b) In the case of health services or facilities proposed to be provided, the efficiency and appropriateness of the use of existing services and facilities similar to those proposed;

(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. The assessment of the conformance of a project with this criterion shall include, but not be limited to, consideration as to whether the proposed services makes a contribution toward meeting the health-related needs of members of medically underserved groups which have traditionally experienced difficulties in obtaining equal access to health services, particularly those needs identified in the applicable regional health plan, annual implementation plan, and state health plan as deserving of priority. Such consideration shall include an assessment of the following:

(a) The extent to which medically underserved populations currently use the applicant's services in comparison to the percentage of the population in the applicant's service area which is medically underserved, and the extent to which medically underserved populations are expected to use the proposed services if approved;

(b) The past performance of the applicant in meeting obligations, if any, under any applicable federal regulations requiring provision of uncompensated care, community service, or access by minorities and handicapped persons to programs receiving federal financial assistance (including the existence of any unresolved civil rights access complaints against the applicant);

(c) The extent to which medicare, medicaid, and medically indigent patients are served by the applicant; and

(d) The extent to which the applicant offers a range of means by which a person will have access to its services (e.g., outpatient services, admission by house staff, admission by personal physician).

2.6 WAC 246-310-220 sets forth the "determination of financial feasibility" criteria to be considered in reviewing CN Applications, to wit:

> The determination of financial feasibility of a project shall be based on the following criteria.
>
> (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 can be appropriately financed.

2.7 WAC 246-310-230 sets forth the "criteria for structure and process of care" to be used in evaluating CN Applications, to wit:

> 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.
>
> (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 included in 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 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 accord with applicable federal and state laws, rules, and regulations. The assessment of the conformance of a project to this criterion shall include but not be limited to consideration as to whether:

2.8 WAC 246-310-240 sets forth the "determination of cost containment" criteria to be used in evaluation a CN Application, to wit:

> 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.

2.9 WAC 246-310-288 sets forth the procedure to resolve ties between two applications. However, when reading WACs 246-310-200 through WAC 246-310-240 together, it is clear that one never gets to the tie-breakers if one application is superior to another. WAC 246-310-240 states: "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." (Emphasis added.) WAC 246-310-200(2) states: "Criteria contained in this section and in WAC 246-310-210, 246-310-220, 246-310-230, *and* 246-310-240 *shall* be used by the department in making the required determinations." (Emphasis added.) WAC 246-310-288 states: "If two or more applications meet *all* applicable review criteria and there is not enough station need projected for all applications to be approved, the department will use tie-breakers to determine which application or applications will be approved." (Emphasis added.) Statutory construction requires these rules to be read together and applied in such a way that no part of any rule is invalidated.[42] WAC 246-310-240(1) requires a comparison of the existing alternatives which includes the competing application under concurrent review. If neither alternative is superior, then, and only then, does the decision maker apply the tiebreakers in WAC 246-310-288.

2.10 As indicated, WAC 246-310-288 sets forth the "tie-breakers", to wit:

> If two or more applications meet all applicable review criteria and there is not enough station need projected for all applications to be approved, the department will use tie-breakers to determine which application or applications will be approved. The department will approve the application accumulating the largest number of points. If sufficient additional stations remain after approval of the first application, the department will approve the application accumulating the next largest number of points, not to exceed the total number of stations projected for a planning area. If the applications remain tied after applying all the tie-breakers, the department will award stations as equally as possible among those applications,

[42] In addition, WAC 246-10-602(3)(c) prohibits a Presiding Officer from declaring any rule invalid.

without exceeding the total number of stations projected for a planning area.

(1) The department will award one point per tie-breaker to any applicant that meets a tie-breaker criteria in this subsection.

(a) ***Training services (1 point)*:**

(i) The applicant is an existing provider in the planning area and either offers training services at the facility proposed to be expanded or offers training services in any of its existing facilities within a thirty-five mile radius of the existing facility; or

(ii) The applicant is an existing provider in the planning area that offers training services in any of its existing facilities within thirty-five miles of the proposed new facility and either intends to offer training services at the new facility or through those existing facilities; or

(iii) The applicant, not currently located in the planning area, proposes to establish a new facility with training services and demonstrates a historical and current provision of training services at its other facilities; and

(iv) Northwest Renal Network's most recent year-end facility survey must document the provision of these training services by the applicant.

(b) ***Private room(s) for isolating patients needing dialysis (1 point)*.**

(c) ***Permanent bed stations at the facility (1 point)*.**

(d) ***Evening shift (1 point)*:** The applicant currently offers, or as part of its application proposes to offer at the facility a dialysis shift that begins after 5:00 p.m.

(e) ***Meeting the projected need (1 point)*:** Each application that proposes the number of stations that most closely approximates the projected need.

(2) Only one applicant may be awarded a point for each of the following four tie-breaker criteria:

(a) ***Economies of scale (1 point)*****:** Compared to the other applications, an applicant demonstrates its proposal has the lowest capital expenditure per new station.

(b) ***Historical provider (1 point)*****:**

(i) The applicant was the first to establish a facility within a planning area; and

(ii) The application to expand the existing facility is being submitted within five years of the opening of its facility; or

(iii) The application is to build an additional new facility within five years of the opening of its first facility.

(c) ***Patient geographical access (1 point)*****:** The application proposing to establish a new facility within a planning area that will result in services being offered closer to people in need of them. The department will award the point for the facility located farthest away from existing facilities within the planning area provided:

(i) The facility is at least three miles away from the next closest existing facility in planning areas that qualify for 4.8 patients per station; or

(ii) The facility is at least eight miles from the next closest existing facility in planning areas that qualify for 3.2 patients per station.

(d) ***Provider choice (1 point)*****:**

(i) The applicant does not currently have a facility located within the planning area;

(iii) The department will consider a planning area as having one provider when a single provider has multiple facilities in the same planning area;

(iii) If there are already two unrelated providers located in the same planning area, no point will be awarded.

2.11 Based on the above Findings of Fact and Conclusions of Law, the Presiding Officer determines that both DaVita's and PSKC's applications meet the criteria for CN set forth in WAC 246-310-210, WAC 246-310-220, WAC 246-310-230, and WAC 246-310-240. However, because PSKC wins the majority of the tiebreaker points under WAC 246-310-288, the CN is awarded to PSKC.

ORDER

A Certificate of Need is approved for PSKC to establish a nine station dialysis facility in Anacortes pursuant to its application and in conformity with requirements set by the Program.

Dated this _22___ day of July, 2013.

_____/s/_____
FRANK LOCKHART, Health Law Judge
Presiding Officer

NOTICE TO PARTIES

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
P.O. Box 47879
Olympia, WA 98504-7879

and a copy must be sent to:

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

The petition must state the specific grounds for reconsideration and what relief is requested. WAC 246-10-704. The petition is denied if the Presiding Officer 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 is resolved. RCW 34.05.470(3).

The order is in effect while a petition for reconsideration or 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/PublicHealthandHealthcareProviders/HealthcareProfessionsandFacilities/Hearings.aspx