

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

In the Matter of:

EVALUATION DATED OCTOBER 27, 2014
OF THE CERTIFICATE OF NEED
APPLICATIONS SUBMITTED BY
NORTHWEST KIDNEY CENTERS,
FRESENIUS MEDICAL CARE HOLDINGS,
INC., AND DAVITA HEALTHCARE
PARTNERS, INC., PROPOSING TO ADD
DIALYSIS CAPACITY TO KING COUNTY
PLANNING AREA #1

DAVITA HEALTHCARE PARTNERS, INC.,

Petitioners.

Master Case No. M2015-102

FINDINGS OF FACT,
CONCLUSIONS OF LAW,
AND INITIAL ORDER

APPEARANCES:

Petitioner, DaVita Healthcare Partners, Inc. (DaVita) by
Perkins Coie LLP, per
Brian W. Grimm and Anastasia Anderson, Attorneys at Law

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

Intervenor, Northwest Kidney Centers, Inc. (Northwest), by
Davis Wright Tremaine LLP, per
Brad Fisher and Lisa Rediger Hayward, Attorneys at Law

PRESIDING OFFICER: John F. Kuntz, Review Judge

The Presiding Officer conducted a hearing on June 8-9, 2015, regarding two Certificate of Need (CN) applications in King County Planning Area #1. DaVita submitted an application to establish a new five-station kidney dialysis facility at 18503 Firlands Way North, Seattle, Washington. Northwest submitted an application to

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CONCLUSIONS OF LAW,
AND INITIAL ORDER

expand its existing facility in its Lake City facility, located at 14524 Bothell Way NE, Lake Forest Park, Washington, by five additional stations.

ISSUES

- A. Does DaVita's CN application to establish a five-station dialysis facility in King County Planning Area #1 meet the criteria set forth WAC 246-310-210, WAC 246-310-220, WAC 246-310-230, and WAC 246-310-240?
- B. Does Northwest's CN application to expand its existing facility by five additional stations in King County Planning Area #1 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 the DaVita and Northwest CN applications meet the above criteria, then which application better meets the criteria set forth in WAC 246-310-288?

PROCEDURAL HISTORY

On November 27, 2013, DaVita applied for a CN to establish a five-station dialysis facility in King County Planning Area #1. DaVita's proposal included renting and remodeling an existing building at an estimated capital expenditure of \$1,923,388.

On November 27, 2013, Northwest applied for a CN to expand its 13-station kidney dialysis facility by five additional stations in King County Planning Area #1, at an estimated capital expenditure of \$128,616. The capital expenditure figure represented an actual expenditure associated with the project (\$77,538), plus the costs previously spent on Northwest's earlier expansion project (\$51,078).

On October 27, 2014, the Program issued an evaluation that approved the Northwest application and denied the DaVita application.¹

SUMMARY OF PROCEEDINGS

The Presiding Officer admitted the following exhibits at hearing:

Program Exhibits:

Exhibit P-1: The Application Record.

DaVita Exhibits:

Exhibit D-2: CON application submitted by NKC on August 22, 2013, to expand its Lake City Kidney Center.

Exhibit D-5: Brad Fisher email, dated April 14, 2015, (containing NKC response to DaVita discovery request).

Exhibit D-6: NKC Lake City Kidney Center Pro Forma Operating Statement November 2013 (N000310-04).

Exhibit D-8: ESRD Need projection for King 1 based on Northwest Renal Network data through year-end 2013, dated March 2014.

Northwest Exhibits:

Exhibit N-2: Marketing materials for DaVita site [DaVita 435];

Exhibit N-3: Emails re DaVita site [DaVita 440-442];

Exhibit N-4: Emails re DaVita site [DaVita 449-451];

Exhibit N-5: Emails re DaVita site and capital expenditures [DaVita 510];

¹ There was a third applicant, Fresenius Medical Care Holdings, Inc. (Fresenius), which also proposed to establish a new five-station dialysis facility. The Program's evaluation denied the Fresenius CN application. Fresenius initially requested an adjudicative proceeding to contest the Program's denial decision, but withdrew its request. For that reason, Fresenius is no longer a party in this matter.

Exhibit N-6: Emails re environmental contamination on DaVita site [DaVita 980-982];

Exhibit N-7: Emails re DaVita site [DaVita 984-987];

Exhibit N-8: Emails re DaVita site [DaVita 988-989];

Exhibit N-9: Emails re DaVita site [DaVita 994-997];

Exhibit N-10: Emails re DaVita's amended application [DaVita 1134]; and

Exhibit N-11: Payer mix and commercial charges for the "Seattle area facilities" that were used in the preparation of DaVita's pro forma.

The Presiding Officer heard testimony from the following witnesses:

Program witnesses:

1. Robert Lee (Bob) Russell, Department of Health, CN Program Analyst.

DaVita's witnesses:

1. Kathryn Cullen, Director of Special Projects, DaVita HealthCare Partners, Inc.

Northwest's witnesses:

1. Austin Ross, Vice President of Planning, Administration, Northwest;
2. Mary Carol (Carrie) McCabe, Chief Financial officer, Northwest; and
3. Jody Carona, Consultant, Health Facilities Planning and Development.

The parties were allowed to submit briefs in lieu of closing arguments in accordance with RCW 34.05.461(7). To accommodate vacation schedules, the initial closing briefs were due by July 31, 2015, and final responsive closing briefs by

August 7, 2015. See Prehearing Order No. 6.² The hearing record closed on August 7, 2015.

References to the application record are designated AR and references to the hearing transcript are designated TR in this order.

I. FINDINGS OF FACT

1.1 Northwest is a non-profit provider that operates 14 kidney dialysis facilities in King County and one in Clallam County. DaVita is a publicly held, for-profit corporation that provides dialysis services to approximately 2,042 kidney dialysis facilities in multiple states including Washington. DaVita owns or operates 35 kidney dialysis facilities in the state of Washington.

1.2 Both Northwest and DaVita applied for a kidney dialysis CN.³ Northwest's CN application was to add five stations, and DaVita's CN application was to establish a five-station facility, in King County Planning Area #1. A planning area is generally defined as a county. See *generally* WAC 246-310-010(43). King County is divided into 12 smaller planning areas that are identified by specified zip codes. See WAC 246-310-280(9)(a).

1.3 In order to qualify for a CN, the applicant must show that its application meets all of the relevant criteria in chapter 246-310 WAC. See WAC 246-10-606(2). The CN applicant must show that the proposed project: (a) is needed; (b) is financially

² Prehearing Order No. 6 was issued by Health Law Judge Heather Francks. She subsequently left the Department of Health Adjudicative Service Unit and the case was transferred to the undersigned Presiding Officer. The hearing was conducted by the undersigned Presiding Officer.

feasible; (c) will meet certain criteria for structure and process of care; and (d) will foster containment of costs of health care. The Presiding Officer reviewed both Northwest's and DaVita's CN applications under these criteria in the adjudicative process.

WAC 246-310-210 "Determination of Need"

1.4 Pursuant to WAC 246-310-210(1), a CN applicant must demonstrate a need exists for the proposed project. For a kidney dialysis treatment facility CN, an applicant must use the need methodology set forth in WAC 246-310-284 to calculate whether a need exists. The need methodology includes a linear regression analysis to calculate the future dialysis need based on the historical number of dialysis patients that reside in the planning area and the annual population growth rate for the same area.

1.5 Using verified population and patient information from the Northwest Renal Network⁴, both DaVita and Northwest determined that there would be a need for five additional kidney dialysis stations in the planning area by the third year of operation. Northwest's third year was 2017; DaVita's third year was 2018. The Program's calculations verified this need. See AR 461. Subtracting the 35 stations already in existence in King County Planning Area #1, and with a projected need of 40 stations in the relevant time period, there is a confirmed need for five additional kidney dialysis stations in King County Planning Area #1.

³ A "certificate of need" means a written authorization for a person to implement a proposal for one or more undertaking. See WAC 246-310-010(11).

⁴ Northwest Renal Network is a private not-for-profit corporation that is independent of any dialysis company. It collects and analyzes data on patients enrolled in the Medicare end stage renal disease programs, serves as an information resource, and monitors the quality of care given to dialysis and transplant patients in the Pacific Northwest. AR 459.

1.6 Determining need also requires an examination of whether there are existing facilities in the planning area that can be utilized to fill the need for additional stations. Pursuant to WAC 246-310-284(5), a CN for additional kidney dialysis stations may only be granted when the existing planning area facilities are operating at 80 percent capacity (4.8 in-center patients per approved station). Northwest currently operates the only two planning area facilities (NKC Scribner Kidney Center in Seattle, WA and NKC Lake City Kidney Center, Lake Forest Park, WA). Both Northwest facilities are operating in excess of the 80 percent capacity requirement (5.32 patients per station at the NKC Scribner facility and 4.92 patients per station at the NKC Lake City facility), so the WAC 246-310-284(5) criterion is met. See AR 461 (Table 2).

1.7 Pursuant to WAC 246-310-210(2), a need analysis also requires a determination that all residents of the planning area (low-income, racial and ethnic minorities, women, handicapped persons, other underserved groups and the elderly) will have adequate access to the proposed project. Both the Northwest and DaVita applications show that they would accept patients with end stage renal disease who require hemodialysis without regard to age, race, color, ethnicity, sex or sexual orientation, religious or political beliefs, medical disease, disorder or disability. A review of the admission policies, charity care policies, and Medicare eligibility certifications and policies of both applicants show that Northwest and DaVita will provide all residents with adequate access as required by WAC 246-310-210(2).⁵

⁵ WAC 246-310-210 has additional subsections (3) through (6) that are not applicable in the present matter.

1.8 Based on the Application Record, the reliability of the underlying population and patient data used by the parties, and the above analysis, there is need for an additional five kidney dialysis stations in the King County Planning Area #1 by 2017.

WAC 246-310-220 “Financial Feasibility”

1.9 Pursuant to WAC 246-310-220, a CN applicant must demonstrate that the proposed project is financially feasible. The CN applicant must show that: the capital and operating costs can be met under WAC 246-310-220(1); the costs of the project will probably not result in an unreasonable impact on the costs for health services under WAC 246-310-220(2); and that the applicant can appropriately finance the proposed project under WAC 246-310-220(3).

1.10 Starting with an analysis under WAC 246-310-220(3), Northwest’s project involves expanding its existing Lake City Kidney Center at an estimated cost of \$128,616. This amount reflects the purchase of additional equipment to complete the five additional kidney dialysis stations that were previously shelled out in 2002. DaVita’s project involves the rental and renovation of an existing building located at 18503 Firlands Way North, Seattle, Washington, at an estimated cost of \$2,131,188. A review of both the Northwest and DaVita applications shows that each of the parties can finance their respective projects from existing cash reserves. AR 473-474. Both Northwest and DaVita meet the WAC 246-310-220(3) criterion to show that the project can be appropriately financed.

1.11 Northwest and DaVita must also meet the two remaining

WAC 246-310-220 criteria (can either or both projects meet the operating costs; will either project have an unreasonable impact on the costs of health services). WAC 246-310-220(1) does not specifically provide a method of analyzing whether a CN project's operating costs can be met. The accepted practice is to look at the facility's income and expense pro forma⁶ statement for a three-year period.⁷ If the facility can be profitable by the third year of operation, it will meet the WAC 246-310-220(1) operating cost criterion.⁸ The applicant must also show that the new or expanded facility is operating at 4.8 patients per station by the end of the third year (or operating at 80 percent capacity) as required by WAC 246-310-284.

1.12 Northwest anticipates making a net profit for each of the three years in its pro forma statement. Northwest's pro forma statement is for the three-year period from 2015 to 2017, and the statement shows an increase in the number of patients and the number of treatments each year to account for the increase in its net profits. AR 465 (Table 4). DaVita contends that Northwest's pro forma statement contains fundamental inaccuracies that undercut Northwest's predicted net profits. DaVita argues that: (1) Northwest uses an average commercial revenue per treatment figure; (2) a typographical error in the narrative assumptions (using 70 patients in 2014 rather than 2015) skews Northwest's entire pro forma statement; and (3) the Northwest pro

⁶ "Pro forma" is used to describe accounting, financial and other statements or conclusions based upon assumed or anticipated facts. Black's Law Dictionary, Sixth Edition, page 1212 (1990).

⁷ For example, if a CN applicant files an application in 2014, the first full year of operation would be 2015. The three-year period would then be 2015 to 2017.

⁸ See AR 467-68.

forma statement is incorrect because Northwest fails to allocate a portion of the 2012 purchase price of the land as a capital expenditure. DaVita Post-Hearing Brief, pages 17-19. None of these arguments is persuasive.

1.13 First, Northwest used an \$835 average commercial revenue per treatment (an average of all of Northwest's 14 treatment facilities in King County) to calculate its revenue rather than the \$1,439.89 figure identified by DaVita. This is because the Lake City facility specific figure of \$1,439.89 was a statistical anomaly. This figure was based on a small sample size (four patients out of 60). Therefore, the \$835 average commercial revenue per treatment is a more realistic number. DaVita's argument against the use of a rate based on the average commercial revenue per treatment rate is disingenuous here, as DaVita itself uses a blended average (based on its nationwide revenue per treatment and not Washington state revenue per treatment) in calculating its revenue. Northwest's use of the average commercial revenue per treatment does not make its pro forma statement inaccurate.

1.14 Second, Northwest's typographic error showed it projected the number of patients it would treat in 2014 as 70 patients, rather than showing the 70-patient projection in year 2015. See AR 44 to AR 45. If Northwest projected 70 patients in 2014, DaVita argues that Northwest's patient number for 2015 should be 76. Whether Northwest projects a 70-patient count in 2014 or 2015 does not invalidate Northwest's pro forma statements. The pro forma is based on a *reasonable* projection of patient and treatment numbers. Northwest projects a six-patient increase in each year of the 2015-2017 pro forma. The projected increase in patients (six per year) is reasonable here

and accounts for Northwest's projected increase in the number of treatments per year.⁹ The typographical error identified by DaVita does not invalidate Northwest's pro forma statement here.

1.15 DaVita's next argument is that Northwest's project failed to account for or allocate a part of Northwest's \$2.9 million dollar land purchase in 2012 as a part of the current CN application. The kidney dialysis rules in place in 2002 allowed Northwest to design and construct the Lake City Kidney Center to accommodate a total of 18 kidney dialysis stations. The 2002 project included leasing the land for the building site. While built to accommodate 18 stations, Northwest received a CN to operate only 10 of those stations. Subsequently the CN Program granted Northwest a CN for a three-station increase, which increased the total number of stations to 13. Northwest then purchased the property for \$2.9 million dollars in 2012 and filed its present 2013 kidney dialysis application to permit the operation of the remaining five stations originally constructed in 2002.

1.16 Kidney dialysis applicants are not required to allocate a portion of the historic land costs as a capital cost in expansion projects. See TR 283-84 (Carona). Northwest notified the Program of the \$2.9 million dollar purchase of the land in its application. See AR 465, 468; see also AR 8-9; TR 197 (Ross). As there is no historical requirement to allocate land purchase costs in projects involving the expansion of kidney dialysis stations at an existing facility, Northwest was not required

⁹ Note that DaVita's patient projections are similar: DaVita projects an eight patient increase from year one to year two and a seven patient increase from year two to year three in its own pro forma.

to allocate a portion of the \$2.9 million dollar purchase price here. Northwest meets the WAC 246-310-220(1) criterion.

1.17 DaVita's three-year pro forma statement period is 2016 to 2018. It anticipates a net loss in 2016, but a net profit in years 2017 and 2018. It likewise anticipates an increase of patients for each year to account for the increase in net profits. AR 467 (Table 6). As previously stated, there are no standards for analyzing revenue projections other than "reasonableness" (a comparison with past similar applications and a comparison of the current applications to each other). Under that approach it is reasonable that DaVita's projected net revenues will exceed their operating expenses in the third full year of operation based on the information provided in the applications. DaVita meets the WAC 246-310-220(1) criterion here.

1.18 Finally, WAC 246-310-220(2) requires that "[t]he cost of the project, including construction costs, *will probably not result in an unreasonable impact on the costs and charges for health care.*" (Emphasis added). WAC 246-310-220(2), as written, is less than clear and can be more easily understood if the regulation is broken down into two questions:

- (1) Will the project's costs have an impact on the costs and charges for health services?
- (2) If there is an impact, is the impact of the project's costs and charges a reasonable or an unreasonable one?

WAC 246-310-200(2)(a)(ii) and (b) does not identify specific standards for measuring whether a project's costs will probably not result in an unreasonable impact on costs and charges for health care. One approach is to compare the CN applicant's proposed

project costs with other similar CN projects.

1.19 The cost for Northwest's five-station project was \$128,616 (moveable equipment and taxes of \$77,538 and an allocation of historical costs from the original project of \$51,078). See AR 468. Northwest argued that there is no procedure in rule requiring the allocation of historical costs from an earlier expansion project. However, the allocation of the historical costs for those kidney dialysis stations from Northwest's 2002 project permits a more realistic cost analysis for Northwest's present CN project. While disagreeing with the underlying reasoning, Northwest followed the Program's guidance to include the historic costs for five of the stations from the construction of the 2002 project in cost analysis of the current CN project. AR 468. Even with the allocation of the constructions costs, the total amount of Northwest's current 2013 kidney dialysis facility project has an impact on the cost and charges of health care but it will not be an unreasonable impact. Northwest's project meets the WAC 246-310-220(2) criterion.

1.20 DaVita described its project as a five-station kidney dialysis facility. DaVita's single line drawing for the project shows that it intends to build out space for 16 kidney dialysis stations. AR 2210. The CN Program has permitted CN applicants to include additional space for some unfinished kidney dialysis stations as a part of the project (for example, a five-station facility may include space for a two- or three-station expansion). The number of unfinished stations is not set in rule. There are practical reasons for this approach. It is significantly less expensive to include expansion space when building a CN facility than to build it after a facility is open and operating. TR 54

and 89 (Cullen). It also reduces the disruption to patient care. TR 54 (Cullen); TR 316 (Carona).

1.21 There is another obvious but unspoken benefit for building out additional space that is apparent in the present concurrent review of the Northwest and DaVita projects: prior expansion provided Northwest with an opportunity to be ready for future expansion in King County Planning Area #1 at a lower cost. The question is not whether DaVita can plan for some expansion beyond the required planning area need under WAC 246-310-220(2). Rather, the question is how much expansion is DaVita allowed in addition to need under WAC 246-310-220(2)? As an applicant, DaVita must establish that its application meets the WAC 246-310-220(2) criterion. See WAC 246-10-606(2). Therefore, the question is whether DaVita has provided sufficient evidence to support the building of 11 additional kidney dialysis stations beyond the five stations that are needed and identified as a part of its proposed kidney dialysis project.

1.22 DaVita offers several reasons in support of its request for space for an 11-station expansion beyond the five kidney dialysis stations for which need currently exists. The first factor was DaVita's ability to pay for the project with existing cash reserves from its parent company. See AR 1467 (Appendix 10 SEC 10K Statements for 2010, 2011, and 2012); see *also* AR 474. The availability of these funds means that DaVita's proposal to build the 11 additional stations will probably not impact health care costs and charges given that existing cash reserves precludes the need to pass these costs on to kidney dialysis patients.

1.23 Next, DaVita cites a possible need exists for an additional 18 kidney

dialysis stations in the King County Planning Area #1 in 2018, based on a need projection prepared in March 2014. See Exhibit D-8.¹⁰ However, DaVita's witness admitted that DaVita did not have the future need figures at the time it filed its amended CN application and these need figures were not influential in the application decision. TR 77-78 (Cullen). There is also evidence that the Exhibit D-8 need figures are an anomaly (the figures represent a bump in King County Planning Area #1 need that does not reflect a consistent increase in the planning area). TR 308 (Carona). Exhibit D-8 does not support DaVita's application to expand the proposed facility beyond the five stations that are needed in the planning area.

1.24 Another measure to determine if DaVita's application will result in unreasonable costs is a comparison of the cost per kidney dialysis station. This is measured by dividing the total cost of DaVita's project (\$2,131,188) by the number of stations needed (here five). The total cost per station is \$426,238. This cost per station is comparable to other kidney dialysis applications. See AR 2270. The cost-per-station amount is not an unreasonable amount when compared to other like projects. For that reason the cost per station does not create an unreasonable impact on health care costs or charges. Additionally, DaVita's application shows that the 11 additional stations only account for ten percent of the total project space (that is, 80 square feet

¹⁰ Although Judge Francks permitted the admission of Exhibit D-8, it can be argued that the information contained in that exhibit is outside the snapshot in facts as anticipated in CN hearings. See *University of Washington Medical Center v. Department of Health*, 164 Wn. 2d 95, 103 (2008).

per station, multiplied by 11 stations, which equals 880 square feet of an 8,820 square foot facility). See AR 2210.

1.25 Much of the evidence presented at the hearing and argued in the post-hearing briefs speaks to whether there is a direct correlation between the negotiated commercial insurance rates and an unreasonable impact on health costs and charges. CN Program Analyst Bob Russell evaluated DaVita's kidney dialysis application. After the close of the WAC 246-310-190 comment period, Mr. Russell determined that: (1) the 16 stations (five that were supported by need; 11 that were included for possible future expansion) were an integral part of DaVita's facility; and (2) DaVita would support the expansion space by charging higher commercial insurance rates in the five operating stations until such time as DaVita received a CN to operate the 11 additional stations.

1.26 The first issue is whether the 16 stations are an integral part of the CN project. It would be clearer if DaVita had provided a specific cost breakout for a five-station project and the 16-station project. The total cost per station (\$426,238) for the five-station facility described by DaVita is comparable to other kidney dialysis facilities. See AR 2270. DaVita also provided the total cost of the project (\$2,131,188). The 11 additional stations for the planned expansion constituted only 10 percent of the project. So subtracting ten percent from the project's cost (\$213,118) leaves a total project cost for the five-station project of \$1,918,070. The total cost is comparable to other projects:

Applicant	Project	Total Cost	CN Stations
FMC	Fife	\$2,130,056	9 stations
FMC	Morton	\$3,357,789	6 stations
FHS	Bonney Lake	\$2,356,175	6 stations
FMC	Milton	\$2,896,891	6 stations
FMC	North Seattle	\$1,923,388	5 stations
NKC	Enumclaw	\$2,550,205	5 stations
FMC	Olympia	\$2,587,359	6 stations
PSKC	Monroe	\$5,951,783	12 stations
OPKC	Belfair	\$1,581,490	5 stations
PSKC	Anacortes	\$4,053,082	9 stations
DaVita	North Seattle	\$2,131,188	5 stations

See AR 2270 (information obtained from chart for comparable new facility costs during the period 2011-2014). Given that the costs are within the range for similar projects, it is arguable that DaVita would proceed even without the 11 potential expansion stations. In other words, DaVita could or would proceed with the five-station project without the 10 percent of the project that was set aside for the 11 potential expansion stations. See AR 2189 (DaVita's single line drawing of the proposed facility).

1.27 The second issue is that DaVita would need to support the expansion space by charging higher commercial insurance rates. DaVita provided Information regarding its sources of revenue by type of payor and percentage of patients by payor:

Table 12
Estimated Sources of Revenue and Patients by Payor
Based on DaVita “Company Wide”

Percentages of Patients by Payor Type	% of Patients	Percentage of Revenue by Payor	% of Revenue
Medicare	79%	Medicare	57%
Medicaid/State	8%	Medicaid/State	4%
Insurance/HMO	13%	Insurance/HMO	39%
Total	100%	Total	100%

See AR 1477 (DaVita application) and 472 (Program evaluation). Payments to Medicare and Medicaid are similar among all dialysis providers in Washington State and are unaffected by capital and operating costs at Washington dialysis centers. See AR 289-290. As 39 percent of DaVita’s anticipated reimbursement was generated by its commercial insurance rates, Mr. Russell assumed that DaVita would negotiate higher commercial insurance rates to support or subsidize the 11 additional stations. These higher rates would therefore result in an unreasonable impact on the costs and charges for health services. Mr. Russell did not test this assumption or evaluate whether there was a connection between the higher rates and an unreasonable impact on the costs and charges for health services.

1.28 DaVita denies it will increase its commercial reimbursement rates to recapture the operating costs (TR 67, 71). However, DaVita’s witness lacked personal knowledge about how DaVita negotiates its commercial rates.¹¹ TR 176-77 (Cullen).

¹¹ The only conclusive way to determine whether the commercial insurance rates do or do not unreasonably impact health care costs is to examine the rate information. There is no evidence regarding how DaVita determines its commercial rates or how they negotiate their commercial insurance rates.

Northwest's CFO opined that overbuilding might increase commercial insurance rates and thus create an unreasonable impact on costs and charges. TR 260-61 (McCabe). However, she also does not have personal knowledge regarding how DaVita negotiates its commercial insurance rates. TR 260-61, 265, and 269.

1.29 There is no evidence showing that DaVita's negotiated commercial insurance rates will have a direct impact on the costs and charges of health services.¹² Even assuming there is a direct impact on the costs and charges of health services, the evidence does not allow for a determination whether the impact is reasonable or unreasonable. The CN Program evaluation *assumed* that DaVita would need to charge the higher commercial insurance rates to support the 11 unfinished kidney dialysis stations. The assumption is not supported by the evidence in the record. Absent such evidence, the Presiding Officer relies on the remaining and available evidence (e.g. cost per station and DaVita's ability to finance the project with available funds). Using this evidence, the Presiding Officer finds that DaVita meets the WAC 246-310-220(2) criterion here. Given that finding, the Presiding Officer need not address DaVita's argument that the denial of its application on the "overbuilding" issue is a change of the Department's position and requires the adoption of a new rule on this issue.¹³

¹² In fact, there is evidence in the application record that the CN Program has consistently taken the contrary view. See AR 2271; AR 2279-2281; and AR 2284.

¹³ In Appendix C of its Post-Hearing Brief, DaVita submitted copies of the rules the Department is considering that would set a cap on the number of expansion stations an applicant can include in its application. See DaVita's Brief, footnote 12, page 15 and Appendix C. However, this information is evidence that exists outside the snapshot in time (that is, the application record). The Presiding Officer does not consider it for this reason.

WAC 246-310-230 “Structure and Process of Care”

1.30 For the project to qualify for a CN, the applicant must meet the five criteria set forth in WAC 246-310-230. These criteria include: adequate staffing; appropriate organizational structure and support; conformity with licensing requirements; continuity of health care; and the provision of safe and adequate care.

1.31 Both Northwest and DaVita have experience in staffing and operating dialysis facilities. Northwest operates 14 facilities in King County and one in Clallam County. Northwest identified Dr. Jung Joh as the facility’s medical director as evidenced by the submitted medical director agreement. Northwest provided its staffing plan to provide for the five-station increase at its facility. It also provided evidence of the relationship with local hospitals, physicians, and long-term care facilities in the planning area. This included copies of executed transfer agreements with Swedish Medical Center. See AR 90-92. Northwest has a good track record on compliance issues.

1.32 DaVita operates 35 kidney dialysis facilities in 17 separate counties in the state of Washington. As a part of its application, DaVita identified Dr. Andrew Somlyo as its proposed medical director and submitted the medical director agreement. DaVita submitted its staffing plan to provide for care at the five-station increase at its facility. DaVita included an example of a hospital transfer agreement, but without an operating facility it could not execute an actual transfer agreement. See AR 1491. So long as DaVita could execute an acceptable agreement prior to the award of a CN, DaVita can meet the transfer requirement by agreeing to submit an executed agreement prior to the receipt of a CN. Although there was safety issue identified in DaVita facilities in other

states, it is not reflected in DaVita's safety track record in Washington.

1.33 The Presiding Officer finds that Northwest and DaVita meet the criteria set forth in WAC 246-310-230 for structure and process of care.

WAC 246-310-240 "Cost Containment"

1.34 The final criteria for CN applications are set forth in WAC 246-310-240. There are three sub-criteria: are there superior alternatives in terms of cost, efficiency, or effectiveness" (WAC 246-310-240(1); the costs of projects involving construction (WAC 246-310-240(2); and does the project involve improvements or innovations in the financing or delivery of health services (WAC 246-310-240(3).

1.35 The Program did not perform an analysis under WAC 246-310-240(1) for DaVita.¹⁴ See AR 483-84. The Program's current practice for a concurrent review of two applications is to analyze the two applications under the first three requirements (WAC 246-310-210; WAC 246-310-220; and WAC 246-310-230). If both applications meet the criteria in those three regulations, the Program then proceeds to the "tie-breaker" analysis under WAC 246-310-288. In other words, the Program only looks at whether each applicant has considered any other alternatives to that applicant's own project, not whether one application is superior to the other application. This method of

¹⁴ Although the Program does not perform a WAC 246-310-240(1) evaluation, it did consider the applications under WAC 246-310-240(2) (a) and (b). See AR 485-86. The Program finds that failure to meet the WAC 246-310-220(2) criterion requires a finding that DaVita could not meet the WAC 246-310-240(2) criteria. *Id.*

evaluating CN applications has been reviewed and rejected in other CN cases.¹⁵ 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 of the criteria in WAC 246-310-210 through WAC 246-310-240, and no one application is clearly superior under WAC 246-310-240(1), should the “tie-breakers” of WAC 246-310-288 be applied.

1.36 WAC 246-310-240(2) states:

In the case of a project involving construction: (a) the costs, scope, and methods of construction and energy 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.

DaVita’s proposed project involves the lease and renovation of an existing building and this requires an analysis under WAC 246-310-240(2). The capital expenditure associated with the project is \$2,131,188, of which 62 percent relates to construction and site preparation. Based on the application record and the testimony at the hearing, the costs and scope of DaVita’s project are reasonable. The Program found that DaVita did not meet the WAC 246-310-240(2) criterion, based on the Program’s finding that

¹⁵ See Prehearing Order No. 4 (Order Granting Partial Motion for Summary Judgment) In Re Certificate of Need on the Application of Puget Sound Kidney Centers and DaVita, Inc., to Establish Dialysis Centers in Snohomish County Planning Area No. 1, Master Case No. M2008-118573, page 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 No. M2008-118469, pages 11-12, John F. 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. 2012-360, pages 13-15, Frank Lockhart, Presiding Officer

DaVita failed to meet the WAC 246-310-220(2) criterion. See AR 485-486. As DaVita met the WAC 246-310-220(2) criterion,¹⁶ DaVita meets the WAC 246-310-240(2) criterion here. Northwest is not required to meet the criterion here as it is not engaged in construction in its CN project.

1.37 WAC 246-310-240(3) states:

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.

A review of the Northwest and DaVita kidney dialysis applications does not show any specific improvements or innovations in the financing and delivery of health services here. The WAC 246-310-240(3) criterion is not applicable to either applicant and it does not enter into the superiority analysis for that reason.

1.38 The last consideration is the superiority analysis required under WAC 246-310-240(1). However, a word needs to be said about “superiority.” In order to make CN decisions in a logical and consistent manner, the law allows the use of certain legal fictions.¹⁷ Legal Fiction No. 1: a CN decision is only based on the information and data available within the “snapshot in time”. See *University of Washington Medical Center v. Department of Health*, 164 Wn.2d 95, 103-104 (2008). The snapshot in time or snapshot of facts includes the timeframe of the application period, through the public comment period, to when the application is closed. This rule

¹⁶ See Findings of Fact 1.23 through 1.28

¹⁷ As used here, “legal fiction” is simply an assumption of fact used as a basis for deciding a legal question necessary to dispose of the matter.

is absolutely vital to managing the CN process because there is always more up-to-date data. If the Application Record remained open to capture the most up-to-date data, there would never be a decision on a CN application because there is always more recent data available. Therefore, there must be a cutoff date or end point beyond which more data will not be considered.

1.39 Legal Fiction No. 2: Each planning area is an island unto itself. In order to make a CN decision on the available data, one must assume that no prospective patient who resided in the planning area will leave the planning area to seek treatment in a different planning area. Likewise, it is assumed that no prospective patient from another planning area will come into this planning area to seek treatment. In the instant case, the data indicates there is a need for five additional kidney dialysis stations in King County Planning Area #1. It is assumed that the patients in need in King County Planning Area #1, and only those patients, will obtain their treatment in the planning area. The CN Program and CN applicants all rely on this assumption even if there is a kidney dialysis facility in an adjacent planning area that is located closer to where the patients reside.

1.40 As counterintuitive as these legal fictions appear to be, they actually create a more statistically reliable result, as the alternative would be to speculate on patient migration, on a mile-by-mile basis, radiating out from every proposed location or facility. There is no detailed or accurate data to support such a speculation. 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 kidney

dialysis stations are, no matter where they are located within the planning area. Under these legal fictions, the geographical location of the proposed kidney dialysis stations is irrelevant.

1.41 The above legal fictions are counterbalanced by the “superiority alternative” test of WAC 246-310-240(1), which gives the Program, and ultimately the Presiding Officer, the ability to apply practical human discernment to the analysis. As an example, while geographical location does not matter in the legal fiction, a proposed project that is extremely difficult to reach would not be superior in terms of travel, cost, or efficiency of the delivery of treatment. Similarly, a proposed project that was easy to travel to but could not provide cost-effective or efficient delivery of treatment might lose the superiority test to a project that was slightly more inconvenient to reach, but provided cost-effective or efficient health care. Determining superiority under WAC 246-310-240(1) should examine the totality of factors for each application. A Presiding Officer can consider the WAC 246-310-240(2) and (3) criteria to determine if any factor regarding construction costs or innovations in health care delivery might cause one project to be superior to the other. If no superiority determination is possible under WAC 246-310-240(1), then, and only then, are the WAC 246-310-288 tie-breaker criteria applied.

1.42 In performing a superiority analysis as a part of its application, DaVita considered two alternatives: do nothing; or establish a new five-station facility in the planning area. Northwest considered several alternatives: build a new facility; expand a different facility; postpone any CN project; offer night-time services; shortening

treatment times; and increase the use by patients of home dialysis. Northwest did not choose any of the above alternatives. It decided to expand its Lake City facility by five stations.

1.43 As stated above, both the Northwest and DaVita projects would fulfill the need in King County Planning Area #1. Both projects can be adequately financed. Northwest and DaVita are experienced providers that are capable of staffing and managing their respective projects. Both projects reasonably anticipate meeting or exceeding their operating expenses by the third full year of operation and neither project would have an unreasonable impact on the cost and charges for health services.

1.44 However, the legislative purpose for the certificate of need program is to provide accessible health services. See RCW 70.38.015(1); see also *Overlake Hospital Association v. Department of Health*, 170 Wn.2d 43, 55 (2010). In its December 2014 amended application, DaVita anticipated its project would become operational by June 2015. Northwest's proposed project involves the expansion of its existing Lake City facility from 13 stations to 18 stations and does not involve construction. Northwest anticipated its project would be operational by November 2014. The cost for this expansion is \$128,616, and requires the installation of moveable equipment. DaVita's cost for building a new facility and installing equipment is \$2,131,188. DaVita's project is roughly 16 times more expensive than the Northwest proposal. Northwest's kidney dialysis project is both easier to complete, costs less, and would be accessible to provide needed kidney dialysis treatment to patients seven months earlier than DaVita's project. Given these advantages, Northwest's project is superior to DaVita's project

here. There is no need to complete the WAC 246-310-288 tiebreaker analysis because there is no tie here.

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 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 in CN application hearings 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 initial 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 WAC 246-310-200 sets forth the "bases for findings and actions" on CN Applications, to wit:

FINDINGS OF FACT,
CONCLUSIONS OF LAW,
AND INITIAL ORDER

(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.

2.4 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).

2.5 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.

2.6 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:

2.7 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.

2.8 Based on the above Findings of Fact and Conclusions of Law, the Presiding Officer concludes that Northwest's application meets the applicable criteria in WAC 246-310-210, WAC 246-310-220, WAC 246-310-230, and WAC 246-310-240(1). DaVita's application meets the criteria set forth in WAC 246-310-210, WAC 246-310-220, WAC 246-310-230, and WAC 246-310-240(2) and (3). DaVita does not meet the superiority criterion in WAC 246-310-240(1). Therefore, the CN is awarded to Northwest as the superior application.

III. ORDER

Based on the foregoing Procedural History and Findings of Fact, and Conclusions of Law, it is ORDERED:

3.1 A Certificate of Need for Northwest to expand its existing kidney dialysis facility, Lake City Dialysis Center in Lake Forest Park, pursuant to its application and in conformity with the requirements set by the Program is APPROVED.

3.2 A Certificate of Need for DaVita to establish a new kidney dialysis facility in King County Planning Area #1 is DENIED.

Dated this _27th____ day of October, 2015.

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

NOTICE TO PARTIES

When signed by the presiding officer, this order shall be considered an initial order. RCW 18.130.095(4); Chapter 109, law of 2013 (Sec. 3); WAC 246-10-608.

Any party may file a written petition for administrative review of this initial order stating the specific grounds upon which exception is taken and the relief requested.

WAC 246-10-701(1). A petition for administrative review must be served upon the opposing party and filed with the adjudicative clerk office within 21 days of service of the initial order. WAC 246-10-701(3).

“Filed” means actual receipt of the document by the Adjudicative Clerk Office. RCW 34.05.010(6). “Served” means the day the document was deposited in the United States mail. RCW 34.05.010(19). The petition for administrative review must be filed within twenty-one (21) calendar days of service of the initial order with:

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

and a copy must be sent to the opposing party. If the opposing party is represented by counsel, the copy should be sent to the attorney. If sending a copy to the Assistant Attorney General in this case, the mailing address is:

FINDINGS OF FACT,
CONCLUSIONS OF LAW,
AND INITIAL ORDER

Agriculture and Health Division
Office of the Attorney General
PO Box 40109
Olympia, WA 98504-0109

Effective date: If administrative review is not timely requested as provided above, this initial order becomes a final order and takes effect, under WAC 246-10-701(5), at 5:00 pm on _____. Failure to petition for administrative review may result in the inability to obtain judicial review due to failure to exhaust administrative remedies. RCW 34.05.534.

Final orders will be reported as provided by law. Initial and Final orders will be placed on the Department of Health's website, and otherwise disseminated as required by the Public Records Act (Chap. 42.56 RCW). All orders are public documents and may be released.

For more information, visit our website at:

<http://www.doh.wa.gov/PublicHealthandHealthcareProviders/HealthcareProfessionsandFacilities/Hearings.aspx>