STATE OF WASHINGTON
DEPARTMENT OF HEALTH
ADJUDICATIVE SERVICE UNIT

In the Matter of: CERTIFICATE OF NEED APPLICATION OF FRANCISCAN HEALTH SYSTEM TO ESTABLISH A 6-STATION DIALYSIS CENTER IN THE BONNEY LAKE, PIERCE 1 DIALYSIS PLANNING AREA Franciscan Health System, Petitioner.	Master Case No. M2015-386 FINDINGS OF FACT, CONCLUSIONS OF LAW, AND INITIAL ORDER

APPEARANCES:

Petitioner, Franciscan Health System (Franciscan), by
Jeff Freimund, Attorney at Law

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

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

PRESIDING OFFICER: John F. Kuntz, Review Judge

The Presiding Officer conducted a hearing on September 9, 10 and 11, 2015, regarding two Certificate of Need (CN) applications in Pierce County Planning Area #1. Franciscan submitted an application to establish a new six-station kidney dialysis facility to be located in Bonney Lake, Washington. DaVita submitted an application to expand its existing facility in Puyallup by six kidney dialysis stations.

ISSUES

A. Does DaVita's CN application to expand its Puyallup facility by six stations in Pierce 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?

B. Does Franciscan's CN application to establish a six-station kidney dialysis facility in Bonney Lake, WA 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 Franciscan applications meet the above criteria, then which application better meets the criteria set forth in WAC 246-310-288?

PROCEDURAL HISTORY

On May 30, 2014, DaVita applied for a CN to expand its existing kidney dialysis facility in Puyallup by six stations. DaVita's estimated capital expenditure to add the six stations is $212,140.

On May 30, 2014, Franciscan applied to establish a new six-station kidney dialysis station in Bonney Lake, Washington. Franciscan's estimated capital expenditure associated with the project is $2,356,175.

On February 20, 2015, the Program issued an evaluation that approved the DaVita application and denied the Franciscan application.

SUMMARY OF PROCEEDINGS

At the hearing, the Program presented the testimony of Certificate of Need Executive Director Bart Eggen. Franciscan presented the testimony of Richard Petrich, Franciscan's Vice President of Planning and Business Development; Mike Fitzgerald,

Franciscan's Chief Financial Officer; Peter Agabi, Certificate of Need Analyst; and Jody Carona, Franciscan's consultant. DaVita presented the testimony of Kathryn Cullen, Director of Special Projects, DaVita Healthcare Partners, Inc., and Peter Agabi.

The Presiding Officer admitted the following exhibits at hearing:

A. The following exhibits are admitted as numbered:

Certificate of Need Program

Exhibit P-1: The 3324-page Application Record

Franciscan Health System

Exhibit F-1: The complete administrative record prepared by the Department for this comparative review.

Exhibit F-2: ESRD Need Projection for Pierce County Planning Area 1, based on Northwest Renal Network data through year end of 2014.

Davita HealthCare Partners Inc:

Exhibit D-1: Complete Application Record.

Exhibit D-2: ESRD Need Projection for Pierce County Planning Area 1, based on Northwest Renal Network data through year end 2014.

The parties submitted briefs in lieu of closing arguments. RCW 34.05.461(7). The initial closing briefs were due on October 9, 2015. The responsive closing briefs were due by October 16, 2015. The hearing record closed on **October 16, 2015**.

References to the application record are designated by AR and the page number. References to the hearing transcript are designated by TR and the relevant page number.

I. FINDINGS OF FACT

1.1 On May 30, 2014, both DaVita Health Care (DaVita) and Franciscan Health Systems (Franciscan) applied for a kidney dialysis certificate of need.[1] DaVita applied to add six kidney dialysis stations to its existing facility in the South Hill area of Puyallup, Washington.[2] Franciscan applied to establish a new six-station facility in Bonney Lake, Washington.[3] Both of these locations are in Pierce County Planning Area #1. Franciscan (an affiliate of Catholic Health Initiatives) is a healthcare provider based in Tacoma, Washington. Franciscan provides healthcare services to residents of Pierce and King Counties through seven health care facilities. DaVita is a publicly held, for-profit corporation providing dialysis services at approximately 2,042 kidney dialysis facilities in multiple states, including Washington.

1.2 In order to qualify for a certificate of need (CN), an applicant must show that its application meets all of the relevant criteria in chapter 246-310 WAC. These criteria include a showing by the applicant that the CN project: (a) is needed; (b) is financially feasible; (c) will meet certain criteria for structure and process of care; and (d) will foster cost containment of health care costs and charges.

1.3 The state is divided up into planning areas for purposes of determining need. A planning area is normally defined as a county. See WAC 246-310-010(43). However, due to its size and population, Pierce County is divided into five smaller planning areas that are identified by specified zip codes. See WAC 246-310-280(9)(b).

---

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

[2] DaVita's existing facility is at 716C South Hill Park Drive, Puyallup, Washington.

[3] Franciscan's proposed location is at 19420 State Route 410, Bonney Lake, Washington.

Pierce County Planning Area #1 is located in Southeast Pierce County.

WAC 246-310-210 "Determination of Need"

1.4 WAC 246-310-210(1) states in relevant part:

> The population served or to be served has a 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.

To determine whether there is a need for a kidney dialysis treatment facility or additional kidney dialysis stations, the applicant uses the need methodology set forth in WAC 246-310-284.[4] The need methodology includes a linear regression analysis[5] 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 DaVita (a 16-station facility) and Franciscan (a 12-station facility) are currently the only two kidney dialysis facilities in Pierce County Planning Area #1. Using verified population and patient information provided by the Northwest Renal Network[6], both DaVita and Franciscan calculated that there would be a need for 34 stations in 2018 (the third year of operation). The Program's need calculations verified this 34-station need using the formula set forth in WAC 246-310-284. *See* AR 691. Subtracting the existing 28 stations in Pierce County Planning Area #1 from the projected 34-station need in 2018, there is a confirmed need for six additional kidney

---

[4] The sub-criteria contained in WAC 246-310-210(3), (4), (5), and (6) are not applicable to DaVita's or Franciscan's kidney dialysis projects. They are not discussed further in this decision.

[5] In statistics, a "regression" is an estimation technique in which functions or coefficients within functions are designed to estimate values of a dependent variable. Webster's New College Dictionary, page 1207 (2009).

[6] 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 and Medicaid 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 689, footnote 6.

dialysis stations in Pierce County Planning Area #1.

1.6 Determining need also requires an examination 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 facility or facilities in the planning area are operating at 80 percent capacity (this is 4.8 in-center patients per approved station). DaVita's utilization per station was 5.0; Franciscan's utilization per station was 5.2. Both DaVita and Franciscan are operating at 80 percent capacity and therefore meet the WAC 246-310-284(5) requirement.

1.7 Despite the fact that both DaVita and Franciscan met the above two need requirements, Franciscan argues that the WAC 246-310-210(1) need criterion includes or should include an access component. *See* Franciscan's Post-Hearing Closing Argument Brief, pages 5-9; TR 439. Franciscan refers to the WAC 246-310-210(1) language that states:

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

Franciscan argues that it is not enough to improve access by providing additional kidney dialysis stations in the planning area. Improving access under the need requirement includes assessing the ability of patients to get to the additional kidney dialysis stations or facility where they are located. Franciscan considered several factors it believed applied to the access issue, including traffic patterns, public transportation, and the geographic proximity of the kidney dialysis facilities to the kidney dialysis patients.

Weighing all of these factors, Franciscan argues that its Bonney Lake facility provides this enhanced accessibility and that the DaVita facility does not. DaVita disputes Franciscan's analysis. It argues that the traffic data Franciscan relies on is obsolete, that there are public transportation issues relating to public transportation to the Bonney Lake area and that DaVita's current Puyallup facility is better positioned geographically for the majority of kidney dialysis patients (as measured by the zip codes that comprise the planning area). *See* DaVita's Post-Hearing Brief, page 7-9. Program Analyst Peter Agabi testified that in his nine years of analyzing CN applications he had never evaluated traffic as a factor affecting accessibility. TR 172.

1.8 The existing DaVita and Franciscan kidney dialysis facilities are located about 190 feet apart in the heavily congested South Hill area of Puyallup. Franciscan believes that locating its new facility in Bonney Lake (approximately seven to nine miles east from the South Hill area of Puyallup) improves patient access, especially to those kidney dialysis patients living in the eastern portion of Pierce County Planning Area #1 (Bonney Lake and portions of Sumner). However, Franciscan admits there is no public transportation from Puyallup to the Bonney Lake/Sumner area (or for that matter, in the opposite direction). The majority of the kidney dialysis patients (80 percent) currently reside in the five zip codes in that part of the planning area where DaVita and Franciscan have their current facilities. AR 338. This five zip code area is served by public transportation options. AR 581.

1.9 The Program does not traditionally include the issue of access in its WAC 246-310-210(1) analysis.[7] The Program includes access in conjunction with WAC 246-310-210(2) regarding access for low income and minority patients and as a part of the tie-breaker analysis. However, the legislature has made clear its intent to promote access. *See Overlake Hospital Association v. Department of Health*, 170 Wn. 2d 43, 55 (2010). WAC 246-310-210(1) has an access component. However, the totality of the evidence relating to traffic congestion and issues regarding public transportation argue against awarding the CN to Franciscan here.

1.10 Pursuant to WAC 246-310-210(2), a need determination also requires an examination of whether all residents of the planning area, including 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 DaVita and Franciscan applications show that they would accept patients with end stage renal disease symptoms and who require hemodialysis (that is, kidney dialysis treatment) 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 DaVita and Franciscan will provide all residents with adequate access as required under WAC 246-310-210(2). AR 694-695.

---

[7] Franciscan argues that the Program's failure to consider the accessibility criterion in WAC 246-310-210(1) erroneously conflicts with the principle that all language must be given effect and renders meaningless the WAC 246-310-210(1) access requirement. *See* Franciscan Post-Hearing Closing Argument Brief, page 6. Franciscan further argues that the Program's approach also renders meaningless the WAC 246-310-240(1) requirement to perform a superiority analysis. Given that the Presiding Officer consistently performs a WAC 246-310-240(1) analysis, Franciscan's concern is baseless here.

1.11 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 six kidney dialysis stations in Pierce County Planning Area #1 by 2018.

WAC 246-310-220 "Financial Feasibility"

1.12 Pursuant to WAC 246-310-220, an applicant for a CN 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); and that the applicant can appropriately finance the proposed project under WAC 246-310-220(3).

1.13 Starting with an analysis under WAC 246-310-220(3), DaVita's project involves expanding its existing Puyallup facility at an estimated cost of $ 212,140. This amount reflects the purchase of additional equipment to complete the six additional kidney dialysis stations that were previously shelled out. Franciscan's project involves the construction of a new facility located in Bonney Lake, Washington, at an estimated cost of $ 2,356,175. A review of both the DaVita and Franciscan applications show that each party can finance their respective projects from existing cash reserves. AR 707-708. Both DaVita and Franciscan meet the WAC 246-310-220(3) criterion to show that the project can be appropriately financed.

1.14 DaVita and Franciscan 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 and charges for health

services). WAC 246-310-220(1) does not specifically provide a method of analyzing whether a CN project's immediate and long-range capital and operating costs can be met. The accepted practice is to look at the applicant's pro forma statement for the project covering a three-year period.[8] If an applicant can show its project can be profitable by the third year of operation, it will meet the WAC 246-310-220(1) operating cost criterion.[9] The applicant must also show that the new or expanded facility will operate at 4.8 patients per station by the end of the third year. The 4.8 patient per station figure by the end of the third year represents the applicant is operating at 80 percent capacity per station as required by WAC 246-310-284.

1.15 DaVita anticipates making a net profit for all three years (2016-2018) in its pro forma statement. The increase of its net profits was based on DaVita's reasonable anticipation that the number of kidney dialysis treatments and kidney dialysis patients would increase along with the increase in the planning area population. AR 699. Franciscan's pro forma statement anticipates a net loss in year 2016 but shows an anticipated net profit in years 2017 and 2018. AR 699. The increase from a net loss to a net profit was based on Franciscan's figures that showed an increase in both the number of treatments and the number of patients. Both DaVita and Franciscan meet the WAC 246-310-220(1) criterion here.

1.16 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*

---

[8] "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).

[9] Here DaVita and Franciscan filed their applications in May 2014. The Program's decision was issued in 2015. The first full year of operation would therefore be 2016. The applicable three-year period is 2016-2018.

costs and charges for health care." (Emphasis added). WAC 246-310-220(2) is more easily understood if the regulation it 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?

Certificate of need law requires that applications be compared to each other in a comparative review. DaVita v. Northwest Kidney Center No. 73630-2-I (Division I Court of Appeals filed December 28, 2015).

1.17 DaVita's project will cost $212,140 and will be financed entirely from existing reserves from DaVita's capital expenditure budget. AR 705. Based on the historical financial statements provided by DaVita, there are sufficient cash assets and board approval to support the funding of this project. AR 705, 744, 746, and 897. The majority (85 percent) of DaVita's income is derived from Medicare/Medicaid reimbursements. AR 705, Table 13. Medicare/Medicaid sets uniform nationwide reimbursement rates that are paid to all providers. TR 262-63. Medicare/Medicaid payments are not cost-based payments and therefore do not have an impact on costs or charges for that reason.[10] The remaining reimbursement sources (15 percent) are derived from private insurance/HMO payments. *Id.* DaVita is only seeking to build six

---

[10] Providers do submit cost reports with Centers for Medicare & Medicaid Services (CMS) that include construction costs, which are used in setting the uniform reimbursement rates. The Program argues that if providers in this country overbuild, the costs would be reflected in the cost reports and would probably result in Medicare paying higher reimbursement rates. *See* Certificate of Need Program's Post-Hearing Brief, pages 4-5. But Medicare rates have gone down despite the overbuilding practice. TR 96, 253-54, 271-72, and 366-67. For that reason, the Presiding Officer does not find this argument compelling. It also does not address private insurance reimbursement rates.

additional stations or the actual number needed in Pierce County Planning Area #1. DaVita is not using private insurance/HMO reimbursements to support excess kidney dialysis stations (an argument made by the Program and discussed in Paragraphs 1.18 – 1.23 below). The reimbursements do not cause an unreasonable impact to the costs and charges under WAC 246-310-220(2). DaVita meets the WAC 246-310-220(2) criterion.

1.18 The WAC 246-310-210(1) need calculations show a need for an additional six kidney dialysis stations in the planning area. The line drawing[11] for Franciscan's $2,356,175 kidney dialysis project anticipates the creation or building out for 12 stations, which is double the actual need in the planning area. AR 56. In its application, Franciscan anticipates it will derive 81 percent of its reimbursement from Medicare/Medicaid. These are not cost-based reimbursements. As they are not cost-based, these reimbursements are not viewed as unreasonable costs and charges here. Franciscan obtains the remaining 19 percent reimbursements from private insurance/HMO payments. While the percentages were similar to those found in DaVita's application, the Program did not find Franciscan's approach to be cost effective under WAC 246-310-220(2). AR 704.

1.19 Past CN applicants have been permitted to plan for or include additional space for some unfinished kidney dialysis stations as part of the project (for example, an applicant might be permitted to include or provide for space for a two- or

[11] In this context, a line drawn is a two dimensional representation of the facility. It shows the location of the administrative offices and location of the dialysis stations.

three-station expansion as a part of the project).[12] The number of unfinished or expansion stations is not currently set in rule. There are practical reasons to provide for some expansion in a project. It is significantly less expensive to include the expansion space when building a CN facility than to build it after the facility is open and operating. AR 704. It also reduces the disruption to patient care if the facility does expand at a later date.

1.20 There is another obvious but unspoken reason for building out additional space that is apparent in the present concurrent review of the DaVita and Franciscan projects, namely that DaVita's prior expansion provided it with the opportunity to be ready for future expansion in Pierce County Planning Area #1 at a lower cost. The question is not whether Franciscan can plan for some future kidney dialysis station expansion beyond the required planning area need under WAC 246-310-220(2). Rather, the question is how much expansion is Franciscan allowed to build in addition to the six-station need under the WAC 246-310-220(2) criterion. As the applicant, Franciscan must establish that its application meets the WAC 246-310-220(2) criterion.[13] The Program believes that Franciscan would pay for the future six dialysis stations by the costs and charges for the current six dialysis stations.[14] AR 704. Given that the Medicare/Medicaid fees are set by the federal government, the Program

[12] There was some dispute whether additional space included unfinished shelled-in-only space or finished space with many of the required components (for example installed plumbing). TR 453. The common practice was allowing finished expansion space to avoid patient disruption (such as closing down the facility or unit and relocating patients while renovation was completed). *See* TR 451-453 (Carona).

[13] *See* WAC 246-10-606(2).

[14] Since it is not disputed that prior projects could provide for additional space for two or three additional stations, it can be argued that the analysis of Franciscan's project should actually be a review whether three additional spaces (that is, six additional spaces minus the three generally permitted to CN applicants) beyond the six that are actually proven to be needed is unreasonable here.

concluded that Franciscan would support the future dialysis stations by costs and charges through the monies received from the 19 percent of the patients billed under private insurance/HMO. The Program determined that such an approach is unreasonable under WAC 246-310-220(2). *Id.*

1.21 On its face the Program's conclusion appears logical. However, it is not supported by the facts in this case. As a starting point, kidney dialysis patients are eligible for Medicare 18 months after beginning dialysis regardless of age. Franciscan and other providers (including DaVita) obtain a major percentage of their reimbursement for providing dialysis from Medicare. TR 254-55, 367. In addition, the 19 percent of Franciscan's revenue reimbursements are negotiated with private or commercial insurers. The negotiated rates are not based on the size or location of the facility, and the fees do not vary based on the square footage or the cost of space of the facility. AR 347-48; TR 256-64, and TR 277-78. To remain a viable choice as a provider, Franciscan negotiates rates with commercial insurers at levels that are lower than or equal to the rates charged by its competitors. TR 259-64, TR 277-78. Franciscan is a hospital-based system that negotiates rate changes with insurers on a global basis. It does not single out specific services such as kidney dialysis or specific facilities such as its proposed Bonney Lake facility in determining its reimbursement rates. TR 259-64; TR 277-80.

1.22 Finally, the issue of including kidney dialysis finished expansion space has been allowed since at least 2007. TR 94, 351, 451-52. Franciscan consultant Jody Carona notes the Program's past guidance to kidney dialysis applicants was that if the

applicant built additional stations, it did so at their own peril. TR 451. Such peril included being non-competitive in the tiebreaker process or building without any guarantee that the facility would obtain any future kidney dialysis CN in the planning area. There is no evidence that this common practice has caused reimbursement rates to rise. TR 96, 253-254, 271-272, and 366-367. The impact of building additional stations beyond the actual calculated need, without further evidence that there is an unreasonable impact on the costs and charges, is not enough.

1.23 Franciscan can pay for the project with existing cash reserves. AR 32, 140, and 707-708. The availability of these funds means that Franciscan's proposal to build the six additional stations will probably not impact health care costs and charges, given that the availability of existing cash reserves precludes the need to pass these costs on to the kidney dialysis patients.

1.24 Given the above analysis, Franciscan meets the WAC 246-310-220(2) criterion.

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

1.25 There are five criteria that an applicant must meet for the project to qualify under 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.

1.26 WAC 246-310-230(1) requires a sufficient supply of qualified staff (both management and health personnel) are available or can be recruited. WAC 246-310-230(2) requires that the proposed services will have an appropriate

relationship to ancillary and support services. Both DaVita and Franciscan have providers in these two criteria. DaVita operates 35 kidney dialysis facilities in 17 separate counties in the state of Washington. DaVita identified Zhuowei Wang, M.D., as the facility's medical director, as evidenced by the medical director agreement. *See* AR 770-807. DaVita also provided a staffing plan to provide for the facility. AR 761. It further provided evidence of the relationship with local hospitals, physicians, and long-term care facilities in the planning area. AR 828-830. DaVita has a good track record on compliance issues.

1.27 Franciscan operates five kidney dialysis facilities in Pierce County, Washington. As part of its application, Franciscan identified Amandeep Gill, M.D., as its proposed medical director and submitted the medical director agreement. AR 268-298. Franciscan submitted its staffing plan to provide for care at the six-station facility at the proposed Bonney Lake site. AR 34, AR 710. Franciscan did not provide an executed transfer agreement with a local hospital as a part of its application. Because its proposed Bonney Lake project will be operated as a department of Franciscan's St. Joseph Medical Center, Franciscan was under the impression that it need not complete such an agreement. Franciscan's belief was mistaken, as obtaining a CN would require such an executed agreement. Before it could be awarded a CN for its Bonney Lake facility, Franciscan would need to provide a copy of such an executed transfer agreement with a local hospital. AR 712; *see* WAC 246-310-490(3). Both parties meet the WAC 246-310-230(1) and (2) criteria.

1.28 WAC 246-310-230(3) requires that there is reasonable assurance that the project will conform with applicable state licensing requirements and, if the applicant is or plans to be certified under the Medicare or Medicaid programs, that the applicant will meet the applicable conditions of participation related to those programs. Chapter 246-310 does not contain specific WAC 246-310-230(3) criteria. There are no known recognizable standards that a facility must meet when it is to be Medicare certified and Medicaid eligible. One approach is to examine the applicant's history in meeting these standards at other facilities owned or operated by the applicant.

1.29 Franciscan is currently a provider of dialysis services within Pierce County Planning Area #1. Franciscan's project has complied with the state licensing requirements and conditions of participation in the Medicare and Medicaid program in the past. Given Franciscan's compliance history, there are reasonable assurances that Franciscan could operate its proposed Bonney Lake facility in compliance with the applicable state and federal regulations. Franciscan meets the WAC 246-310-230(3) criterion.

1.30 Franciscan argues that DaVita is unable to provide reasonable assurances that DaVita's project will conform to the WAC 246-310-230(3) criterion. Franciscan's argument rests on the fact that DaVita entered into a Corporate Integrity Agreement (2014 Agreement) with the U.S. Department of Justice in October 2014. The 2014 Agreement addressed improper billing to the federal government relating to the payment of kickbacks to physicians and physician groups to induce referrals to DaVita's dialysis facilities between March 2005 and February 2014. AR 343-44, and

473-74. DaVita disputes Franciscan's argument that this 2014 Agreement prevents it from complying with the WAC 246-310-230(3) criterion. The Program's written evaluation did not specifically address this issue. Executive Director Bart Eggen explained that it is a factor that should have been considered. TR 408. Program Analyst Peter Agabi explained at the hearing that he did in fact consider the 2014 Agreement information, although it does not appear in the written evaluation. TR 151.

1.31 The 2014 Agreement involved 11 transactions that impacted 26 facilities. AR 526-529 and 587. The 2014 Agreement does not contain any admission of wrongdoing TR 56 (Cullen); AR 474. None of the facilities at issue are located in Washington State. TR 58 (Cullen); AR 526-529. The Department of Justice will engage in oversight of any future joint venture structuring of the type that were addressed in the 2014 Agreement. AR 478-551; TR 56-57 (Cullen). The Puyallup facility that DaVita is proposing to expand has an excellent compliance record. TR 58 (Cullen) and TR 149 (Agabi). There is evidence that the joint venture issues that were addressed in the 2014 Agreement are sufficiently segregated from DaVita's CN application here. DaVita meets the WAC 246-310-230(3) criterion here.

1.32 WAC 246-310-230(4) requires that the proposed project will: promote continuity of care; not result in the unwarranted fragmentation of services; and have an appropriate relationship to the service area's existing health care system. There are no known recognized standards for measuring unwarranted fragmentation of services or what type of relationship an applicant should have with the existing health care system.

One method is to examine the applicant's historical approach and the documentation the applicant provided in support of the application.

1.33 Franciscan has provided dialysis services in the planning area for some time. It has organized its kidney dialysis program so that all of the services are contained in a single service line. AR 37. The organizational structure integrates inpatient, outpatient, and home services in a single continuum. AR 37. Franciscan also maintains well established working relationships with the area nursing homes and Pierce County providers. AR 37. Franciscan anticipates that its proposed Bonney Lake facility will be operated as a department of St. Joseph Medical Center, which gives it the ability to transfer patients when required. Franciscan meets the WAC 246-310-230(4) criterion.

1.34 DaVita has provided dialysis services in the planning area and statewide for many years. DaVita has created a continuous quality improvement program to improve patient safety and dialysis outcomes. AR 881-883. In addition, DaVita has created "Kidney Smart," a community-based kidney disease education program that encourages participants to take control of the participant's kidney disease process. AR 885. These courses are offered at no cost. AR 885. DaVita's application will continue to participate with existing providers. DaVita meets the WAC 246-310-230(4) criterion.

1.35 WAC 246-310-230(5) requires that an applicant provide reasonable assurances that the services provided will be done in a manner that ensures safe and adequate care to the public, and in accordance with federal and state laws, rules, and

regulations. As the evidence shows that the DaVita and Franciscan applications comply with the WAC 246-310-230(3) above, the Presiding Officer finds that the same evidence shows that both DaVita and Franciscan meet the WAC 246-310-230(5) criterion.

WAC 246-310-240 "Cost Containment"

1.36 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); what are 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).

1.37 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.

Franciscan's proposed project involves the lease and renovation of an existing building and this requires an analysis under WAC 246-310-240(2). AR 59-108. Franciscan's Bonney Lake site meets the necessary zoning requirements. AR 58. The capital expenditure associated with the project is $2,356,175 ($2,128,681 of which is contributed by Franciscan; $183,694 of which represents the landlord's contribution). AR 31. At least $957,557[15] of the total project amount relates to construction and site preparation. AR 31. Based on the application record and the testimony at the hearing, the cost and scope of Franciscan's project are reasonable. The Program found that

[15] This figure is derived from the two building construction figures from the amended estimates in the Estimated Capital Expenditure figures in Table 11. AR 31.

Franciscan did not meet the WAC 246-310-240(2) criterion, based on the Program's finding that Franciscan failed to meet the WAC 246-310-220(2) criterion due to the "overbuilding" of the proposed Bonney Lake site. AR 721. Franciscan's project does meet the WAC 246-310-240(2) criterion, the building cost are consistent with similar kidney dialysis facilities, and Franciscan has sufficient cash reserves to construct the facility. The Presiding Officer finds that Franciscan meets the WAC 246-310-240(2) criterion. DaVita's project does not involve construction and its project is not required to meet the WAC 246-310-240(2) criterion.

1.38 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 DaVita and Franciscan 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.

1.39 The Program did not perform an analysis under WAC 246-310-240(1) for Franciscan. *See* AR 718-721. The Program's current practice for a concurrent review of two or more applications is to analyze the applications under the first three requirements (WAC 246-310-210; WAC 246-310-220; and WAC 246-310-230). If the applications meet the criteria in those three regulations, the Program then immediately proceeds to the "tie-breaker" analysis under WAC 246-310-288. The Program's analytical approach only considers whether the CN applicant considered other

alternatives to that applicant's own project. The Program does not consider whether one CN applicant compares its project to the other applicant and determines if one application is superior to the competitor's application. This method of evaluating CN applications has been reviewed and rejected in other CN cases and recently by the Washington State Court of Appeals in DaVita v. Northwest Kidney Center No. 73630-2-I (Division I Court of Appeals filed December 28, 2015). No. 73630-2-I (Division I Court of Appeals filed December 28, 2015).[16] WAC 246-310-240(1) requires a comparison of the concurrent applications to determine if one application may be superior to the competitor's application. Only where the competing 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-breaker" provisions of WAC 246-310-288 be applied.

1.40 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

[16] *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. M2012-360, pages 13-15, Frank Lockhart, Presiding Officer.

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 is absolutely vital to the managing of 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 CN application decision because there is always more recent data available. There must therefore be a cutoff date or end point beyond which more data will not be considered.

1.41 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 resides 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 indicated there is a need for six additional kidney dialysis stations in the Pierce County Planning Area #1. It is assumed that the patients in need in Pierce County Planning Area #1, and only those patients, will obtain their treatment in the planning area. The CN Program and the 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 patient resides.

---

[17] As used here, "legal fiction" is simply an assumption of facts used as a basis for deciding a legal question necessary to dispose of the matter.

1.42 As counterintuitive as these two legal fictions appear to be, they actually create a more statistically reliable result. 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 application, 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 located, 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.

1.43 The above legal fictions are counterbalanced by the "superiority alternative" test of RCW 34.05.240(1), which provides a framework 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 extremely easy to reach 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. A superiority determination under WAC 246-310-240(1) examines the totality of factors for each application. This includes a consideration of 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.

1.44 In performing a superiority analysis as a part of its application, DaVita considered three alternatives: (1) add no new stations; (2) build a new six-station facility; or (3) expand the existing 16-station Puyallup by six additional stations. Franciscan considered three alternatives in performing its superiority analysis including: (1) do nothing; (2) expand its existing Puyallup facility; or (3) undertake the proposed Bonney Lake project. After considering these alternatives, Franciscan decided to establish a new six-station facility in Bonney Lake. As there is clear need for six additional kidney dialysis stations in the planning area, both DaVita and Franciscan ruled out the "do nothing or add no new stations" alternative.

1.45 As stated above, both the DaVita and Franciscan projects would fulfill the need in Pierce County Planning Area #1. Both projects can be adequately financed. Both are experienced providers that are capable of staffing and managing their kidney dialysis projects. Both DaVita and Franciscan 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.

1.46 However, the stated legislative purpose of 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). DaVita's proposed project involves the expansion of its existing facility from 16 stations to 22 stations, at a cost of $212,140, and it can be operational within three months of the approval of the kidney dialysis project. See AR 748, Table 8. Franciscan's proposed

project involves the construction of a new six-station facility in Bonney Lake, at a cost of $2,356,175, and it would not be operational until December 2015, which was eight months following the Program's anticipated decision date. AR 14 and AR 685. DaVita can therefore improve patient access by the speed by which it can implement its project. In examining the total cost of the respective projects, Franciscan's project is roughly ten times more expensive ($2,356,175) when compared to DaVita's project ($212,140).

1.47 As it previously argued as a part of the need criteria, Franciscan argues that a component of patient access is whether kidney dialysis services are sufficiently available or accessible, which can be viewed as an issue of geographic access. In other words, it is the ability of the patient to travel to the facility. A person with end stage renal disease who requires kidney dialysis treatment normally requires dialyzing three times a week. TR 436. In the best of all worlds a kidney dialysis patient would have a local facility that minimizes any travel or traffic issues.

1.48 The DaVita and Franciscan facilities are currently the only two providers in the planning area. Their facilities are approximately 190 feet apart. Pierce County Planning Area #1 is comprised of eight zip codes.[18] Five of the relevant zip code areas are associated with the city of Puyallup. AR 690. There is traffic congestion in the Puyallup area that is consistent with most Western Washington cities. Patient access outside the five zip code area is compromised by the lack of public transportation to the eastern portion of Pierce County Planning Area #1, which includes Bonney Lake and portions of Sumner. AR 339, 565, 568; TR 431-32. If it were awarded the CN for its

---

[18] *See* WAC 246-310-280(9). Pierce County is one of four counties that provides for planning subareas. The subareas are defined by specified zip codes.

proposed Bonney Lake facility (which would be approximately seven miles from the current facilities), Franciscan's project would improve access for the Pierce County patients residing outside the five zip codes associated with the city of Puyallup, particularly the patients who reside in the Sumner and Bonney Lake areas. Of the 137 planning area dialysis patients, 24 patients (or 17.5 percent) live in the Bonney Lake or Sumner area.

1.49 The remaining 113 patients (or 72.5 percent) live within or near the city of Puyallup. While traffic congestion exists, there is no evidence to suggest that kidney dialysis patients are experiencing difficulty in reaching either the DaVita or Franciscan's current facility. Both the DaVita and Franciscan facilities have operated above the 80 percent utilization rate for several years. AR 691-92. Public transportation does exist in the five zip code area immediately surrounding the city of Puyallup. The majority of the dialysis patients therefore have ready access to the two existing facilities. While the transportation issue is not ideal, it is not an overwhelming factor in Franciscan's favor.

1.50 DaVita's kidney dialysis project is both easier to complete, costs less, and would be sufficiently accessible to provide needed kidney dialysis treatment to patients earlier than Franciscan's project. Given these advantages, DaVita's project is superior to Franciscan's project here. DaVita meets the WAC 246-310-240(1) criterion. Franciscan does not. There is no need to complete the WAC 246-310-288 tie-breaker analysis because there is no tie between the applications.

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. The Program issues a written analysis which grants or denies the CN application. The written analysis must contain sufficient evidence to support the Program's decision. WAC 246-310-200(2)(a). 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 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.

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 Based on the above Findings of Fact and Conclusions of Law, the Presiding Officer determines that DaVita's application 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. Franciscan meets all of the relevant criteria but one, which is WAC 246-310-240(1). Given that it is the superior applicant, the CN is awarded to DaVita.

//

III. ORDER

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

3.1 A Certificate of Need for DaVita to expand its existing Puyallup kidney dialysis facility at 716C South Hill Park Drive, Puyallup, Washington in Pierce County Planning Area #1 is GRANTED.

3.2 A Certificate of Need for Franciscan to establish a new kidney dialysis facility at 19420 State Route 410, Bonney Lake, Washington in Pierce County Planning Area #1 is DENIED.

Dated this _19th__ day of January, 2016.

_/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:

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