

CERTIFICATE OF NEED EVALUATION OF THE DAVITA, INC. APPLICATION PROPOSING TO ESTABLISH A NEW 8-STATION KIDNEY DIALYSIS FACILITY IN GOLDENDALE TO SERVE THE RESIDENTS OF KCLICKITAT AND SKAMANIA COUNTIES.

PROJECT DESCRIPTION

DaVita, Inc. is a for-profit corporation that currently operates or provides administrative services to over 1,300-outpatient dialysis centers and serves about 103,000 dialysis patients and is located in 42 states and the District of Columbia. DaVita, Inc. also provides acute inpatient dialysis services in over 850 hospitals throughout the country. [Source: Application page 4]

In Washington State, DaVita owns or operates a total of fourteen kidney dialysis facilities in six separate counties—Clark, Franklin, King, Kittitas, Pierce, and Yakima. [Source: CN historical files; & Application, page 4]

Clark

Vancouver Dialysis Center

Franklin

Mid-Columbia Kidney Center

Pierce

Lakewood Community Dialysis Center
Puyallup Community Dialysis Center
Tacoma Dialysis Center

Kittitas

Ellensburg Dialysis Center

Yakima

Mt. Adams Kidney Center
Union Gap Dialysis Center
Yakima Dialysis Center

King

Bellevue Dialysis Center
Federal Way Community Dialysis Center
Kent Community Dialysis Center
Olympic View Dialysis Center (management only)
Westwood Dialysis Center

This application proposes to establish a new 8-station kidney dialysis facility in Goldendale to be located at 310 South Roosevelt within Klickitat County. It will be known as DaVita, Inc. Goldendale Dialysis Center. [Source: DaVita supplemental information, dated: May 11, 2007, page 1]

The capital expenditure associated with the establishment of the 8-station dialysis center is \$1,339,661, of which approximately 54.27% is related to leasehold improvements at the site; 37.19% is related to both fixed and moveable equipment and the remaining 8.54% is related to architectural, engineering, application, consulting and legal fees. [Source: Application page 7]

DaVita, Inc. anticipates that all 8 stations would become operational within six months of certificate of need approval. Under this timeline, the proposed facility first full calendar year of operation is 2008 and the third full calendar year of operation would be year 2010. [Source: Application, page 10] For ease of reference, the department will refer to the proposed kidney dialysis facility as “DaVita Goldendale” and the applicant as “DaVita”

APPLICABILITY OF CERTIFICATE OF NEED LAW

This project is subject to Certificate of Need review as the establishment of a new healthcare facility under the provisions of Revised Code of Washington (RCW) 70.38.105(4) (a) and Washington Administrative Code (WAC) 246-310-020(1) (a).

CRITERIA EVALUATION

To obtain Certificate of Need approval, each applicant must demonstrate compliance with the criteria found in WAC 246-310-210 (need); 246-310-220 (financial feasibility); 246-310-230 (structure and process of care); 246-310-240 (cost containment); and 246-310-280 through 286 (the dialysis station projection methodology and standards).¹

APPLICATION CHRONOLOGY

As directed under WAC 246-310-282(1) the department accepted this project under the Kidney Disease Treatment Centers-Concurrent Review Cycle #1. No other kidney disease treatment center applications were submitted for Klickitat County and Skamania County Planning Areas during Review Cycle #1; therefore, as allowed under WAC 246-310-282(5), this application was converted to a regular review

January 30, 2007	Letter of Intent Submitted
February 28, 2007	Application Submitted
March 1, 2007 through May 14, 2007	Department's Pre-review Activities <ul style="list-style-type: none">• Screening Activities and Responses
May 24, 2007	Department Begins Review of Application
July 12, 2007	End of Public Comment/Public Hearing
July 27, 2007	Rebuttal Documents Received at the Department
September 11, 2007	Department's Anticipated Decision Date
October 26, 2007	Department's Actual Decision Date

AFFECTED AND INTERESTED PERSONS

Throughout the review of this project, the Service Employees International Union District 1199 North West (SEIU 1199 NW) claimed an affected persons status. Fresenius Medical Care (FMC) a kidney dialysis provider with facilities in Washington sought and received affected persons status under WAC 246-310-010.

SOURCE INFORMATION REVIEWED

- DaVita's Certificate of Need Application received February 28, 2007
- DaVita's supplemental information received May 14, 2007
- Historical dialysis data obtained from Northwest Renal Network years 2001 through 2006
- Year 2006 Northwest Renal Network 4th Quarter
- Public Comment submitted to the department by J. Hamilton Licht, M.D. received July 2, 2007
- Public Comments submitted to the department by Fresenius Medical Care, Inc. received July 12, 2007
- Comments received at the public hearing on July 12, 2007
- SEIU 1199 NW rebuttal comments dated July 27, 2007
- DaVita, Inc. rebuttal comments dated July 27, 2007
- Medical Quality Assurance Commission Credentialing Records

¹ Each criterion contains certain sub-criteria. The following sub-criteria are not discussed in this evaluation because they are not relevant to this project: WAC 246-310-210(3), (4), (5), and (6); WAC 246-310-240(2) and (3); WAC 246-310-287; and WAC 246-310-288.

- Licensing and/or survey data provided by the Department of Health's Office of Health Care Survey
- Data obtained from the Internet regarding mileage and distance
- Medical information from the Internet regarding Epogen Drug
- Certificate of Need historical files
- Data obtained from Washington State Secretary of State offices and webpage

CONCLUSION

For the reasons stated in this evaluation, DaVita's proposal's to establish a new 8-station kidney dialysis facility in Goldendale within Klickitat County to serve the residents of Klickitat and Skamania Counties is not consistent with the application criteria of the Certificate of Need Program. Therefore, a Certificate of Need is denied

A. Need (WAC 246-310-210)

Based on the source information reviewed, the department determines that the applicant has met the need criteria in WAC 246-310-210(1) and (2) and the kidney disease treatment facility methodology and standards in WAC 246-310-286.

(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.

WAC 246-310-284 contains the methodology for projecting numeric need for dialysis stations within a planning area. This methodology, adopted January 1, 2007, projects the need for kidney dialysis treatment stations through a regression analysis of the historical number of dialysis patients residing in the planning area using verified utilization information obtained from the Northwest Renal Network.²

The first step in the methodology calls for the determination of the type of regression analysis to be used to project resident in-center station need. [WAC 246-310-284(4) (a)] This is derived by calculating the annual growth rate in the planning area using the year-end number of resident in-center patients for each of the previous six consecutive years, concluding with the base year. In planning areas experiencing high rates of growth in the dialysis population (6% or greater growth in each of the last 5 annual change periods), the method uses exponential regression to project future need. In planning areas experiencing less than 6% growth in any of the last five annual change periods, linear regression is used to project need.

Once the type of regression is determined as described above, the next step in the methodology is to determine the projected number of resident in-center stations needed in the planning area based on the planning area's previous five consecutive years NRN data, again concluding with the base year. [WAC 246-310-284(4) (b) and (c)]

WAC 246-310-284(5) identifies that for all planning areas except Adams, Columbia, Douglas, Ferry, Garfield, Jefferson, Kittitas, Klickitat, Lincoln, Okanogan, Pacific, Pend Oreille, San Juan, Skamania, Stevens, and Wahkiakum counties, the number of projected patients is divided by 4.8 to determine the number of stations needed in the planning area. For the specific counties listed above, the number of projected patients is divided by 3.2 to determine needed stations. Additionally, the number of stations projected as needed in the target year is rounded up to the nearest whole number.

Finally, once station need has been calculated for the project years, the number of CN approved in-center stations are then subtracted from the total need, resulting in a net need for the planning area. [WAC 246-310-284(4) (d)]

² Northwest Renal Network was established in 1978 and is a private, not-for-profit corporation independent of any dialysis company, dialysis unit, or transplant center. It is funded by Centers for Medicare and Medicaid Services, Department of Health and Human Services. Northwest Renal Network collects and analyzes data on patients enrolled in the Medicare ESRD programs, serves as an information resource, and monitors the quality of care given to dialysis and transplant patients in the Pacific Northwest. [source: Northwest Renal Network website]

DaVita's Application of the Numeric Methodology

DaVita proposes to establish an 8-station kidney dialysis facility in Goldendale within Klickitat County to serve the residents of Klickitat and Skamania Counties. Based on the calculation of the annual growth rate in the planning area as described above the linear regression is used to project need. Given that the facility would be located in Klickitat County, the number of projected patients is divided by 3.2 to determine the number of stations needed in the planning area.

Tables 1 and 2 below are a summary of DaVita's application of the kidney dialysis numeric methodology for both Klickitat and Skamania counties. [Source: Application page 17]

Table 1
Summary of DaVita's Klickitat County Numeric Methodology

	Year 2007	Year 2008	Year 2009	Year 2010
In-center Patients	14.5	16	17.5	19
Patient: Station Conversion Factor	3.2	3.2	3.2	3.2
Total Station Need	4.53	5.00	5.47	5.94
Total Station Need Rounded Up	5	5	6	6
Minus # CN Approved Stations	0	0	0	0
Net Station Need / (Surplus)	5	5	6	6

Table 2
Summary of DaVita's Skamania County Numeric Methodology

	Year 2007	Year 2008	Year 2009	Year 2010
In-center Patients	4	4.6	5.2	5.8
Patient: Station Conversion Factor	3.2	3.2	3.2	3.2
Total Station Need	1.25	1.44	1.63	1.81
Total Station Need Rounded Up	2	2	2	2
Minus # CN Approved Stations	0	0	0	0
Net Station Need / (Surplus)	2	2	2	2

As shown in Tables 1 and 2 above, DaVita projected need for 6 dialysis stations in Klickitat County and need for 2 dialysis stations in Skamania County in year 2010. Based on the results of its methodology, DaVita requested 8 dialysis stations.

Department's Application of the Numeric Methodology

Based on the calculation of the annual growth rate of the planning area as described above, the department also used linear regression to project need for the planning areas. Given that the facility would be located in Klickitat County, the number of projected patients is divided by 3.2 to determine the number of stations needed in the planning areas. Tables 3 and 4 below are a summary of the department's application of the numeric methodology for both Klickitat and Skamania counties. [Source: Appendix A attached to this evaluation]

Table 3
Summary of Department's Klickitat County Numeric Methodology

	Year 2007	Year 2008	Year 2009	Year 2010
In-center Patients	14.5	16	17.5	19
Patient: Station Conversion Factor	3.2	3.2	3.2	3.2
Total Station Need	4.53	5.00	5.47	5.94
Total Station Need Rounded Up	5	5	6	6
Minus # CN Approved Stations	0	0	0	0
Net Station Need / (Surplus)	5	5	6	6

Table 4
Summary of Department's Skamania County Numeric Methodology

	Year 2007	Year 2008	Year 2009	Year 2010
In-center Patients	4	4.6	5.2	5.8
Patient: Station Conversion Factor	3.2	3.2	3.2	3.2
Total Station Need	1.25	1.44	1.63	1.81
Total Station Need Rounded Up	2	2	2	2
Minus # CN Approved Stations	0	0	0	0
Net Station Need / (Surplus)	2	2	2	2

When comparing the results of the four tables above, it is noted that DaVita's projections and the department's projections are exactly the same. In summary, the numeric needs methodology result in a need for 6-stations in Klickitat County and 2-stations in Skamania County.

WAC 246-310-284(5) requires that all CN approved stations in the planning area must be operating at 3.2 in-center patients per station before new stations can be added. The most recent quarterly modality report, or successor report, from the Northwest Renal Network (NRN) as of the first day of the application submission period is to be used to calculate this standard. The first day of the application submission period was February 1, 2007. [Source: WAC 246-310-282] The quarterly modality report from NRN available at that time was December 31, 2007 which became available on January 20, 2007. Currently, there are no kidney dialysis centers in either Klickitat or Skamania counties. Therefore, this criterion is not applicable.

WAC 246-310-286 (6) requires that DaVita Goldendale to be operating at 3.2 in-center patients per approved station by the end of year three (2011). DaVita provided the projected third year utilization for the Goldendale facility as a 8-station facility. A summary of the projections for year 2011 is shown in Table 5 below. [Source: Application, Appendix 9]

Table 5
Year 2010 DaVita Goldendale Projected Utilization

Facility Name	# of Stations	# of Patients	Patients/Per Stations
DaVita Goldendale	8	30	3.75

As shown in Table 5, DaVita Goldendale projects to be operating above the 3.2 standard by the end of the third year of operation, or year 2011.

Based on DaVita's projection with all 8-station operational, the facility would be operating at over 3.8 resident in-centers by the third year of operation or year 2011. The department concludes that DaVita's proposal to establish a new 8-station dialysis facility in Goldendale to serve the residents of Klickitat and Skamania counties meets this criterion. Based on the methodology and both Klickitat and Skamania counties resident's historical dialysis utilization data DaVita has demonstrated need for a new 8-station dialysis facility in Goldendale, within Klickitat County.

During the review of this application, FMC provided comments to the department regarding the proposed new facility. FMC believes that Skamania County residents are least likely to travel to Goldendale for dialysis services and states "*while WAC 246-310-(1)(a) allows an applicant to address need in an adjacent planning area if no provider exists, there needs to be some logic to including adjacent planning areas*". [Source: FMC public comment dated: July 11, 2007]

In response to FMC comments, DaVita states "*Fresenius analysis ignores the governing rules and instead relies on an extremely rough and misleading analysis of distances and travel times. Although unexplained and unclear, it apparently measures distances from undisclosed locations in Skamania County zip codes to undisclosed locations in Vancouver and Goldendale using an unknown method to calculate mileage and travel time. DaVita and the Program all lack information about current and future Skamania patients residences, worksites, physician locations, public transit resources and other factors that would allow a meaningful analysis of access to a new Goldendale facility*". Additionally, DaVita noted that WAC 246-310-284(1) (a) allows an applicant to address need in an adjacent planning area if no facility exist there. [Source: DaVita, Inc. rebuttal comment dated: July 27, 2007]

The Department Response

After reviewing the comments provided by FMC and the responses provided by DaVita, the department concludes that DaVita's decision to include adjacent Skamania County residents in its need projections for Klickitat County follows WAC 246-310-284(1)(a). The department agrees that DaVita's proposed project is consistent with the department's rules regarding identifying need in adjacent planning with no existing facilities. This sub-criterion is met.

- (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.

DaVita is currently a provider of health care services to residents of Washington State, including low-income, racial and ethnic minorities, handicapped and other underserved groups. To determine whether all residents of the service area would continue to have access to an applicant's proposed services, the department requires applicants to provide a copy of its current or proposed admission policy. The admission policy provides the overall guiding principles of the facility as to the types of patients that are appropriate candidates to use the facility and any assurances regarding access to treatment.

To determine whether low income residents would have access to the proposed services, the department uses the facility's Medicaid eligibility or contracting with Medicaid as the measure to make that determination. To determine whether the elderly would have access or continue to have access to the proposed services, the department uses Medicare certification as the measure to make that determination.

A facility's charity care policy should confirm that all residents of the service area including low-income, racial and ethnic minorities, handicapped and other underserved groups have, or would have, access to healthcare services of the applicant. The policy should also include the process one must use to access charity care at the facility.

To demonstrate compliance with this sub-criterion DaVita states that, "*Any patient with end stage renal disease needing chronic dialysis will be accepted for treatment at this facility*" [Source: Application, Appendix 14]. DaVita's admission policy prohibits discrimination on the basis of race, color, national origin, sex, age, religion or disability. That policy outlines the eligibility criteria's and stated the income levels at which charity care is provided to prospective recipients. Additionally, the pro-forma income statements provided by DaVita with its application, included charity care expenses at 1% of the total revenue. The department also reviewed the historical financial statements provided by DaVita and those statements contain charity care expenses.

Based on this information, the department concludes that all residents of the service areas could reasonably be expected to have adequate access to health services at the Goldendale Dialysis facility. This sub-criterion is met.

B. Financial Feasibility (WAC 246-310-220)

Based on the source information reviewed, the department determines that the applicant did not meet the financial feasibility criteria in WAC 246-310-220.

- (1) The immediate and long-range capital and operating costs of the project can be met.
As stated previously in this evaluation, DaVita anticipates commencement of services in May 2008. Based on this timeline, year 2009 would be DaVita's first full calendar year of operation. Summarized in Table 6 below, is DaVita's year one through year four projected financial revenue, expenses, and net income for the DaVita Goldendale Dialysis Center as a 8-stations dialysis facility [Source: Application, Appendix 9]

Table 6
DaVita Goldendale Dialysis Center
Projected Revenue and Expenses Years (1 through 4)

	Partial Year 2008	Full Year 2009	Full Year 2010	Full Year 2011	Full Year 2012
# of Stations	8	8	8	8	8
# of Treatments [1]	1,581	3,231	4,433	5,034	5,486
# of Patients [2]	10	20	27	30	32
Utilization Rate [2]	1.25	2.50	3.38	3.75	4.00
Net Patient Revenue[1]	\$304,858	\$877,625	\$1,378,580	\$1,703,730	\$1,909,182
Total Operating Expenses [1, 3]	\$656,132	\$881,807	\$1,242,271	\$1,485,639	\$1,644,067
Net Profit or (Loss)[1]	(\$351,274)	(\$4,182)	\$136,309	\$218,091	\$265,115
Operating Revenue / Treatment [1]	\$192.83	\$271.63	\$310.98	\$338.44	\$348.01
Operating Exp./ Treatment [1]	\$415.01	\$272.92	\$280.23	\$295.12	\$299.68
Net Profit per Treatment [1]	(\$222.18)	(\$1.29)	\$30.75	\$43.32	\$48.33

[1] Includes both in-center and home dialysis patients; [2] in-center patients only; [3] includes bad debt, charity care and allocated costs.

As shown in Table 6 above, at the projected volumes identified by DaVita, the Goldendale facility would be operating the 8-station dialysis center at a loss in partial year 2008 and during the first calendar year, but would turn to profit in years 2010 through 2012. DaVita states that the proposed facility will be operated at utilization levels consistent with other facilities.

DaVita provided a draft lease agreement for the site between Total Renal Care, Inc. (Tenant) its parent company and Public Hospital District #1, Klickitat County, Washington dba Klickitat Valley Health (Landlord). The costs identified in the lease are not consistent with the pro-forma financial projections used to prepare Table 6 above.

When reviewing DaVita's application, it is noted that the lease agreement and the financial information provided in the pro forma revenue and expense statements are inconsistent. The lease agreement identifies a 4,000 square feet facility with an annual lease amount of \$15 per square foot or \$60,000 annually and states "*Beginning on the 1st anniversary of the commencement date and continuing on every subsequent anniversary of the commencement date, the rent shall be increased by two percent (2%) per rentable square foot annually over the rent for the prior lease year*" [Source: May 14, 2007, Supplemental Information, Attachment 2, Draft Lease Agreement, Rent Adjustments, page 2]

The pro-forma revenue and expense statement provided show consistently different annual lease/rent amounts than those identified in the lease. Table 7 is a comparison of the amounts.

Table 7
Lease Costs and Pro Forma Comparison

	Lease Amounts	Pro Forma Amounts	Differences
Year 1	\$60,000	\$162,400	\$102,400
Year 2	\$61,200	\$125,454	\$64,254
Year 3	\$62,448	\$129,218	\$66,773
Year 4	\$63,696	\$133,094	\$69,398
Year 5	\$64,970	\$137,087	\$72,117
5 yr Total	\$312,314	\$687,253	\$374,942

The overstatement of lease/rent amounts in the pro forma would result in an overstatement of expenses, resulting in an overstatement of net loss in year 2008, and an understatement of net profit in years 2009 through 2012. While this overstatement/understatement issue could be viewed as “conservative pro forma projections,” it is indicative of inconsistencies within the application.

During the screening process, the department requested any necessary updates to the proposed facility pro-forma “that reflects all costs associated with the site for the project”. [March 30, 2007 Supplemental Information, #9] DaVita responded that no changes were necessary in the pro-forma other than the correct calendar year headings previously requested in screening. This would indicate that the draft lease submitted in response to supplemental information may continue to be inaccurate in many of the terms being considered for the lease. The inaccuracies in the stated and projected rent are currently the only means to isolate one, of possible additional modifications, that could affect the viability of this project.

Based on the information presented the department is unable to conclude that the proposed project is financially feasible. This sub-criterion is not 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.

The costs and charges per dialysis for the proposed facility cannot be compared to recent kidney dialysis proposals submitted to the department. The department is not able to calculate the average cost per dialysis with any certainty due to in-consistent pro-forma data.

The estimated capital expenditure associated with the establishment of 8-stations dialysis facility is \$1,339,661. [Source: Application page 1] Summarized in table 8 below, is the capital expenditure.

Table 8
DaVita Goldendale Dialysis Center Capital Cost

Item	Cost	% of Total
Leasehold Improvements	\$727,000	55%
Fixed & Moveable Equipment	\$498,252	37%
Architect/Engineering Fees & CN Fees	\$98,000	7%
Total Project Cost	\$1,339,661	100.0%

The department recognizes that the majority of reimbursements for dialysis services are thorough Medicare ESRD entitlement. To further, demonstrate compliance with this sub-criterion, DaVita provided the sources of its patient revenue shown in Table 9 below. [Source: Application, Page 8]

Table 9
DaVita’s Source of Revenue

Source of Revenue	Percentage of Revenue
Medicare	72%
Medicaid /State	8%
Insurance / HMO	20%
Total	100%

As shown in the table above, Medicare and state (Medicaid) entitlements are projected to equal 80% of DaVita’s revenue.

The department received comments from SEIU 1199 NW. Those comments were focused on the impact of health care costs due to DaVita for-profit status. SEIU 1199NW states “*we are also concerned about the impact on health care costs that will result from a for-profit, rather than non-profit operation of a dialysis center. Finally, we are concerned that DaVita’s priorities are in conflict with Klickitat Valley Hospital’s mission, and believe that DaVita will take precious healthcare dollars out of the community*”. [Source: SEIU 1199NW public comment dated: July 12, 2007, page 1]

In response to the comments above, DaVita provided the following statements summarized below.

- The department has never adopted rules or policies that expressed a preference for either for-profit or not-for-profit business organizations.
- DaVita is the only provider that has found an incentive for offering to “expand/and or improve service to patients” in Goldendale. Not a single not-for-profit organization has found a sufficient incentive to expand or improve service there. The same is true in other planning area such as Yakima County.
- If DaVita does not place its facilities in convenient locations and provide a superior quality of care, it cannot expect its facilities to be chosen by patients and their physicians. [Source: DaVita, Inc. rebuttal comment dated: July 27, 2007, page 3]

The Department Response

Department rules do not distinguish between an organization that is profit versus one that is non-profit. The department accepts applications and evaluates those applications based on the applicable rules in effect at the time of application. As a result, the department does not agree with SEIU 1199NW regarding DaVita’s for-profit status and its intent to provide dialysis services to the residents of Skamania and Klickitat counties.

As shown in Table 9, Medicare and state (Medicaid) entitlements as stated by DaVita are projected to equal 80% of the proposed facility revenue sources that are not cost based reimbursement. The department cannot conclude that costs associated with this project will not have unreasonable impact on the remaining 20% because of the inconsistencies in the pro forma. Therefore, the department cannot conclude that the cost of the project will not result in an un-

reasonable impact on the costs and charges for healthcare services within the service area. This sub-criterion is not met.

(3) The project can be appropriately financed.

The source of financing for the proposed facility is DaVita’s cash reserves. A review of DaVita’s historical financial statements for years 2004 through 2006, demonstrates that the funds necessary to finance the project are available. [Source: Application Exhibit 10]

DaVita’s financial reserves as documented by Exhibit 10 are more than adequate to fund the new 8-station dialysis facility. Based on the information provided, the department concludes that the applicant has demonstrated that establishment of the new 8-station Goldendale Dialysis Center in Klickitat County will not adversely affect DaVita’s financial stability. The department concludes that DaVita’s application to establish a new 8-station dialysis center in Goldendale to serve the residents of Skamania and Klickitat Counties can be appropriately financed. This sub-criterion is met

C. Structure and Process (Quality) of Care (WAC 246-310-230)

Based on the source information reviewed, the department determines that the applicant has met the structure and process (quality) of care criteria in WAC 246-310-230.

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

To implement this project DaVita proposes to hire the equivalent of 2.20 new staff during the first partial year of operation and increase the number of new staff to 7.10 by the end of the fourth full year of operation. The proposed project staff increase is summarized in Table 10 below.

**Table 10
Goldendale Dialysis Center Proposed FTE’s**

Category	Partial Year 2008	Year 2009 Increase.	Year 2010 Increase.	Year 2011 Increase.	Year 2012 Increase.	Total FTE’s
Medical Director	<i>Professional Services Contract</i>					
Administrator	0.10	0.20	0.50	0.20	-	1
Registered Nurses	0.80	0.30	0.40	0.40	0.10	2.00
Patient Care Tech	0.80	0.40	0.80	0.30	0.20	2.50
Biomedical Techs	0.20	-	-	-	-	0.20
Re-Use Tech	0.10	0.10	-	-	-	0.20
Administrative Asst	-	-	-	0.30	0.10	0.40
Social Worker	0.10	0.10	0.10	-	-	0.30
Dietitian	0.10	0.10	0.10	-	-	0.40
Number of FTE'S	2.20	1.20	1.90	1.20	0.60	7.10

As shown in Table 10 above, DaVita expects to hire 7.10 new FTE’s to staff the dialysis center and states that it does not anticipate any difficulty in recruiting the necessary staff to the proposed facility. Additionally, DaVita states that “*DaVita offers a competitive wage and benefit package to employees by posting openings nationally and externally and several current employees*

have expressed interest in working at the DaVita Goldendale facility” Furthermore, DaVita also stated that it has an extensive employee traveling program that guarantee that DaVita’s facilities will continue to have access to appropriate staff necessary for continuity of care”. [Source: Application page 24]

DaVita identified Jeffrey Hamilton Licht, MD as the Medical Director for the proposed DaVita Goldendale Dialysis Center and provided a draft medical director agreement between DaVita and Dr. Licht. The costs for the medical director services are substantiated in the pro-forma financial information provided in the application. If this project is approved, DaVita must agree to the following term:

Prior to commencing services, at the DaVita Goldendale facility, DaVita must provide to the department for review and approval an executed medical director agreement.

Based on the information presented and with agreement to the term stated above, the department concludes that staffing is expected to be available for recruitment by the applicant when the dialysis center commences services in May 2008. This sub-criterion is met.

- (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.

Information provided by DaVita states that ancillary and support services such as social services, nutrition services, pharmacy, patient and staff education, financial counseling, human resources, material management, administration, and technical services would be provided on site upon the commencement of services at the proposed facility. The applicant states that services would be coordinated through DaVita’s corporate office in El Segundo, California and support offices in Washington. [Application page 24] To further demonstrate compliance with this sub-criterion, DaVita provided draft transfer agreement template. [Application, Appendix 12] If this project is approved, the department would include a term requiring DaVita to provide a copy of the executed transfer agreement with a local hospital in Klickitat County.

Prior to providing services at the DaVita Goldendale facility DaVita, Inc. will provide an executed copy of the Patient Transfer Agreement for the department’s review and approval.

Based on the evaluation of supporting documents provided, and with agreement to the term above, the department concludes that there is reasonable assurance that the Goldendale Dialysis Center will have appropriate ancillary and support services with healthcare providers in Klickitat and Skamania counties. This sub-criterion is met.

- (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.

As stated earlier, DaVita, Inc. is a provider of dialysis services in over 1,300 outpatient centers located in 42 states (including Washington State) and the District of Columbia. [Source: DaVita Webpage] Prior to the October 1, 2005, acquisition of the dialysis operations of Gambro Healthcare US, DaVita operated 665 centers in 37 states and the District of Columbia. Currently within Washington State, DaVita owns and operates fourteen kidney dialysis treatment centers. As part of its review, the department must conclude that the proposed services would be

provided in a manner that ensures safe and adequate care to the public³. To accomplish this task, in January 2007 the department requested quality of care compliance history from the state licensing and/or surveying entities responsible for the 42 states and the District of Columbia where DaVita, Inc. or any subsidiaries of the parent company has health care facilities. Of the 43 entities, the department received responses from 28 states or 66% of the 42 states.⁴ The compliance history of the remaining 13 states and the District of Columbia is unknown.⁵

Ten of the 28 states responding to the survey indicated that significant non-compliance deficiencies had been cited at DaVita facilities in the past three years. Of those states, with the exception of one facility in Delaware, one in New York and one in Texas, none of the deficiencies were reported to have resulted in fines or enforcement action. All other facilities were reported as currently in compliance with applicable regulations. The Delaware facility had been scheduled for decertification in 2006 due to several condition-level citations, but was operating in compliance at the time of survey. The New York facility was cited with condition-level deficiencies. This facility was voluntarily de-certified and closed by DaVita. In Texas, DaVita's Houston Dialysis was fined \$16,500 for non-compliance issues in 2005. No further fines were identified for this facility.

The department concludes that considering the 1,300 facilities owned/managed by DaVita, few out-of-state facilities listed above demonstrated substantial non-compliance issues, with only three reported as subject to fines or actually decertified. Therefore, the department concludes the out-of-state compliance surveys are acceptable.

For Washington State, since January 2000, the Department of Health's Office of Health Care Survey (OHCS) has completed more than 32 compliance surveys for the operational facilities that DaVita either owns or manages.⁶ Of the compliance surveys completed, all revealed minor non-compliance issues related to the care and management at the DaVita facilities. These non-compliance issues were typical of a dialysis facility and DaVita submitted and implemented acceptable plans of correction. [Source: facility survey data provided by the Office of Health Care Survey]

The department received comments from SEIU 1199NW regarding DaVita's quality of care and the excessive use of Epogen the trademark name of "Epoetin Alfa" a synthetic anemic treatment medication used to stimulate red blood cells production in dialysis patients. [Source: http://www.epogen.com/pdf/epogen_ppi.pdf, issued March 2007] Those concerns are summarized below.

- Epogen over use by for-profit organizations suggests that the drug is excessively used in dialysis patients because reimbursement rate is favorable.

³ WAC 246-310-230(5).

⁴ Alabama, Arizona, Connecticut, Delaware, Florida, Idaho, Illinois, Indiana, Iowa, Kansas, Kentucky, Maryland, Michigan, Minnesota, Mississippi, Missouri, Nevada, New Hampshire, New York, Oregon, Pennsylvania, South Dakota, Tennessee, Texas, Utah, Virginia, Washington, West Virginia, and Wisconsin.

⁵ Arkansas, California, Colorado, Georgia, Louisiana, Massachusetts, Nebraska, New Mexico, North Carolina, Ohio, Oklahoma, and South Carolina.

⁶ DaVita's Ellensburg Dialysis Center and Tacoma Dialysis Center are not yet operational. Olympic View Dialysis Center is owned by Group Health and managed by DaVita.

- DaVita uses Epogen more aggressively than any other dialysis provider and generally administers injections of Epogen in an inefficient manner. [Source: SEIU 1199NW public comments dated: July 12, 2007]

In response to the concerns raised above, DaVita provided the following statements summarized below.

- DaVita significantly exceeds the national quality averages, as indicated by the (CMS-CPM) Center for Medicare Services Clinical Performance Measures Report and Fistula Vascular Access Improvement Initiative.
- DaVita has significantly smaller percentages of patients with outcomes below the CMS-CPM targets, as compared to the national average.
- Studies shows patients meeting all four CMS-CPM targets archive lowest mortality.
- DaVita's 2006 gross mortality rate of 17.9% compares favorably to the United States Renal Data System Annual Report of 23% in 2004.
- DaVita cannot prescribe Epogen rather a patient physician makes all treatment decisions, including the amount of Epogen to prescribe and the drug is administers based on the physician order.
- SEIU 1199NW ignores the fact that both Federal Drug Administration and vast majority of physicians recommend that Epogen be administered via IV versus subcutaneous as well as the fact that patients prefer IV administration.
- DaVita is unaware of any evidence that not-for-profit facilities in the State of Washington enjoy any quality of care advantage over for-profit facilities. [Source: DaVita rebuttal comments dated: July 12, 2007, pages 3-4]

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The department is aware of the EPO debate however, DaVita has not been determined to be out of compliance with any quality of care standards based on EPO practices. Therefore, the department cannot fail DaVita for the particular treatment practice.

Compliance history review of the proposed medical director Dr. Jeffery Hamilton Licht did not reveal any recorded sanctions. DaVita provided a draft medical director agreement with Dr. Licht. The agreement outlines the roles and responsibilities of the medical director and identifies the annual compensation. Given the compliance history of DaVita and that of the proposed facility medical director, the department concludes that there is reasonable assurance that DaVita Goldendale would be operated in conformance with state and federal regulation. This sub-criterion is met.

- (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.

In response to this criterion, DaVita provided a summary of its quality and continuity of care indicators used in its Continuous Quality Improvement Program (CQI). The CQI program incorporates all of DaVita's stated kidney dialysis objectives. The program monitors and evaluates all activities related to clinical outcomes, operations management, and process flow.

Further, the DaVita states, “*Continuing employee and patient education are integral parts of the program*”. [Source: Application, Appendices 18 and 19] Additionally, DaVita also provided samples of its quality index data and its physician community, and patient services education offered through its quality of care program.

The department also considered DaVita’s history of providing care to residents in Washington State and concludes that DaVita has been providing dialysis services to the residents of Washington for several years and has appropriate relationships with healthcare providers in the communities where DaVita’s dialysis facilities are located. The department does not expect that the approval of this project would change those relationships. Therefore, the department concludes that the applicant has demonstrated an ability to provide services in a manner appropriate to the health care delivery system and the establishment of a new 8-station dialysis facility in Goldendale will not result in an unwarranted fragmentation of service. This sub-criterion is met.

- (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.

This is addressed in sub-criterion (3) of this evaluation. The department concludes that there is reasonable assurance that the services to be provided will ensure safe and adequate care to the public and in accord with applicable federal and state laws, rules and regulations. This sub-criterion is met.

D. Cost Containment (WAC 246-310-240)

Based on the source information reviewed, the department determines that the applicant has not met the cost containment criteria in WAC 246-310-240.

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

To comply with this sub-criterion, DaVita stated that it considered two alternatives to DaVita’s alternative and the rationale for rejecting those two alternatives are summarized below.

- Alternative 1: Do nothing or maintain the status quo.
This alternative was rejected because according to DaVita, there is no dialysis facility in Klickitat County. Currently, all Klickitat County patients must leave the planning area to receive dialysis services. This alternative was also rejected because DaVita states that access to facilities is below acceptable levels.
- Alternative 2: Establish 6-stations
This alternative was rejected because the establishment of 6-station facility in Klickitat County creates inadequate capacity to initially serve the planning area through the first 3 full years of operation without taking into account in-flow of patients from Skamania County and Wasco County in Oregon.

The department cannot conclude that the current DaVita Goldendale project is the best available alternative. While the department determined that need was demonstrated in Klickitat County and in Skamania County, the project as proposed failed to meet financial feasibility. Therefore, this criterion is not met.

APPENDIX A