STATE OF WASHINGTON DEPARTMENT OF HEALTH

May 29, 2012

CERTIFIED MAIL 7011 1570 0002 7802 6111

Jason Bosh, Regional Operations Director DaVita, Inc.—North Star Division, Region 1 1301 A Street, Suite 400 Tacoma, Washington 98402

RE: CN12-03A

Dear Mr. Bosh:

We have completed the review of DaVita, Inc's application proposing to establish a new 8-station kidney dialysis center in the city of Zillah within Yakima County. For the reasons stated in this evaluation, the application is consistent with applicable criteria of the Certificate of Need Program, provided DaVita, Inc. agrees to the following in its entirety.

Project Description:

This project approves the establishment of an eight-station dialysis center to be located at 823 Zillah West Road, #300 in Zillah, within Yakima County. At project completion, DaVita Zillah Dialysis Center would be approved to certify and operate eight dialysis stations. Services to be provided at DaVita Zillah Dialysis Center include hemodialysis and treatments shifts beginning after 5:00 pm, a permanent bed station, and an isolation station. A breakdown of all eight stations is below:

Private Isolation Room	1
Permanent Bed Station	1
Other In-Center Stations	6
Total	8

Conditions:

- 1. DaVita, Inc. agrees with the project description stated above.
- 2. Prior to providing services, DaVita will provide an executed copy of the Patient Transfer Agreement for department's review and approval. The executed transfer agreement must be consistent with the draft provided in the application.

Jason Bosh, Regional Operations Director DaVita, Inc. May 29, 2012 Page 2

- 3. Prior to providing services, DaVita will provide a copy of the adopted Accepting Patients for Treatment Policy for the department's review and approval. The adopted admission policy must be consistent with the draft provided in the application.
- 4. Prior to providing services, DaVita will provide a copy of the adopted Indigent Care Policy for the department's review and approval. The adopted charity care policy must be consistent with the draft provided in the application.

Approved Capital Costs:

The approved capital expenditure associated with this project is \$1,407,382. This amount represents the total capital expenditure of \$2,190,270, minus the landlord's project costs of \$782,888.

You have two options, either accept or reject the above in its entirety. If you accept the above in its entirety, your application will be approved and a Certificate of Need sent to you. If you reject any provision of the above, you must identify that provision, and your application will be denied because approval would not be consistent with applicable Certificate of Need review criteria. Please notify the Department of Health within 20 days of the date of this letter whether you accept the above in its entirety. Your written response should be sent to the Certificate of Need Program, at one of the following addresses.

Mailing Address:
Department of Health
Certificate of Need Program
Mail Stop 47852
Olympia, WA 98504-7852

Other Than By Mail:
Department of Health
Certificate of Need Program
111 Israel Road SE
Tumwater, WA 98501

If you have any questions, or would like to arrange for a meeting to discuss our decision, please contact Janis Sigman with the Certificate of Need Program at (360) 236-2955.

Sincerel

Steven M. Saxe, FACHE

Director, Health Professions and Facilities

Enclosure

EVALUATION DATED MAY 29, 2012 FOR THE CERTIFICATE OF NEED APPLICATION SUBMITTED BY DAVITA, INC., PROPOSING TO ESTABLISH A NEW EIGHT STATION KIDNEY DIALYSIS CENTER IN YAKIMA COUNTY

APPLICANT DESCRIPTION

DaVita Inc. (DaVita) is a for-profit corporation that currently operates or provides administrative services to approximately 1,642 dialysis facilities located in 43 states and the District of Columbia. DaVita also provides acute inpatient kidney dialysis services in over 720 hospitals throughout the country. [Source: Amended Application, p5] In Washington State, DaVita owns or operates 29 kidney dialysis facilities in 13 separate counties. Below is a listing of the 29 facilities. [Source: CN historical files & Amended Application, pp5-6]

Benton	Pacific
Chinook Dialysis Center	Seaview Dialysis Center
Kennewick Dialysis Center	·
Clark	Pierce
Battleground Dialysis Center	Graham Dialysis Center
Vancouver Dialysis Center	Lakewood Dialysis Center
	Parkland Dialysis Center
Douglas	Puyallup Dialysis Center
East Wenatchee Dialysis Center	Tacoma Dialysis Center
Franklin	Snohomish
Mid Columbia Kidney Center	Everett Dialysis Center ²
	Mill Creek Dialysis Center
Island	
Whidbey Island Dialysis Center	Spokane
	Downtown Spokane Renal Center
King	North Spokane Renal Center
Bellevue Dialysis Center	Spokane Valley Renal Center
Des Moines Dialysis Center	
Federal Way Dialysis Center	Thurston
Kent Dialysis Center	Olympia Dialysis Center
Olympic View Dialysis Center (management only)	
Westwood Dialysis Center	Yakima
	Mt. Adams Dialysis Center
Kittitas	Union Gap Dialysis Center
Ellensburg Dialysis Center	Yakima Dialysis Center

¹ Battleground Dialysis Center, Des Moines Dialysis Center, East Wenatchee Dialysis Center, and Kennewick Dialysis Center are CN approved but not yet operational.

² Refuge Dialysis, LLC, whose ownership is 80% DaVita and 20% The Everett Clinic, owns this facility.

PROJECT DESCRIPTION

DaVita proposes to establish a new 8-station facility known as 'DaVita Zillah Dialysis Center.' The new facility would be located at 823 Zillah West Road #300 within the city of Zillah in Yakima County. [source: Application, p8] Services to be provided at Zillah Dialysis Center include in-center hemodialysis and treatments shifts beginning after 5:00 p.m., a permanent bed station, and an isolation station. [source: Amended Application, p9]

The capital expenditure associated with the new 8-station kidney dialysis facility is \$2,190,270. Approximately 39.9% is related to leasehold improvements, 35.7% is related to direct cost or building owner expenses, 20.4% is related to both fixed and moveable equipment, and the remaining 3.9% is related to water treatment and biomedical ancillaries. [source: Amended Application, p10]

If this project is approved, DaVita anticipates the new 8-station facility would become operational within six months of approval. Under this timeline, calendar year 2012 would be a partial year of operation, year 2013 would be the first full year of operation, and 2015 would be the third year. [source: Amended Application, p12]

APPLICABILITY OF CERTIFICATE OF NEED LAW

This project is subject to Certificate of Need (CN) 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

WAC 246-310-200(1)(a)-(d) identifies the four determinations that the department must make for each application. WAC 246-310-200(2) provides additional direction on how the department is to make its determinations. It states:

"Criteria contained in this section and in WAC 246-310-210, 246-310-220, 246-310-230, and 246-310-240 shall be used by the department in making the required determinations.

- (a) In the use of criteria for making the required determinations, the department shall consider:
 - (i) The consistency of the proposed project with service or facility standards contained in this chapter;
 - (ii) In the event the standards contained in this chapter do not address in sufficient detail for a required determination the services or facilities for health services proposed, the department may consider standards not in conflict with those standards in accordance with subsection (2)(b) of this section; and
 - (iii) The relationship of the proposed project to the long-range plan (if any) of the person proposing the project".

In the event WAC 246-310 does not contain service or facility standards in sufficient detail to make the required determinations, WAC 246-310-200(2)(b) identifies the types of standards the department may consider in making its required determinations. Specifically WAC 246-310-200(2)(b) states:

"The department may consider any of the following in its use of criteria for making the required determinations:

- (i) Nationally recognized standards from professional organizations;
- (ii) Standards developed by professional organizations in Washington State;
- (iii) Federal Medicare and Medicaid certification requirements;
- (iv) State licensing requirements;
- (v) Applicable standards developed by other individuals, groups, or organizations with recognized expertise related to a proposed undertaking; and
- (vi) The written findings and recommendations of individuals, groups, or organizations with recognized expertise related to a proposed undertaking, with whom the department consults during the review of an application".

WAC 246-310-280 through 289 contains service or facility specific criteria for dialysis projects and must be used to make the required determinations. To obtain Certificate of Need approval, DaVita 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); and 246-310-240 (cost containment)³. Additionally, DaVita must demonstrate compliance with the applicable kidney disease treatment center criteria outlined in WAC 246-310-280 through 284.

APPLICATION CHRONOLOGY

As directed under WAC 246-310-282(1) the department accepted this application under the Kidney Disease Treatment Centers Concurrent Review Cycle #3 for year 2011. No other kidney disease treatment center applications were received for Yakima County planning area during Cycle #3, therefore; the review was converted to a regular review. A chronological summary of the review activities is shown below.

Action	Dates
Letter of Intent Submitted	July 29, 2011
Application Submitted	August 31, 2011
Amended Application Submitted	September 30, 2011
Department's pre-review activities	October 1, 2011 through
including screening and responses	February 12, 2012
Beginning of Review	February 13, 2012
End of Public Comment/No Public	March 20, 2012
Hearing Requested or Conducted Rebuttal Comments Received	A mril 2, 2012
	April 3, 2012
Department's Anticipated Decision Date	May 18, 2012
Department's Actual Decision Date	May 29, 2012

AFFECTED AND INTERESTED PERSONS

Washington Administrative Code 246-310-010(2) defines "affected person as:

³ 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), (6); WAC 246-310-240(3), WAC 246-310-286; WAC 246-310-287; and WAC 246-310-288.

- "...an "interested person" who:
 - (a) Is located or resides in the applicant's health service area;
 - (b) Testified at a public hearing or submitted written evidence; and
 - (c) Requested in writing to be informed of the department's decision."

An interested person is defined as:

- ".. Interested persons means:
- (a) The applicant;
- (b) Health care facilities and health maintenance organizations providing services similar to the services under review and located in the health service area;
- (c) Third-party payers reimbursing health care facilities in the health service area;
- (d) Any agency establishing rates for health care facilities and health maintenance organizations in the health service area where the proposed project is to be located;
- (e) Health care facilities and health maintenance organizations which, in the twelve months prior to receipt of the application, have submitted a letter of intent to provide similar services in the same planning area;
- (f) Any person residing within the geographic area to be served by the applicant; and
- (g) Any person regularly using health care facilities within the geographic area to be served by the applicant." [Emphasis Added]

For this project, no entities sought and received affected person status. Although not an "interested person" by WAC 246-310-010(34), the department permitted Fresenius Medical Care to comment on this proposal. Since Fresenius is not a dialysis provider located in Yakima County and had not submitted a Letter of Intent within the previous twelve months prior to the submission of DaVita's application, Fresenius did not qualify as an affected person.

SOURCE INFORMATION REVIEWED

- DaVita, Inc's Certificate of Need application submitted August 31, 2011
- DaVita, Inc's amended application submitted September 30, 2011
- DaVita, Inc's supplemental information received December 15, 2011, and February 6, 2012
- Years 2005 through 2010 historical kidney dialysis data obtained from the Northwest Renal Network
- Year 2011 Northwest Renal Network 1st Quarter Data available on May 16, 2011
- Public comments received from Fresenius Medical Care on March 3, 2012
- Rebuttal Comments received from DaVita, Inc. on April 3, 2012
- Licensing and/or survey data provided by the Department of Health's Office of Investigation and Inspections
- Licensing and/or survey data provided by out of state health care survey programs
- Certificate of Need historical files
- Medical Quality Assurance compliance data

CONCLUSION

For the reasons stated in this evaluation, the application submitted by DaVita, Inc. proposing to establish a new 8-station kidney dialysis center in the city of Zillah within Yakima County is consistent with applicable criteria of the Certificate of Need Program, provided DaVita, Inc. agrees to the following in its entirety.

Project Description:

This project approves the establishment of a eight-station dialysis center to be located at 823 Zillah West Road, #300 in Zillah, within Yakima County. At project completion, DaVita Zillah Dialysis Center would be approved to certify and operate eight dialysis stations. Services to be provided at DaVita Zillah Dialysis Center include hemodialysis and treatments shifts beginning after 5:00 pm, a permanent bed station, and an isolation station. A breakdown of all eight stations is below:

Private Isolation Room	1
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Conditions:

- 1. DaVita, Inc. agrees with the project description stated above.
- 2. Prior to providing services, DaVita will provide an executed copy of the Patient Transfer Agreement for department' review and approval. The executed transfer agreement must be consistent with the draft provided in the application.
- 3. Prior to providing services, DaVita will provide a copy of the adopted Accepting Patients for Treatment Policy for the department's review and approval. The adopted admission policy must be consistent with the draft provided in the application.
- 4. Prior to providing services, DaVita will provide a copy of the adopted Indigent Care Policy for the department's review and approval. The adopted charity care policy must be consistent with the draft provided in the application.

Approved Capital Costs:

The approved capital expenditure associated with this project is \$1,407,382. This amount represents the total capital expenditure of \$2,190,270, minus the landlord's project costs of \$782,888.

A. Need (WAC 246-310-210) and Need Forecasting Methodology (WAC 246-310-284)

Based on the source information reviewed and provided the applicant agrees to the conditions stated in the 'conclusion' section of this evaluation, the department determines that DaVita, Inc.'s project has met the need criteria in WAC 246-310-210(1) and (2) and the kidney disease treatment facility methodology and standards in WAC 246-310-284.

(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 requires the department to evaluate kidney disease treatment center applications based on the populations need for the service and determine whether other services and facilities of the type proposed are not, or will not, be sufficiently available or accessible to meet that need as required in WAC 246-310-210. The kidney disease treatment center specific numeric methodology applied is detailed in WAC 246-310-284(4). WAC 246-310-210(1) criteria is also identified in WAC 246-310-284(5) and (6).

Kidney Disease Treatment Center Methodology WAC 246-310-284

WAC 246-310-284 contains the methodology for projecting numeric need for dialysis stations within a planning area. This methodology 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.⁴

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 five 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)]

⁴ 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]

⁵ WAC 246-310-280 defines base year as "the most recent calendar year for which December 31 data is available as of the first day of the application submission period from the *Northwest Renal Network's Modality Report* or successor report."

WAC 246-310-284(5) identifies that for all planning areas <u>except</u> 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)]

DaVita's Application of the Numeric Methodology

To determine the type of regression analysis to be used to project station need, DaVita used 2005 through 2010 data for the planning area. Based on that data DaVita used linear regression. The table below shows DaVita's application of the numeric methodology for Yakima County Planning area. [source: Amended Application, p17]

Table 1 Summary of DaVita's Yakima County ESRD Planning Area Numeric Methodology

	Year	Year	Year	Year
	2011	2012	2013	2014
In-center Patients	219.50	227.20	234.90	242.60
Patient: Station Conversion Factor	4.8	4.8	4.8	4.8
Total Station Need (rounded)	46	48	49	51
Minus # CN Approved Stations	43	43	43	43
Net Station Need / (Surplus)	3	5	6	8

As shown above, DaVita projected need for eight stations in year 2014, and submitted an application requesting to establish a new eight-station facility within the planning area.

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 used linear regression to project need. The number of projected patients (unrounded) was divided by 4.8 to determine the number of new stations needed in the planning area. The net station need for Yakima County ESRD planning area is eight stations. The table below summarizes the department's application of the numeric methodology for the planning area.

Table 2
Summary of Department's Numeric Methodology
Yakima County ESRD Planning Area

	Year	Year	Year	Year
	2011	2012	2013	2014
In-center Patients	219.50	227.20	234.90	242.60
Patient: Station Conversion Factor	4.8	4.8	4.8	4.8
Total Station Need Rounded Up	46	48	49	51
Minus # CN Approved Stations	43	43	43	43
Net Station Need / (Surplus)	3	5	6	8

When comparing the results of Tables 1 and 2 above, both DaVita and the department projected a numeric need for eight stations in year 2014. The department's numeric methodology for Yakima County ESRD planning area is attached to this evaluation as Appendix A.

The department received public comments from Fresenius Medical Care (Fresenius) related to DaVita's proposed project. Below is a summary of the comments received from Fresenius. [source: Public comments received March 20, 2012, p1]

• "FMC request that the Department of Health (Department) deny the current DaVita application in favor of a process that would allow for a comparative review of applications." DaVita submitted its application shortly before ESRD quarter #2 letters of intent were due. The department received updated NWRN data, which showed that eight stations were needed in Yakima County, instead of the three stations previously projected. However, because DaVita had a filed application, under WAC 246-310-284(4)⁶ no new application could be submitted.

DaVita provided responses to Fresenius's public comment. DaVita's responses are summarized below. [source: Comments received April 2, 2012, pp2-3]

- The dialysis rules use public data to project dialysis station need in planning areas under strict quarterly application schedules. FMC had all the information it needed to anticipate a possible withdrawal of our small expansion application and the resubmission of another application requesting more stations. FMC only needed to submit a letter of intent in Cycle 3 for year 2011 to protect its Yakima County options, but it failed to do so.
- For this application cycle, FMC filed five LOI's in other planning areas, including an LOI for a five-station facility in Klickitat County, which is adjacent to Yakima County.

⁶ Fresenius's reference to WAC 246-310-284(4) should have been WAC 246-310-282(4).

Departments Evaluation

The department understands Fresenius's frustration by DaVita's withdrawal of its Union Gap⁷ three-station expansion during the ex parte period and its subsequent submission of this application. The department also understands why Fresenius did not submit a LOI or application during the third concurrent review cycle since the decision on DaVita's three-station dialysis expansion was not expected until September 2011. However, WAC 246-310 does not prohibit a potential applicant from submitting a LOI during any of the concurrent review cycles even if there is an application under review in that planning area. Nor does WAC 246-310 prohibit an applicant from withdrawing its application during the ex parte period even if its withdrawal has the potential of affecting another potential applicant's application submission. Therefore, the department has no basis to deny DaVita's application on this issue.

WAC 246-310-284(5)

WAC 246-310-284(5) requires all CN approved stations in the planning area be operating at 4.8 in-center patients per station before new stations can be added. There are three facilities in the planning area and all are owned by DaVita. The most recent quarterly modality report, or successor report, from the Northwest Renal Network (NWRN) 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 for this project is August 1, 2011. [WAC 246-310-282] The quarterly modality report from NWRN available at that time was March 31, 2011, which became available on May 16, 2011. Below is DaVita Mt Adams, DaVita Union Gap, and DaVita Yakima utilization as of March 31, 2011.

Table 3
NWRN Facility Utilization

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Facility Name	#of Stations	# of Pts	Pts/Station Standard	Pts/Station		
DaVita Mt. Adams	14	81	4.8	5.78		
DaVita Union Gap	8	48	4.8	6.00		
DaVita Yakima	21	104	4.8	4.95		

As shown in the table above, **this standard is met**.

WAC 246-310-284(6)

WAC 246-310-284(6) requires new in-center dialysis stations be operating at a required number of in-center patients per approved station by the end of the third full year of operation. The DaVita Zillah Dialysis Center would be located in the Yakima County ESRD planning area; therefore, the standard for this criterion is 4.8 in-center patients per approved station. DaVita states that year 2015 would be the third year of operation and its year 2015 projected utilization is shown in table 4.

⁷ The Union Gap expansion application was submitted February 28, 2011 and withdrawn August 17, 2011. NWRN 2010 year-end data was released February 16, 2011. The 3rd quarter LOI period ended the last working day of July and the application submission period ended the last working day of August 2011.

Table 4 DaVita Zillah Dialysis Center Third Full Year Projected (2015) Facility Utilization

Facility Name	#of Stations	# of Pts	Pts/Station
DaVita Zillah Dialysis Center	8	48	6.0

As shown above, the DaVita Zillah Dialysis Center expects to be operating above 4.8 patients per station by year 3 using their information. [source: Amended Application Appendix 9] **This sub-criterion is met.**

(2) <u>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.</u>

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 Yakima County ESRD planning area would 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 demonstrate compliance with this sub-criterion, DaVita provided a copy of its current Accepting Patients for Treatment Policy used at its dialysis centers. Since this facility is a new facility, the policy submitted with the application is considered a draft. The draft policy outlines the process and guidelines that DaVita uses to admit patients for treatment at any of its dialysis centers. The policy also states that any patient needing treatment will be accepted to any facility without regard to race, creed, color, age, sex, or national origin. [source: Amended Application, Appendix 14] If approved, a condition would be necessary for the submission of an adopted Accepting Patients for Treatment Policy.

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. DaVita currently provides services to Medicaid eligible patients at the existing dialysis center. The applicant intends to provide services to Medicaid patients at the DaVita Zillah Dialysis Center. A review of the anticipated revenue sources indicates that the facility expects to receive Medicaid reimbursements. [source: Amended application, p22 and February 6, 2012, supplemental information, p4]

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. DaVita intends to provide services to Medicare patients at the proposed facility. A review of the anticipated revenue sources indicates that it expects to receive Medicare reimbursements. [source: Amended application, p22 and February 6, 2012, supplemental information, p4]

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.

DaVita demonstrated its intent to provide charity care to patients receiving treatment at the facility by submitting its current Indigent Care Policy used at its operational facilities. Since this facility is a new facility, the policy submitted with the application is considered a draft. The policy outlines the process one would use to access this service. DaVita also included a 'charity care' line item as a deduction from revenue within the pro forma income statements documents. [source: Amended application, Appendix 14 and February 6, 2012, supplemental information, p4] If approved, a condition would be necessary for the submission of an adopted Indigent Care Policy.

The department concludes that with the agreement to the conditions stated in the 'conclusion' section of this evaluation in the all residents of the planning area would have access to the health services at the proposed Zillah Dialysis Center. **This sub-criterion is met**.

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

Based on the source information reviewed and provided the applicant agrees to the conditions stated in the 'conclusion' section of this evaluation, the department determines that DaVita, Inc.'s project has met 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.

WAC 246-310 does not contain specific WAC 246-310-220(1) financial feasibility criteria as identified in WAC 246-310-200(2)(a)(i). There are also no known recognized standards as identified in WAC 246-310-200(2)(a)(ii) and (b) that directs what the operating revenues and expenses should be for a project of this type and size. Therefore, using its experience and expertise the department evaluates if the applicant's pro forma income statements reasonably project the proposed project is meeting its immediate and long-range capital and operating costs by the end of the third complete year of operation.

As stated in the project description portion of this evaluation, if this project is approved, DaVita anticipates that the new stations would become operational by the end of November 2012. Under this timeline, year 2013 would be the facility's first full calendar year of operation and 2015 would be year three. [source: Amended Application, p12]

DaVita provided its projected revenue and expense statement for the proposed dialysis center. The table below summarizes that information. [source: February 6, 2012, supplemental information, Exhibit B]

Table 5
DaVita Zillah Dialysis Center
Projected Revenue and Expenses for Partial Year 2012 and Full Years 2013-2015

	Partial Year 2012	CY 1 2013	CY 2 2014	CY 3 2015
# of Stations	8	8	8	8
# of Treatments [1]	369	5,990	6,589	7,188
# of Patients [2]	16	40	44	48
Utilization Rate [2]	2.0	5.0	5.5	6.0
Net Patient Revenue[1]	\$136,284	\$2,212,405	\$2,583,880	\$2,326,717
Total Operating Expenses [1, 3]	\$157,124	\$1,546,812	\$1,710,635	\$1,853,515
Net Profit or (Loss)[1]	(\$20,840)	\$665,593	\$873,515	\$473,202

^[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 above, DaVita Zillah Dialysis Center would be operating at a loss in partial year 2012 and a profit beginning in calendar year 2013 through 2015.

DaVita provided an executed lease agreement between JG Development, LLC ("Landlord") and Total Renal Care, Inc., ("Tenant"). [source: Amended Application, Appendix 15] The department's review of the executed lease agreement shows that rent costs identified in the lease are consistent with the pro-forma financial projections.

DaVita provided an executed copy of a medical director's services agreement for the proposed dialysis center signed and dated August 26, 2011. The agreement identifies the annual compensation for the medical director position. Additionally, DaVita's pro-forma financial statement also confirms the annual compensation for the medical director. [source: Amended Application, Appendices 3 and 7]

Fresenius provided comments related to this sub-criterion. The comments are summarized below. [source: Fresenius public comments received March 20, 2012, p3]

• In addition to the capital costs outlined in its amended application, DaVita has expended other resources related to these two applications. All capital costs associated with the resources DaVita has invested to date in pursuit of additions of stations in Yakima County, must be included as part of its overall capital expenditure. Without this information, the department cannot determine the projects conformance with WAC 246-310-220(1).

The department received comments from DaVita in response and they are summarized below. [source: DaVita's comments received April 2, 2012, p4]

• FMC argues that we did not disclose all of the expenditures in our amended application for the Zillah site and this action prevents evaluation of the overall expenses for this project. We fully disclosed all capital cost according to the department's definitions and program's interpretations. FMC does not identify what expenditures, if any, have not been disclosed from our previous Yakima County applications.

Department's Evaluation

Fresenius asserts that any capital costs DaVita incurred for the previously withdrawn three-station addition application must be included as a capital cost of this application. The department disagrees. That was a separate project from the one currently under review by the department. FMC's comments were general in nature and did not specifically identify what type of costs it believes DaVita did not include when it changed the site and capital costs of the new 8-station dialysis facility. Within this amended application, DaVita provided an executed lease agreement, an executed medical director agreement, and a breakdown of the capital expenditures to be incurred by both DaVita and the landlord. Additionally, in response to the Program's request for supplemental information, DaVita also provided cost breakdown clarification for line items within its projected pro-forma operating statement. Absent any documentation to show any undisclosed costs for other resources incurred by DaVita, the department would base its review of this project on documents provided in this application. The department concludes that the projected revenue and expenses are reasonable. **This sub-criterion is 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.

WAC 246-310 does not contain specific source of financing criteria as identified in WAC 246-310-200(2) (a) (i). There are also no known recognized standards as identified in WAC 246-310-200(2) (a) (ii) and (b) that directs how a project of this type and size should be financed. Therefore, using its experience and expertise the department compared the proposed project's source of financing to those previously considered by the department.

DaVita identified the capital expenditure associated with the establishment of new 8-station kidney dialysis center to be \$2,190,270, which is broken down in the table below. [source: Amended Application, Appendix 7]

Table 6
DaVita Zillah Dialysis Center Capital Cost

Item	Cost	% of Total
Leasehold improvements	\$875,000	39.9%
Indirect Costs (landlord expenses)	\$782,888	35.7%
Fixed & Moveable Equipment	\$446,882	20.4%
Water Treatment/Biomed Reuse	\$85,500	3.9%
Total Project Cost	\$2,190,270	100.0%

To further demonstrate compliance with this sub-criterion, DaVita provided the sources of its revenue by payer shown below. [source: Amended Application, p10]

Table 7
DaVita Zillah Dialysis Center Source of Patient Revenue

Revenue Source	% of Revenue
Medicare	59%
State (Medicaid)	6%
Commercial /HMO	35%
Total	100%

The proposed DaVita Zillah Dialysis Center is expected to have 65% of its revenue from Medicare and Medicaid entitlement programs. These programs are not cost based reimbursement and are not expected to have an unreasonable impact on the charges for services. Based on the department's review of the application materials, this same conclusion can be made for those with insurance or HMO patients that make up 35% of the project's revenue.

Based on the information provided, the department concludes that this project would not result in an unreasonable impact on the costs and charges for health services. **This subcriterion is met**.

(3) The project can be appropriately financed.

WAC 246-310 does not contain specific source of financing criteria as identified in WAC 246-310-200(2) (a) (i). There are also no known recognized standards as identified in WAC 246-310-200(2) (a) (ii) and (b) that directs how a project of this type and size should be financed. Therefore, using its experience and expertise the department compared the proposed project's source of financing to those previously considered by the department.

The capital expenditure associated with the establishment of the 8-station DaVita Zillah Dialysis Center is \$2,190,270, and DaVita's portion of the costs is \$1,407,382. DaVita states its portion of the project will be funded from its own reserves. A letter from DaVita's chief operating officer was provided confirming the corporate funding. A review of DaVita's audited financial statements shows the funds necessary to finance the project are available. [source: Amended Application, Appendices 6 and 10]

Based on the information provided, the department concludes that the project 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 and provided the applicant agree to the conditions stated in the 'conclusion' section of this evaluation, the department determines that DaVita, Inc.'s project 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.

WAC 246-310 does not contain specific WAC 246-310-230(1) criteria as identified in WAC 246-310-200(2)(a)(i). There are also no known recognized standards as identified in WAC 246-310-200(2)(a)(ii) and (b) that directs what specific staffing patterns or numbers of FTEs (full time equivalents) that should be employed for projects of this type or size.

Since Zillah Dialysis Center would be a new facility, DaVita provided a breakdown of all proposed staff beginning in partial year 2012, through full year 2015. [source: Amended Application, p22] A breakdown of the proposed staffing is summarized below.

Table 8
DaVita Zillah Dialysis Center proposed FTE's Year 2012 – 2015

Staff/FTEs	Partial Year 2012	CY 1-2013 Increase	CY 2-2014 Increase	CY 3-2015 Increase	Total FTEs		
Medical Director		Professional Services Contract					
Administrator	1.00	0.00	0.00	0.00	1.00		
Registered Nurses	2.00	0.30	0.20	0.30	2.80		
Patient Care Tech	4.50	0.00	0.50	0.50	5.50		
Biomedical Tech	0.30	0.00	0.00	0.00	0.30		
Administrative Asst	0.40	0.00	0.10	0.10	0.60		
MSW	0.40	0.10	0.00	0.00	0.50		
Dietician	0.40	0.10	0.00	0.00	0.50		
Total FTEs	9.00	0.50	0.80	0.90	11.20		

As shown above, DaVita expects to open the facility with 9.0 FTEs and increase staffing as the utilization increases through year 2015. DaVita states it does not anticipate any difficulty recruiting staff because it offers competitive wage and benefit packages to employees. Additionally, DaVita states that job openings are posted nationally and internally and it has extensive employee travelling program that guarantee it will maintain staffing at its facilities. [source: Amended Application Page 23]

DaVita identified Sajal Kumar, MD as the medical director for the proposed DaVita Zillah Dialysis Center and provided an executed Medical Director Agreement between Total Renal Care, Inc., ("Company"), and J. Hamilton Licht, P.C., d/b/a Nephrology Associates of Yakima ("Group"), and Sajal Kumar, M.D. ("Physician"). [source: Amended Application, p7 and Appendix 3] The medical director agreement outlines the roles and responsibilities of the Company, Group, and Physician.

In addition, the agreement also identifies the annual compensation for the medical director and the applicant's pro-forma financial statement substantiates the medical director's compensation. [source: Amended Application Appendix 3 and February 6, 2012, supplemental information, Exhibit B] Based on the information provided the department concludes that sufficient staffing is available or can be recruited. **This sub-criterion is met.**

(2) <u>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.</u>

WAC 246-310 does not contain specific WAC 246-310-230(2) as identified in WAC 246-310-200(2)(a)(i). There are also no known recognized standards as identified in WAC 246-310-200(2)(a)(ii) and (b) that directs what relationships, ancillary and support services should be for a project of this type and size. Therefore, using its experience and expertise the department assessed the materials contained in the application.

As a provider of dialysis services in Washington State, DaVita currently maintains the appropriate relationships with ancillary and support services for its existing dialysis centers in the Yakima County planning area. For its proposed Zillah Dialysis Center, 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. Additional services would be coordinated through DaVita's corporate offices in El Segundo, California and support offices in Tacoma, Washington; Denver, Colorado; Nashville, Tennessee; Berwyn, Pennsylvania; and Deland, Florida. [source: Amended Application, p23]

DaVita acknowledges that since this would be a new facility in Yakima County, transfer agreements would have to be established. To further demonstrate compliance with this subcriterion, DaVita provided an example of a draft transfer agreement. [source: Application, Appendix 12]

Based on this information, the department concludes DaVita currently has access to the necessary ancillary and support services that could support the proposed facility. If this project is approved, the department would include a condition requiring DaVita to provide a copy of the executed transfer agreement with a local hospital that is consistent with the example presented in the application. With the condition, 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.

WAC 246-310 does not contain specific WAC 246-310-230(3) criteria as identified in WAC 246-310-200(2) (a) (i). There are known recognized standards as identified in WAC 246-310-200(2) (a) (ii) and (b) that a facility must meet when it is to be Medicare certified and Medicaid eligible. Therefore, using its experience and expertise the department assessed the applicant's history in meeting these standards at other facilities owned or operated by the applicant.

As stated earlier, DaVita, Inc. is a provider of dialysis services in over 1,642 outpatient centers located in 43 states (including Washington State), and the District of Columbia. [source: Application, p1] For Washington State, DaVita owns or operates 25 kidney dialysis treatment centers in 12 separate counties. 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 public. To comply with this sub-criterion, DaVita provided a contact list of the regulatory agencies responsible for surveying its out-of-state facilities and the District of Columbia. [source: Amended Application, Appendix 2]

In February 2010, the department requested quality of care compliance history from out-of-state licensing and/or surveying entities and the District of Columbia where DaVita, Inc. or any subsidiaries have health care facilities. Of the 42 states and entities, the department received responses from 21states or 50% of the 42 states. The compliance history of the remaining 19 states and the District of Columbia is unknown. 10

Five of the 21 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 Iowa that decertified and later reopened, none of the deficiencies is reported to have resulted in fines or enforcement action. All other facilities are reported to be currently in compliance with applicable regulations. [source: compliance history from state licensing and/or surveying entities] The department concludes that considering the more than 1,642 facilities owned/managed by DaVita, one out-of-state facility listed above demonstrated substantial non-compliance issues; therefore, the department concludes the out-of-state compliance surveys are acceptable.

⁸ WAC 246-310-230(5).

⁹ States that provided responses are: California, Colorado, Connecticut, Delaware, Florida, Idaho, Iowa, Kansas, Kentucky, Minnesota, Missouri, Nevada, New Mexico, North Dakota, Ohio, Oregon, South Carolina, Tennessee, South Dakota and West Virginia

¹⁰ States that did not provide responses are Alabama, Arizona, Arkansas, Georgia, Illinois, Indiana, Louisiana, Maryland, Massachusetts, Michigan, Mississippi, Nebraska, New Jersey, New York, North Carolina, Oklahoma, Pennsylvania, Texas, Utah, Virginia and Wisconsin. The department did not send survey to itself. The District of Columbia did not respond to the survey.

¹¹ The Iowa facility chose voluntarily termination in August 2007 due to its inability to remain in compliance with Medicare Conditions for Coverage rather than undergo the termination process with Medicare. This facility is currently operating as a private ESRD facility.

For Washington State, since January 2008, the Department of Health's Investigations and Inspections Office has completed 26 compliance surveys for the operational facilities that DaVita either owns or manages. Of the compliance surveys completed, there were minor non-compliance issues related to the care and management at the DaVita facilities. These non-compliance issues are typical of a dialysis facility and DaVita submitted and implemented acceptable plans of correction. [source: facility survey data provided by the Investigations and Inspections Office]

For medical director services, DaVita provided a copy of its draft medical director agreement with Sajal Kumar, MD, who is part of the Nephrology Associates of Yakima practice. Two other physicians are part of the practice, and according to the draft medical director agreement, may provide backup services if necessary. The department's review of the compliance history for Dr. Sajal Kumar, Dr. J Hamilton Licht, and Dr. Karen Harrison revealed no recorded sanctions or license restrictions.

Given the compliance history of DaVita and that of the medical director and nephrology group, the department concludes that there is reasonable assurance the proposed DaVita Zillah Dialysis Center would be operated in conformance with state and federal regulations. **This sub-criterion is met**.

(4) <u>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.</u>

WAC 246-310 does not contain specific WAC 246-310-230(4) criteria as identified in WAC 246-310-200(2)(a)(i). There are also no known recognized standards as identified in WAC 246-310-200(2)(a)(ii) and (b) that directs how to measure unwarranted fragmentation of services or what types of relationships with a services area's existing health care system should be for a project of this type and size. Therefore, using its experience and expertise the department assessed the materials in the application.

In response to this criterion, DaVita provided a summary of its quality and continuity of care indicators used in its quality improvement program. The quality of care program incorporates all areas of the dialysis program it monitors and evaluates all activities related to clinical outcomes, operations management, and process flow. Further, DaVita provided examples of its quality index data and its physician, community, and patient services program known as 'Empower'.

DaVita also provided a draft sample of its patient transfer agreement used at its existing Washington facilities. [source: Amended Application, Appendices 12, 17 & 18] Since it did not provide an executed patient transfer agreement with a provider in the planning area, the department would attach a condition to the approval of this project.

¹² As of the writing of this evaluation, DaVita's Battleground Dialysis Center and East Wenatchee Dialysis Centers are not yet operational. The Everett Dialysis Center and Olympic View Dialysis Center are both operational, and managed by DaVita.

With agreement to the condition related to the patient transfer agreement, the department concludes approval of this project would promote continuity in the provision of health care for the planning area, and would not result in an unwarranted fragmentation of services. **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.

For this project, this sub-criterion is addressed in sub-section (3) above and is considered met.

D. Cost Containment (WAC 246-310-240) and WAC 246-310-288 (Tie Breakers)

Based on the source information reviewed and provided the applicant agree to the conditions stated in the 'conclusion' section of this evaluation, the department determines that DaVita, Inc.'s project met the cost containment criteria in WAC 246-310-240

(1) <u>Superior alternatives</u>, in terms of cost, efficiency, or effectiveness, are not available or practicable.

To determine if a proposed project is the best alternative, the department takes a multi-step approach. Step one determines if the application has met the other criteria of WAC 246-310-210 thru 230. If it has failed to meet one or more of these criteria then the project is determined not to be the best alternative, and would fail this sub-criterion.

If the project met WAC 246-310-210 thru 230 criteria, the department would move to <u>step</u> <u>two</u> in the process and assess the other options the applicant or applicants considered prior to submitting the application under review. If the department determines the proposed project is better or equal to other options the applicant considered before submitting their application, the determination is either made that this criterion is met (regular or expedited reviews), or in the case of projects under concurrent review, move on to step three.

Step three of this assessment is to apply any service or facility specific criteria (tiebreaker) contained in WAC 246-310. The tiebreaker criteria are objective measures used to compare competing projects and make the determination between two or more approvable projects, which is the best alternative. If WAC 246-310 does not contain any service or facility criteria as directed by WAC 246-310-200(2) (a) (i), then the department would look to WAC 246-310-240(2) (a) (ii) and (b) for criteria to make the assessment of the competing proposals. If there are no known recognized standards as identified in WAC 246-310-200(2) (a) (ii) and (b), then using its experience and expertise, the department would assess the competing projects and determine which project should be approved.

Step One

DaVita's proposal to establish a new 8-station kidney dialysis facility within Yakima County met the review criteria under WAC 246-310-210, 220, and 230. Therefore, the department moves to step two below.

Step Two

Before submitting this application, DaVita considered the three alternatives summarized below. [source: Amended Application p25]

Alternative 1: Expand the Union Gap Dialysis Center

DaVita states that adding stations to the existing Union Gap facility would not improve patient access because the population centers are not evenly dispersed within the planning area. However, if stations are added in the Zillah and Toppenish areas, access could be improved. Therefore, this option was rejected.

Alternative 2: Establish a new 8-station facility in Toppenish

DaVita states it rejected this alternative because Toppenish has limited expansion opportunities for anticipated future volumes within Yakima County.

Alternative 3: Establish a new 13-station facility within Toppenish to serve both Yakima and Klickitat counties

DaVita rejected this alternative because planning for stations in Klickitat County, which is adjacent to Yakima County, might jeopardize the approval of the application in Yakima County.

Fresenius provided public comment related to this sub-criterion. Specifically, Fresenius encouraged the department to deny DaVita's project because Yakima County is large and with only one provider (DaVita), patients do not have a choice of providers. Additionally, Fresenius concluded that DaVita's project should be denied in previous sub-criterion, which would result in a denial of this sub-criterion. [source: Public comments received March 20, 2012]

In response to Fresenius comment, DaVita asserts that denial of this project would negatively affect patients requiring dialysis services. Additionally, with the rapid growth rate, DaVita states it conservatively projected the Zillah facility will be operating in excess of 80% occupancy in its first full year of operation (2013) and 100% occupancy by the end of the third year of operation (2015). As a result, DaVita states it expects FMC would have another opportunity in the very near future to submit an application for a dialysis facility Yakima County. [source: April 2, 2012, comments, p3]

Departments Evaluation

The department would agree with Fresenius's statement that DaVita is the only dialysis provider in Yakima County. The same as Fresenius is in other dialysis services areas in the state. The need for eight additional stations in Yakima County is projected. All existing stations are operating above the 4.8 patients per station demonstrating that additional stations are needed in the planning area. The use of the existing stations range from 4.95 patients per station at the Yakima facility to 6 at the Union Gap facility. Therefore, the department concludes the best available alternative for the residents of the Yakima County planning area is to approve the current application. **This sub-criterion is met**.

Step Three

This step is used to determine the best available alternative between two or more approvable projects. There was no other project submitted to add dialysis stations in Yakima County ESRD planning area during the Kidney Disease Treatment Centers Review Cycle #3. This step is not applicable to the project.

(2) *In the case of a project involving construction:*

(a) <u>The costs, scope, and methods of construction and energy conservation are reasonable;</u> DaVita's proposes to lease a "built to suit" facility from a real estate developer. DaVita states that the scope and methods of the facility will meet Medicare certification and the local authority construction and energy conservation code. The cost the developer would incur to construct the proposed dialysis center building is reflected in the negotiated lease costs provided by DaVita. The proposed property lease costs were evaluated in the financial feasibility section of this analysis. Within this evaluation, the department concluded the overall project meet the financial feasibility criterion. Based on the information, the department concludes that **this sub-criterion is met**.

(b) The project will not have an unreasonable impact on the costs and charges to the public of providing health services by other persons.

This sub-criterion is evaluated within the financial feasibility criterion under WAC 246-310-220(2). Based on that evaluation, the department concludes that **this sub-criterion is met.**



2011 Yakima County ESRD Need Projection Methodology

	Planning Area 6 Year Utilization Data - Resident Incenter Patients						
	Yakima Yakima	2005 185	2006 181	2007 190	2008 196	2009 201	2010 214
	TOTALS	185	181	190	196	201	214
246-310-284(4)(a)	Rate of Change		-2.16%	4.97%	3.16%	2.55%	6.47%
	6% Growth or Greater?		FALSE	FALSE	FALSE	FALSE	TRUE
	Regression Method:	Linear			-	-	-
246-310-284(4)(c)				Year 1	Year 2	Year 3	Year 4
				2011	2012	2013	2014
Projected Resident Incenter Patients	from 246-310-284(4)(b)			219.50	227.20	234.90	242.60
Station Need for Patients	Divide Resident Incenter	Patients by	4.8	45.7292	47.3333	48.9375	50.5417
	Rounded to next whole n	umber		46	48	49	51
246-310-284(4)(d) Existing CN Approved S	subtract (4)(c) from approv	ed stations		43	42	43	43
Results of (4)(c) above	otations			43	43 48	43	43 51
Net Station Need			_	-3	-5	-6	-8
Negative number indicates ne	eed for stations						
246-310-284(5)							
Name of Center	# of Stations	Patients	Utilization (Patients per	Station)		
DaVita Mt. Adams	14	74	5.29				
DaVita Union Gap	8	48					
DaVita Yakima	21	99	4.71				
Total	43	221					
Source: Northwest Renal							
Most research user and date	a: 2010 year-end data as of	00/46/2011	1				



2011 Yakima County ESRD Need Projection Methodology

