

EXECUTIVE SUMMARY

EVALUATIONS OF THE FOLLOWING TWO CERTIFICATE OF NEED APPLICATIONS PROPOSING TO ADD DIALYSIS STATION CAPACITY TO BENTON COUNTY:

- **DAVITA, INC. PROPOSING ESTABLISH A TWENTY-STATION DIALYSIS CENTER IN RICHLAND**
- **FRESENIUS MEDICAL CENTER PROPOSING TO ESTABLISH A TWENTY-STATION DIALYSIS CENTER IN RICHLAND**

BRIEF PROJECT DESCRIPTIONS

DaVita, Inc.

This application proposes to establish a 20-station dialysis facility to be located at 1351 Aaron Drive in Richland. The new dialysis center would be known as Chinook Dialysis Center and would serve the residents of Benton County.

The capital expenditure associated with the establishment of the 20-station facility is \$1,789,908. If this project is approved, DaVita anticipates all 20 stations would become operational immediately. Under this timeline, year 2010 would be a partial year of operation and 2011 would be the facility's first full calendar year of operation. [source: Application, p4, p8, & p12]

Fresenius Medical Center

This application proposes to establish a 20-station dialysis facility to be located at 3920 Keene Road in Richland. The new dialysis center would be known as Richland Dialysis Center and would serve the residents of Benton County.

The capital expenditure associated with the establishment of the 20-station facility is \$1,483,113. If this project is approved, Fresenius Medical Center anticipates all 20 stations would become operational by the end of July 2011. Under this timeline, year 2011 would be a partial year of operation and 2012 would be the facility's first full calendar year of operation. [source: Amendment Application, p2, p10, & p14]

APPLICABILITY OF CERTIFICATE OF NEED LAW

Both projects are 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).

CONCLUSIONS

DaVita, Inc.

For the reasons stated in this evaluation, the application submitted on behalf of DaVita, Inc. proposing to establish a twenty-station dialysis center in Richland within Benton County is not consistent with applicable criteria of the Certificate of Need Program. A Certificate of Need is denied.

Fresenius Medical Care

For the reasons stated in this evaluation, the application submitted on behalf of Fresenius Medical Care proposing to establish a twenty-station dialysis center in Richland within Benton County is not consistent with applicable criteria of the Certificate of Need Program. A Certificate of Need is denied.

**EVALUATIONS OF THE FOLLOWING TWO CERTIFICATE OF NEED APPLICATIONS
PROPOSING TO ADD DIALYSIS STATION CAPACITY TO BENTON COUNTY:**

- **DAVITA, INC. PROPOSING ESTABLISH A TWENTY-STATION DIALYSIS CENTER IN RICHLAND**
- **FRESENIUS MEDICAL CENTER PROPOSING TO ESTABLISH A TWENTY-STATION DIALYSIS CENTER IN RICHLAND**

APPLICANT DESCRIPTIONS

DaVita Inc.

DaVita, Inc. (DaVita) is a for-profit corporation that provides dialysis services in over 1,400 outpatient centers located in 43 states and the District of Columbia. DaVita also provides acute inpatient dialysis services in approximately 700 hospitals throughout the country. [source: Application, p5; DaVita website]

In Washington State, DaVita owns or operates a total of 23 kidney dialysis facilities in 11 separate counties. Below is a listing of the DaVita facilities in Washington.¹ [source: CN historical files; DaVita Application, p5]

Clark

Vancouver Dialysis Center

Pacific

Seaview Dialysis Center

Island

Whidbey Island Dialysis Center

Pierce

Graham Dialysis Center
Lakewood Community Dialysis Center
Parkland Dialysis Center
Puyallup Community Dialysis Center
Tacoma Dialysis Center

Franklin

Mid-Columbia Kidney Center

Kittitas

Ellensburg Dialysis Center

Yakima

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

Thurston

Olympia Dialysis Center

King

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

Snohomish

Everett Dialysis Center
Mill Creek Dialysis Center

Benton

Kennewick Dialysis Center
Chinook Dialysis Center

¹ Four facilities—Whidbey Island Dialysis Center, Parkland Dialysis Center, Everett Dialysis Center, and Kennewick Dialysis Center—were recently approved by the department and are not yet operational.

Fresenius Medical Care

Fresenius Medical Care Holdings, Inc. (FMC) is the parent corporation of the following five subsidiaries:

QualiCenters Inc.	Pacific Northwest Renal Services
Inland Northwest Renal Care Group, LLC	Renal Care Group, Inc.
National Medical Care, Inc.	

Under the four of the five subsidiaries listed above, FMC operates 1,700 outpatient dialysis centers in 45 states and the District of Columbia.² [source: CN historical files; Amendment Application, pp1-2]

In Washington State, FMC or one of its subsidiaries owns, operates, or manages 20 kidney dialysis facilities in fourteen separate counties. Below is a listing of the 20 facilities in Washington.³ [CN historical files]

Benton County

Columbia Basin Dialysis Center

Clark County

Fort Vancouver Dialysis Facility
Salmon Creek Dialysis Facility

Lewis County

Chehalis Facility

Grant County

Moses Lake Dialysis Facility
Western Grant County Dialysis Facility

Thurston County

Lacey Dialysis Facility
Hawks Prairie Dialysis Facility

Cowlitz County

QualiCenters Longview

Pend Oreille

Pend Oreille Dialysis Facility

Spokane County

Northpointe Dialysis Facility
Spokane Kidney Center
North Pines Dialysis Facility
North Spokane Dialysis Center

Mason County

Shelton Dialysis Facility

Okanogan County

Omak Dialysis Facility

Stevens County

Colville Dialysis Center

Gray Harbor County

Aberdeen Dialysis Facility

Walla Walla County

QualiCenters Walla Walla

Adams County

Othello Dialysis Center

² The National Medical Care, Inc. subsidiary does not operate any dialysis facilities.

³ Four facilities—Pend Oreille Dialysis Center, Western Grant County Dialysis Center, Hawks Prairie Dialysis facility, and North Spokane Dialysis Center—were recently approved by the department and are not yet operational.

PROJECT DESCRIPTIONS

DaVita Inc.

DaVita proposes to establish a 20-station facility to be located at 1351 Aaron Drive in Richland. The new dialysis center would be known as Chinook Dialysis Center (referenced as “CDC” in this evaluation) and would serve the residents of Benton County.

Services to be provided at CDC include hemodialysis, peritoneal dialysis, and training/support for dialysis patients. The 20-station facility would include a permanent bed station and an isolation station. [source: Application, p9]

The capital expenditure associated with the establishment of the 20-station facility is \$1,789,908. Of that amount 59% is related to leasehold improvements; 35% for fixed/moveable equipment; and the remaining 6% is related to fees. [source: Application, Appendix 7]

If this project is approved, DaVita anticipates all 20 stations would become operational immediately. Under this timeline, year 2010 would be a partial year of operation and 2011 would be the facility’s first full calendar year of operation; 2013 would be year three. [source: Application, p8 & p12]

Fresenius Medical Care

Under its QualiCenters, Inc. subsidiary, FMC proposes to establish a 20-station facility to be located at 3920 Keene Road in Richland. The new dialysis center would be known as Richland Dialysis Center (referenced as “RDC” in this evaluation) and would serve the residents of Benton County.

Services to be provided at RDC include hemodialysis, peritoneal dialysis, and training/support for dialysis patients. The 20-station facility would include a permanent bed station and an isolation station. [source: Amendment Application, p11]

The capital expenditure associated with the establishment of the 20-station facility is \$1,483,114. Of that amount 59% is related to leasehold/construction; 33% for fixed/moveable equipment; and the remaining 8% is related to fees. [source: Amendment Application, p30]

If this project is approved, FMC anticipates all 20 stations would become operational by the end of July 2011. Under this timeline, year 2011 would be a partial year of operation and 2012 would be the facility’s first full calendar year of operation. [source: Amendment Application, p14]

APPLICABILITY OF CERTIFICATE OF NEED LAW

Both projects are 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

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 in 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 the 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 contain service or facility specific criteria for dialysis projects and must be used to make the required determinations.

To obtain Certificate of Need approval, each applicant must demonstrate compliance with the applicable 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). Additionally, each applicant must demonstrate compliance with applicable kidney disease treatment center criteria outlined in WAC 246-310-280 through 289.⁴

⁴ 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 246-310-286; WAC 246-310-287; and WAC 246-310-289.

APPLICATION CHRONOLOGY

As directed under WAC 246-310-282(1) the department accepted these two projects under the year 2009 Kidney Disease Treatment Centers-Concurrent Review Cycle #4. Below is a chronologic summary of the projects.

Action	DaVita	FMC
Letter of Intent Submitted	October 30, 2009	October 30, 2009
Initial Application Submitted	November 30, 2009	November 30, 2009
Amendment Application Submitted	N/A	December 30, 2009
Department's pre-review Activities including screening and responses	January 1, 2010 through March 15, 2010	
Beginning of Review	March 16, 2010	
End of Public Comment	May 17, 2010 ⁵	
Rebuttal Comments Received	June 16, 2010	
Department's Anticipated Decision Date	August 2, 2010	
Department's Actual Decision Date	August 11, 2010	

CONCURRENT REVIEW AND AFFECTED PERSONS

The purpose of the concurrent review process is to comparatively analyze and evaluate competing or similar projects to determine which of the projects may best meet the identified need. In the case of the projects submitted by DaVita and FMC, the department will issue one single evaluation regarding whether one, both, or neither of the projects should be issued a Certificate of Need.

For each application, the other applicant sought and received affected person status under WAC 246-310-010. No other entities sought and received affected person status for either of the two projects.

SOURCE INFORMATION REVIEWED

- DaVita, Inc.'s Certificate of Need application submitted November 30, 2009
- Fresenius Medical Care's amended Certificate of Need application submitted December 30, 2009
- DaVita, Inc.'s supplemental information dated February 26, 2010
- Fresenius Medical Care's supplemental information dated February 25, 2009
- Public comment received during the review
- DaVita, Inc.'s rebuttal comments received June 15, 2010
- Fresenius Medical Care's rebuttal comments received June 16, 2010
- Years 2003 through 2008 historical kidney dialysis data obtained from the Northwest Renal Network
- Year 2008 Northwest Renal Network 4th Quarter Data
- Licensing and/or survey data provided by the Department of Health's Investigations and Inspections Office
- Licensing and/or survey data provided by out of state health care survey programs
- Data obtained from DaVita, Inc.'s webpage (www.davita.com)
- Data obtained from Fresenius Medical Center's webpage (www.fmcna.com)
- Data obtained from the Washington Secretary of State office and webpage

⁵ There was no public hearing requested or conducted for these two projects.

SOURCE INFORMATION REVIEWED (continued)

- Data obtained from the Benton County Assessor webpage
- Maps and driving directions (maps.yahoo.com)
- Certificate of Need historical files

CONCLUSIONS

DaVita, Inc.

For the reasons stated in this evaluation, the application submitted on behalf of DaVita, Inc. proposing to establish a twenty-station dialysis center in Richland within Benton County is not consistent with applicable criteria of the Certificate of Need Program. A Certificate of Need is denied.

Fresenius Medical Care

For the reasons stated in this evaluation, the application submitted on behalf of Fresenius Medical Care proposing to establish a twenty-station dialysis center in Richland within Benton County is not consistent with applicable criteria of the Certificate of Need Program. A Certificate of Need is denied.

A. Need (WAC 246-310-210)

Based on the source information reviewed, the department concludes:

- DaVita, Inc.'s project has not 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; and
- Fresenius Medical Center's project has not 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 under 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.⁶

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.⁷ 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)]

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

⁶ 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]

⁷ 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. For this project, the base year is 2008.

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

DaVita proposes to establish a 20-station center in Richland. Based on the calculation of the annual growth rate in the planning area as described above, linear regression was used to project need. Given that CDC would be located in Benton County, the number of projected patients was divided by 4.8 to determine the number of stations needed in the planning area. [source: Application, pp18-20]

FMC’s Application of the Numeric Methodology

FMC proposes to establish a 20-station dialysis center in Richland. Based on the calculation of the annual growth rate in the planning area as described above, linear regression was used to project need. Given that RDC would be located in Benton County, the number of projected patients was divided by 4.8 to determine the number of stations needed in the planning area. [source: Amendment Application, pp18-20]

Department’s Application of the Numeric Methodology

Based on the calculation of the annual growth rate in the planning area as described above, the department also used linear regression to project need for Benton County. The department divided the projected number of patients by 4.8 to determine the number of stations needed as required under WAC 246-310-284(5).

Based on the numeric methodology, Table 1 below shows a summary of the projected net need provided by each applicant and the department for Benton County.

Table 1
Benton County Numeric Methodology Summary of Projected Net Station Need

	4.8 in-center patients per station		
	2012 Projected # of stations	Minus Current # of stations	2012 Net Need / [Surplus]
DaVita	33	13	19.54
FMC	33	13	20
DOH	33	42	9

When comparing the applicants’ and department’s results shown in Table 1 above, it shows that both applicants did not include all CN approved dialysis stations located in Benton County.

FMC operates a 13-station dialysis center in Kennewick, known as Central Basin Dialysis Center. On July 28, 2008, two separate Certificates of Need were issued to DaVita approving the establishment of two separate dialysis centers in Benton County. CN #1376 approved a 10-station facility in Kennewick, and CN #1377 approved a 19-station facility in Richland. As a result, Benton County

has a total of 42 dialysis stations. When all 42 stations are subtracted from the projected number of stations in year 2012, the result is a planning area surplus of 10 stations.

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. 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 for these two projects is November 1, 2009. [WAC 246-310-282] The quarterly modality report from NRN available at that time was December 31, 2008. The 42 stations are located in three separate facilities. Table 2 below shows the December 31, 2008, utilization of the three dialysis centers.

**Table 2
December 31, 2008-Facility Utilization Data**

Facility Name	# of Stations	# of Pts	Pts/Station
FMC-Columbia Basin Dialysis Center	13	75	6.77
DaVita-Chinook Dialysis Center	19	0	0.00
DaVita-Kennewick Dialysis Center	10	0	0.00

As previously stated, on July 28, 2008, two separate Certificates of Need were issued to DaVita approving the establishment of two separate dialysis centers in Benton County. On January 29, 2010, the department acknowledged completion and operation of only one facility—Chinook Dialysis Center. Continuing progress toward completion of DaVita’s Kennewick facility has been demonstrated, however, the facility is not yet operational. As a result, neither DaVita’s nor FMC’s application can demonstrate compliance with the standard under WAC 246-310-284(5).

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. For Benton County, the requirement is 4.8 in-center patients per approved station. [WAC 246-310-284(6)(a)] Both DaVita and FMC propose dialysis stations to be located within Benton County and both applicants must demonstrate compliance with this criterion using the 4.8 in-center patient per station.

DaVita anticipates all 20 stations would become operational immediately after approval. Under this timeline, year 2011 would be the facility’s first full calendar year of operation and 2013 would be year three. FMC anticipates all 20 stations would become operational by the end of July 2011. Under this timeline, year 2012 would be the facility’s first full calendar year of operation and 2014 would be year three. A summary of both applicants’ projected utilization for their respective third year of operation is shown in Table 3 on the following page. [source: DaVita Application, Appendix 9; FMC Amendment Application, February 25, 2010, supplemental information, Attachment 6, p60]

Table 3
Third Year Projected Facility Utilization

Facility Name	Year 3	# of Stations	# of Pts	Pts/Station
DaVita-Chinook Dialysis Center	2013	20	103	5.15
FMC-Richland Dialysis Center	2014	20	100	5.00

As shown in Table 3 above, both applicants project to meet this standard.

DaVita’s Comments

Within its application, DaVita acknowledges its July 2008 approvals of its Richland and Kennewick facilities and confirms that the Richland facility become operational in November 2009. DaVita acknowledges that it submitted its own application to “*protect the continued operation of the new Richland facility.*” DaVita also asserts that FMC submitted its competing application based on an assumption that FMC would prevail in the appeal of DaVita’s July 2008 approvals and the two approvals would be overturned by the health law judge, resulting in only 13 stations operational in the county⁸ [source: DaVita public comment, p1]

FMC’s Comments

Within its comments, FMC also acknowledges DaVita’s July 2008 approvals of its Richland and Kennewick facilities. FMC acknowledges that it submitted its own application as a response to DaVita’s submission of its application. FMC asserts that DaVita submitted its application based on an assumption that FMC would prevail in the appeal of DaVita’s approvals resulting in only 13 stations operational in the county. [source: FMC public comment, p1]

Department’s Review

On July 28, 2008, 29 additional dialysis stations were approved in Benton County, and 19 of the 29 became operational in November 2009. The adjudicative hearing for the 29 station approval is scheduled for early November 2010. As a result, the July 2008 approvals remain valid.

Both applicant’s acknowledged the July 2008 approval of 29 additional dialysis stations in Benton County, and concurred that 19 of the 29 stations are currently operational. Neither applicant counted the 29 additional stations when applying the numeric methodology under WAC 246-310-284(4) or the utilization standard under WAC 246-310-284(5). Absent a ruling from the health law judge to invalidate the July 2008 approvals, these stations must be counted in the numeric methodology. As a result, dialysis station capacity in Benton County is 42 stations, rather than the 13 stations counted by both applicants, resulting in a surplus of 10 stations in the planning area. [WAC 246-310-284] Further, all 42 stations must be operating at or above 4.8 patients per station before new stations can be added. Only 13 of the 42 stations in the planning area meet this standard. [WAC 246-310-284(5)]

Based on the above information and standards, the department’s conclusion regarding this sub-criterion follows.

⁸ FMC submitted an adjudicative appeal with the Department of Health’s Adjudicative Services Unit – Master Case #M2008-118433. The adjudicative hearing is scheduled for early November 2010.

DaVita-Chinook Dialysis Center

DaVita proposes to establish a 20-station dialysis center in Richland within Benton County. Based on the above standards and criteria, the project is not consistent with applicable criteria of the Certificate of Need Program and this sub-criterion is not met for DaVita's project.

FMC-Richland Dialysis Center

FMC proposes to establish a 20-station dialysis center in Richland within Benton County. Based on the above standards and criteria, the project is not consistent with applicable criteria of the Certificate of Need Program and this sub-criterion is not met for FMC's project.

- (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.

As previously stated, both applicants currently provide health care services to out-of-state residents or residents of Washington State. To determine whether all residents of the Benton County service 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.

DaVita, Inc.

To demonstrate compliance with this sub-criterion, DaVita provided a copy of its current Admission and Indigent Care policies that would also be used at CDC in Benton County. The Admission Policy outlines the process/criteria that CDC will use to admit patients for treatment, and ensures that patients will receive appropriate care at the dialysis center. The Admission Policy also states that any patient with end stage renal disease needing chronic hemodialysis will be accepted for treatment at the facility without regard to race, color, national origin, sex, age, religion, or disability. [source: Application, Appendix 14]

Fresenius Medical Care

To demonstrate compliance with this sub-criterion, FMC provided a copy of its current Admission Policy that would also be used at RDC in Benton County. The Admission Policy outlines the process/criteria that FMC uses to admit patients for treatment at its dialysis center. It is intended to ensure that patients will receive appropriate care. The Admission Policy also states that any patient needing treatment will be accepted to any FMC facility without regard to race, creed, color, age, sex, or national origin. [source: Application, Exhibit 8]

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.

DaVita, Inc.

DaVita currently provides services to Medicare patients at its existing dialysis centers. It intends to also provide services to Medicare patients at the proposed Benton County facility. A review of the anticipated revenue indicates that the facility expects to continue to receive Medicare reimbursements.

DaVita currently provides services to Medicaid eligible patients at its existing dialysis centers. It intends to also provide services to Medicaid patients at the proposed Benton County facility. A review of the anticipated revenue indicates that the facility expects to continue to receive Medicaid reimbursements.

Fresenius Medical Care

FMC currently provides services to Medicare patients at its existing dialysis center. It intends to also provide services to Medicare patients at the proposed Benton County facility. A review of the anticipated revenue indicates that the facility expects to continue to receive Medicare reimbursements.

FMC currently provides services to Medicaid eligible patients at its existing dialysis center. It intends to also provide services to Medicaid patients at the proposed Benton County facility. A review of the anticipated revenue indicates that the facility expects to continue to receive Medicaid reimbursements.

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, Inc.

DaVita demonstrated its intent to provide charity care to Benton County residents by submitting its current charity care policy that 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: Application, Appendices 9 & 14]

Fresenius Medical Care

FMC demonstrated its intent to provide charity care to Benton County residents by submitting its current charity care policy that outlines the process one would use to access this service. FMC also included a 'charity care' line item as a deduction from revenue within the pro forma income statements documents. [source: FMC Amendment Application, Exhibit 9 and February 25, 2010, supplemental information, Attachment , p60]

Based on the above information and standards, the department's conclusion regarding this sub-criterion follows.

DaVita-Chinook Dialysis Center

The department concludes that all residents of the service area would have adequate access to the health services at the proposed Benton County facility. This sub-criterion is met.

FMC-Richland Dialysis Center

The department concludes that all residents of the service area would have adequate access to the health services at the proposed Benton County facility. This sub-criterion is met.

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

Based on the source information reviewed, the department concludes:

- DaVita, Inc.’s project has not met the financial feasibility criteria in WAC 246-310-220; and
- Fresenius Medical Care’s project has not 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.

DaVita, Inc.

If approved, DaVita anticipates CDC will become operational immediately. Based on this timeline, year 2010 would be a partial year of operation and 2011 would be the facility’s first full year of operation. Using the financial information provided as part of the completed application, Table 4 below illustrates the projected revenue, expenses, and net income for years 2010 through 2013 for CDC. [source: Application, Appendix 9]

**Table 4
DaVita-Chinook Dialysis Center
Projected Revenue and Expenses Calendar Years 2010 - 2013⁹**

	Partial Year 2010	Full Year 1 2011	Full Year 2 2012	Full Year 3 2013
# of Stations	20	20	20	20
# of Treatments ^[1]	3,946	7,529	11,578	16,152
# of Patients ^[2]	24	47	73	103
Utilization Rate ^[2]	1.20	2.35	3.65	5.15
Net Patient Revenue ^[1]	\$ 727,427	\$ 2,067,120	\$ 2,754,064	\$ 4,080,229
Total Operating Expense ^[1,3]	\$ 1,083,665	\$ 1,831,422	\$ 2,584,772	\$ 3,382,947
Net Profit or (Loss) ^[1]	(\$ 356,237)	(\$ 235,698)	\$ 169,292	\$ 697,282
Net Patient Revenue/Treatment ^[1]	\$ 199.84	\$ 292.38	\$ 251.15	\$ 265.16
Total Operating Exp./Treatment ^[1]	\$ 297.71	\$ 259.04	\$ 235.71	\$ 219.84
Net Profit per Treatment ^[1]	(\$ 97.87)	\$ 33.34	\$ 15.44	\$ 45.31

[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 4 above, at the projected volumes identified in the application, DaVita anticipates that the 20-station CDC would be operating at a loss in partial year one and a profit in full years one through three.

⁹ Whole numbers may not add due to rounding.

DaVita’s Benton County facility would be located at 1351 Aaron Drive in Richland. The lease agreement provided in the application was executed October 10, 2007, and outlines the terms and the annual rent for the space for 10 years following commencement of the lease. The annual lease costs are substantiated in the pro forma financial documents used to prepare the summary in Table 4. [source: Application, Appendix 15]

Additionally, DaVita provided a copy of the executed Medical Director Agreement between itself and Wassim Khawandi, MD. The medical director service costs are also substantiated in the pro forma documents. [source: Application, Appendix 3]

Fresenius Medical Care

For its Benton County project, FMC anticipates it will become operational in July 2011. Based on this timeline, year 2011 would be a partial year of operation and year 2012 would be RDC’s first full calendar year of operation. Using the financial information provided as part of the completed application, Table 5 below illustrates the projected revenue, expenses, and net income for years 2011 through 2014. [source: Amendment Application, Attachment 6, p60]

**Table 5
FMC-Richland Dialysis Center
Projected Revenue and Expenses Calendar Years 2011 - 2014¹⁰**

	Partial Year 2011	Full Year 1 2012	Full Year 2 2013	Full Year 3 2014
# of Stations	20	20	20	20
# of Treatments ^[1]	3,474	9,908	12,644	15,232
# of Patients ^[2]	45	65	83	100
Utilization Rate ^[2]	2.25	3.25	4.15	5.00
Net Patient Revenue ^[1]	\$ 1,591,108	\$ 4,539,253	\$ 5,792,808	\$ 6,978,510
Total Operating Expense ^[1,3]	\$ 1,122,711	\$ 3,026,017	\$ 3,755,282	\$ 4,445,516
Net Profit or (Loss) ^[1]	\$ 468,397	\$ 1,513,236	\$ 2,037,526	\$ 2,532,994
Net Patient Revenue/Treatment ^[1]	\$ 482.15	\$ 471.86	\$ 471.57	\$ 471.52
Total Operating Exp./Treatment ^[1]	\$ 340.22	\$ 314.55	\$ 305.71	\$ 300.37
Net Profit per Treatment ^[1]	\$ 141.94	\$ 157.30	\$ 165.87	\$ 171.15

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

As shown in Table 5 above, at the projected volumes identified in the application, FMC anticipates that the 20-station RDC would be operating at a profit beginning in partial year 2011 and continuing through 2014.

FMC also selected a site for its Benton County facility located at 3920 Keene Road in Richland. Since FMC does not have an executed lease for the site, FMC provided four separate documents to demonstrate site control and ‘sufficient interest in the site’ as required in the application guidelines. A listing and description of the documents provided are below.

¹⁰ Whole numbers may not add due to rounding.

Letter from Kennewick Irrigation District

[source: February 25, 2010, supplemental information, Attachment 3]

This document is a letter from the Real Estate Manager of Kennewick Irrigation District's Real Estate Division. It confirms that Kennewick Irrigation District is in exclusive and final negotiations with CV Development for a two-acre parcel located between Kennedy and Keene Roads in Richland. A map showing the location of the two-acre parcel is included. This document demonstrates that Kennewick Irrigation District currently owns the property.

Letter of Intent between Kennewick Irrigation District and CV Development

[source: Amendment Application, Exhibit 6]

This document is a letter from the managing member of CV Development to Kennewick Irrigation District. It confirms an intent to purchase a particular two-acre parcel in the Stoneridge Business & Commerce Park. A map showing the location of the parcel is included. The map is similar to the map provided from the Kennewick Irrigation District and the site is specifically identified. Also included is a printout from the Benton County Assessor Office website of the Stoneridge Business & Commerce Park site. The business park consists of 52.88 acres and its property parcel number is 121982000002001. The address is also verified at 3920 Keen Road in Richland. This document demonstrates that CV Development intends to purchase a specific parcel of land located in the Stoneridge Business & Commerce Park from Kennewick Irrigation District.

Letter of Intent to Lease between CV Development and QualiCenters Inland Northwest

[source: Amendment Application, Exhibit 5]

This letter of intent between CV Development and QualiCenters Inland Northwest identifies the new landlord of the site to be CV Development and the tenant to be QualiCenters Inland Northwest. The location of the site is identified by the parcel number shown in the Benton County Assessor Office website document. The primary term of the lease for the site is ten years, with three 5-year options for renewal. This intent to lease was executed on December 29, 2009, and addresses specific details that would be included in a lease agreement, such as space requirements, use of space, rental rate/psf, tenant improvements, and more. Exhibit A attached to the letter of intent is a map of the site and another printout from the Benton County Assessor Office website showing the parcel ID number. Both of these documents are similar to the documents discussed above. The annual lease costs are substantiated in the pro forma financial documents used to prepare the summary in Table 5. [source: Amendment Application, Attachment 6] The documents included with this Letter of Intent to Lease demonstrate QualiCenters Inland Northwest intends to lease the specific site from CV Development.

Letter from City of Richland regarding zoning classification of the site

[source: February 25, 2010, supplemental information, Attachment 4]

This document is a letter from the senior planner with the City of Richland confirming that the site, identified by Benton County Assessor parcel #1-2198-200-0002-001 is currently zoned Business Commerce and the Richland Municipal Code section 23.28.030 states medical, dental, and other clinics are considered permitted uses within the Business Commerce zoning district. This document confirms that the zoning of the site is consistent with the requirements deemed necessary by the City of Richland for a dialysis center.

Additionally, FMC provided a copy of its existing medical director agreement with Mid-Columbia Medical Associates for services provided at its existing dialysis center in Kennewick—Columbia Basin Dialysis Center. The medical director agreement was executed on February 3, 2007. FMC also

provided a draft “Amendment to the Medical Director Agreement” which incorporates RDC in Benton County. The initial contract and the draft amendment contract outline the roles and responsibilities of both FMC and the physicians associated with Mid-Columbia Medical Associates. The draft amendment outlines the compensation for medical director services. [source: February 25, 2010, supplemental information, Attachment 1]

DaVita provided comments on FMC’s application related to this sub-criterion. [source: May 17, 2010, public comments, pp1-6, plus attachments] The comments are summarized below.

- FMC’s developer cannot demonstrate site control.
- FMC cannot demonstrate site control.
- FMC’s site arrangements are incomplete and uncertain, therefore FMC cannot prepare a meaningful pro forma financial statement.

FMC provided rebuttal comments related to DaVita’s comments summarized above. This section of the evaluation addresses the comments above, by topic, and incorporates rebuttal statements made by FMC as appropriate. [source: June 16, 2010, FMC rebuttal comments]

Department’s Review

FMC’s Developer cannot demonstrate site control and FMC cannot demonstrate site control

DaVita states that FMC’s developer—CV Development—cannot demonstrate site control. In turn, if CV Development does not have site control, by default, QualiCenters cannot demonstrate site control. FMC disagrees with DaVita’s assertions and reiterates all of the documents it provided to demonstrate site control by its developer—CV Development and QualiCenters.

While an executed lease agreement or purchase/sales agreement is ideal to demonstrate control of a particular site, the program has allowed a variety of documents to demonstrate site control. The department agrees that both CV Development and QualiCenters must demonstrate site control. The documents provided by FMC above confirm site control by both. Additionally, FMC provided a document from the City of Richland to demonstrate that the zoning for the site is appropriate for the use intended by FMC. The department concludes FMC demonstrated appropriate site control.

FMC cannot prepare a meaningful pro forma financial statement

DaVita bases this statement on its position that FMC cannot demonstrate site control. FMC disagrees with DaVita and reiterates its costs identified in the lease documents and its pro forma documents. Since the documents provided by FMC above confirm site control, the department could conclude that FMC’s pro forma financial states were appropriately reliable, however, neither applicant considered the impact of the need criterion on their respective pro forma financial statements.

In the need section of this evaluation, the department concluded that need for an additional 20 dialysis stations in Benton County was not demonstrated. This conclusion was based on the need methodology under WAC 246-310-284(4) which resulted in a surplus of ten dialysis stations in the county. This conclusion was also based on the minimum operating standard outlined in WAC 246-310-284(5) which requires all CN approved stations in the planning area to be operating at 4.8 in-center patients per station before new stations can be added. Of the 42 stations located in the planning area, only 13 stations were operating at or above the 4.8 standard.

Given that need for additional dialysis stations in Benton County was not demonstrated, the department must also conclude that the number of patients projected to be served by both DaVita and FMC is likely overstated.

Based on the above information, the department’s conclusion regarding this sub-criterion follows.

DaVita-Chinook Dialysis Center

Based on the above information, the department concludes that DaVita’s projected revenues and expenses are likely overstated and this sub-criterion is not met.

FMC-Richland Dialysis Center

Based on the above information, the department concludes that FMC’s projected revenues and expenses are likely overstated and 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.

WAC 246-310 does not contain specific WAC 246-310-220(2) 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 an unreasonable impact on costs and charges would be for a project of this type and size. Therefore, using its experience and expertise the department compared the proposed project’s costs with those previously considered by the department.

DaVita, Inc.

The capital expenditure associated with the establishment of DaVita’s Benton County facility is \$1,789,908 of which 59% is related to leasehold improvements; 35% for both fixed and moveable equipment; and the remaining 6% is related to architect, engineering, and application fees. The capital cost breakdown is shown below. [source: Application, Appendix 7]

Item	Cost	% of Total
Leasehold Improvements	\$ 1,052,254	59%
Fixed & Moveable Equipment (includes tax)	\$ 628,781	35%
Architect & Engineering & CN Fees	\$ 108,873	6%
Total Estimated Capital Costs	\$ 1,789,908	100%

To further demonstrate compliance with this sub-criterion, DaVita provided the following statements:

“...Funding from previously allocated operations funds is the least costly approach. Debt financing for this project will not be required since there is sufficient cash on hand. Furthermore, the method of financing would have no impact on the amount charged for each unit of service.” [source: Application, p24]

The department recognizes that the majority of reimbursements for dialysis services is through Medicare ESRD entitlements. To further demonstrate compliance with this sub-criterion, DaVita also provided the sources of patient revenue shown in Table 6 on the following page. [source: Application, p10]

Table 6
DaVita's Chinook Dialysis Center
Sources and Percentages of Revenue

Source of Revenue	Percentage of Revenue
Medicare	78%
State (Medicaid)	9%
Insurance/HMO	13%
Total	100%

As shown above, the Medicare and State (Medicaid) entitlements are projected to equal 87% of the revenue at CDC. The department concludes that the majority of revenue (87%) is dependent upon entitlement sources that are not cost based reimbursement and are not expected to have an unreasonable impact on charges for services. The remaining 13% will be derived through other or private insurance reimbursements. Further, the cost per dialysis for the proposed project was compared to those of recent kidney dialysis proposals, the average cost per dialysis is reasonable.

Fresenius Medical Care

The capital expenditure associated with the establishment of FMC's Benton County facility is \$1,483,114 of which 59% is related to leasehold improvements; 33% for both fixed and moveable equipment; and the remaining 8% is related to architect, engineering, and application fees. The capital cost breakdown is shown below. [source: Application, p30]

Item	Cost	% of Total
Leasehold Improvements	\$ 873,394	59%
Fixed & Moveable Equipment (includes tax)	\$ 496,055	33%
Architect & Engineering & CN Fees	\$ 113,665	8%
Total Estimated Capital Costs	\$ 1,483,114	100%

To further demonstrate compliance with this sub-criterion, FMC provided the following statements:

"...this project has no impact on either charges or payment, as reimbursement for kidney dialysis services is based on a prospective composite per diem rate." [source: Application, p31]

The department recognizes that the majority of reimbursements for dialysis services is through Medicare ESRD entitlements. To further demonstrate compliance with this sub-criterion, FMC also provided the sources of patient revenue shown in Table 7 below. [source: Amendment Application, p12]

Table 7
FMC's Richland Dialysis Center
Sources and Percentages of Revenue

Source of Revenue	Percentage of Revenue
Medicare	78%
State (Medicaid)	8%
Insurance/HMO	14%
Total	100%

As shown in Table 7, the Medicare and State (Medicaid) entitlements are projected to equal 86% of the revenue at RDC. The department concludes that the majority of revenue (86%) is dependent upon entitlement sources that are not cost based reimbursement and are not expected to have an unreasonable impact on charges for services. The remaining 8% will be derived through other or private insurance reimbursements. Further, the cost per dialysis for the proposed project was compared to those of recent kidney dialysis proposals, the average cost per dialysis is reasonable.

DaVita provided comments on FMC's application related to this sub-criterion. DaVita asserts that since neither FMC nor its developer could demonstrate site control, FMC's capital costs were most likely understated. [source: DaVita public comments, pp4-5] In response, FMC asserted that it did demonstrate site control and all costs for establishment of the 20-station dialysis center have been disclosed. [source: FMC rebuttal documents, pp1-2]

Department's Review

The site control issue was addressed under subsection (1) of this criterion, and the department concluded that both FMC and its developer demonstrated appropriate site control. Based on that rationale, the department would also conclude that FMC's estimated capital expenditure is reasonable.

However, for both DaVita's and FMC's projects, the need section of this evaluation concluded that both applicants failed to demonstrate that the planning area has a need for another 20 dialysis stations.

Based on the above information, the department's conclusion regarding this sub-criterion follows.

DaVita-Chinook Dialysis Center

Based on the information provided, the department concludes that the costs of this project may result in an unreasonable impact on the costs and charges for health services in the Benton County planning area. This sub-criterion is not met.

FMC-Richland Dialysis Center

Based on the information provided, the department concludes that the costs of this project may result in an unreasonable impact on the costs and charges for health services in the Benton County planning area. This sub-criterion is not 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.

DaVita, Inc.

As previously stated, the capital expenditure associated with the establishment of CDC in Richland is \$1,789,908. DaVita states that the project will be funded from DaVita's capital expenditure budget. This statement is supported with a letter confirming the commitment of corporate funding. A review of DaVita's consolidated financial statements shows the funds necessary to finance the project are available. [source: Application, p24 and Appendices 6 & 10]

Fresenius Medical Care

As previously stated, the capital expenditure associated with the establishment of RDC in Richland is \$1,483,114. FMC states that the project will be funded from its own reserves. This statement is supported with a letter confirming the commitment of corporate funding. A review of FMC's financial statements shows the funds necessary to finance the project are available. [source: Amendment Application, Appendix 3 and February 25, 2010, supplemental information, Attachment 5]

Based on the above information, the department's conclusion regarding this sub-criterion follows.

DaVita-Chinook Dialysis Center

Based on the information provided, the department concludes that approval of this project would not adversely affect the financial stability of DaVita as a whole. This sub-criterion is met.

FMC-Richland Dialysis Center

Based on the information provided, the department concludes that approval of this project would not adversely affect the financial stability of FMC as a whole. This sub-criterion is met.

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

Based on the source information reviewed, the department concludes:

- DaVita, Inc.'s project has not met the structure and process of care criteria in WAC 246-310-230; and
- Fresenius Medical Care's project has not met the structure and process 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 that should be employed for projects of this type or size. Therefore, using its experience and expertise the department concludes that the planning would allow for the required coverage.

DaVita, Inc.

To staff its proposed 20-station facility, DaVita intends to recruit a total of 5.20 FTEs in full year one and increase the FTEs to 14.80 by the end of full calendar year three (2013). A breakdown of the proposed FTEs is shown in Table 8 on the following page. [source: Application p25 and Appendix 3]

Table 8
DaVita-Chinook Dialysis Center 2011 – 2013 Projected FTEs

Staff/FTEs	2011 Full CY 1	2012 Increase	2013 Increase	Total FTEs
Medical Director	Professional Services Contract			
Administrator	0.60	0.40	0.00	1.00
RN	1.30	1.60	0.90	3.80
Patient Care Techs	2.10	3.10	2.30	7.50
Biomedical Techs	0.50	0.00	0.00	0.50
Re-Use Techs	0.30	0.10	0.20	0.60
Administrative Assistant	0.00	0.50	0.10	0.60
MSW	0.20	0.10	0.10	0.40
Dietitian	0.20	0.10	0.10	0.40
Total FTE's	5.20	5.90	3.70	14.80

As shown in Table 8 above, after the initial recruitment of FTEs, DaVita expects a continued increase in FTEs for the 20-station facility through year three. DaVita states it expects no difficulty in recruiting staff for CDC because of its competitive wage and benefit package offered to employees. Further, DaVita posts staff openings nationally both internal and external to DaVita. In addition, DaVita states that several employees have already expressed interest in working at its proposed Benton County facility. [source: Application, p26] Based on this information, the department concludes adequate staffing for CDC is available or can be recruited.

Fresenius Medical Care

To staff its proposed 20-station facility, FMC intends to recruit 9.75 FTEs in partial year 2011, which would increase to a total of 19.85 FTEs by the end of full calendar year three (2014). A breakdown of FMC's FTEs is shown in Table 9 below. [source: Amendment Application, p33]

Table 9
FMC-Richland Dialysis Center 2011 – 2014 Projected FTEs

Staff/FTEs	2011 Partial Year 1	2012 Increase	2013 Increase	2014 Increase	Total FTEs
Medical Director	Professional Services Contract				
Nurse Manager	1.00	0.00	0.00	0.00	1.00
RN	2.25	1.05	1.20	1.00	5.50
Patient Care Techs	4.80	2.20	1.50	1.85	10.35
Biomedical Techs	0.50	0.00	0.00	0.00	0.50
Administrative Assistant	0.50	0.50	0.00	0.00	1.00
MSW	0.35	0.15	0.15	0.10	0.75
Dietitian	0.35	0.15	0.15	0.10	0.75
Total FTE's	9.75	4.05	3.00	3.05	19.85

As shown in Table 9 above, after the initial recruitment of FTEs, FMC expects a steady increase in FTEs for the 20-station facility through year 2014. FMC states it expects no difficulty in recruiting staff for RDC because of the increased population growth in Benton County and surrounding areas. FMC states that several months before opening RDC, it would begin staff recruitment. Staff training

would be conducted at its existing dialysis center in Kennewick—Central Basin Dialysis Center. Further, since RDC would be located close to FMC’s Regional Support office in Portland, Oregon, RDC would be efficient through sharing of administrative and support staff. The Regional Support office would also provide a constant staff resource if RDC has any unexpected problems with staffing. In addition, FMC states it offers a competitive wage and benefit package to employees. [source: Amendment Application, p34] Based on this information, the department concludes adequate staffing for RDC is available or can be recruited.

Neither applicant provided comments on this sub-criterion. Based on the above information, the department’s conclusion regarding this sub-criterion follows.

DaVita-Chinook Dialysis Center

Based on the information reviewed, the department concludes adequate staffing for the 20-station facility is available or can be recruited. This sub criterion is met.

FMC-Richland Dialysis Center

Based on the information reviewed, the department concludes adequate staffing for the 20-station facility is available or can be recruited. 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.*

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.

DaVita, Inc.

Documentation provided in the application confirms that DaVita maintains, or will maintain, appropriate relationships with ancillary and support services for its 23 operating and/or CN approved dialysis centers. For its proposed Benton County facility, 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: Application, p26]

DaVita acknowledges that since this would be a new facility in Benton County, transfer agreements would have to be established. To further demonstrate compliance with this sub-criterion, DaVita provided a copy of its transfer agreement with Kadlec Medical Center executed on July 8, 2009. [source: Application, p26 and Appendix 12]

Fresenius Medical Care

Documentation provided in the application confirms that FMC maintains appropriate relationships with ancillary and support services for its 20 operating and/or CN approved dialysis centers. For its proposed Benton County facility, ancillary and support services, such as social services and nutrition services would be provided on site. Additional ancillary services such as pharmacy, laboratory, and

radiology, would be coordinated through FMC's existing dialysis center located in Kennewick—Columbia Basin Dialysis Center. [source: Amendment Application, p35]

While FMC acknowledges this would be a new facility in Benton County, the new facility would be operated similar to its Columbia Basin Dialysis Center. FMC provided a copy of its existing patient transfer agreement with Kadlec Medical Center and stated that RDC would be incorporated within the agreement. [source: Amendment Application, Exhibit 10]

Neither applicant provided comments on this sub-criterion. Based on the above information, the department's conclusion regarding this sub-criterion follows.

DaVita-Chinook Dialysis Center

Based on this information, the department concludes DaVita currently has appropriate relationships with ancillary and support services. This sub-criterion is met.

FMC-Richland Dialysis Center

Based on this information, the department concludes FMC currently has appropriate relationships with ancillary and support services, and would continue to have appropriate relationships if this project is approved. 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.

DaVita, Inc.

As stated earlier, DaVita, Inc. is a provider of dialysis services in over 1,400 outpatient centers located in 43 states (including Washington State) and the District of Columbia. [source: DaVita website at www.davita.com] Currently within Washington State, DaVita owns and operates 23 kidney dialysis treatment centers in 11 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.¹¹ To accomplish this task, in March 2008 the department requested quality of care compliance history from the state licensing and/or surveying entities responsible for the each of the states and the District of Columbia where DaVita, Inc. or any subsidiaries have health care facilities. Of the 44 entities, the department received responses from 24 states or 63% of the 43 states.¹² The compliance history of the remaining 19 states and the District of Columbia is unknown.¹³

¹¹ WAC 246-310-230(5).

¹² States that provided responses are: Arizona, California, Colorado, Delaware, Florida, Idaho, Iowa, Kansas, Kentucky, Maryland, Michigan, Minnesota, Mississippi, Missouri, Nebraska, Nevada, New Hampshire, North Dakota, Oklahoma, Oregon, Pennsylvania, Texas, Utah, Virginia, Washington, and Wisconsin. San Juan Puerto Rico also provided a response.

¹³ States that did not provide responses are: Alabama, Arkansas, Connecticut, Georgia, Illinois, Indiana, Louisiana, Maine, New Mexico, New Jersey, New York, North Carolina, Ohio, South Carolina, South Dakota, Tennessee, and West Virginia. The District of Columbia also did not respond to the survey.

Ten of the 24 states responding to the survey indicated that minor 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, none of the deficiencies were reported to have resulted in fines or enforcement action. All other facilities were reported to have no deficiencies and are currently in compliance with applicable regulations. 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.

The department concludes that considering the more than 1,400 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.

For Washington State, since January 2008, the Department of Health's Investigations and Inspections Office has completed more than 30 compliance surveys for the operational facilities that DaVita either owns or manages.¹⁴ 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 Investigations and Inspections Office]

For medical director services, DaVita provided a copy of its executed contract with Wassim Khawandi, MD. The term of the contract is ten years, with annual automatic renewals. It outlines the roles and responsibilities of both Dr. Khawandi and DaVita, and identifies compensation for medical director services. A review of the compliance history for Dr. Khawandi revealed no recorded sanctions. [source: Application, Appendix 3]

Fresenius Medical Care

As stated earlier, FMC operates over 1,700 outpatient centers in 45 states (including Washington State), the District of Columbia, and San Juan Puerto Rico. Currently, within Washington State, FMC owns and operates 20 dialysis centers in 14 separate counties. As part of its review, the department must conclude that the proposed services by FMC would be provided in a manner that ensures safe and adequate care to the public.¹⁵ To accomplish this task, in February 2010, the department requested quality of care compliance history from the state licensing and/or surveying entities responsible for conducting surveys where FMC or any of its subsidiaries have healthcare facilities. Of the 45 states, the department received responses from 21 states or 47% of the 45 states and from San Juan Puerto Rico. The compliance history of the remaining states that did not provide survey responses and the District of Columbia is unknown.¹⁶

Six of the 21 states responding to the survey indicated that non-compliance deficiencies were cited at FMC facilities in the past three years, but none of the deficiencies were reported to have resulted in fines or enforcement action. In all instances, FMC submitted and implemented acceptable plans of correction. Given the results of the out-of-state compliance history of FMC, the department concludes

¹⁴ As of the writing of this evaluation, four of DaVita's facilities are not yet operational. Those facilities are Everett Dialysis Center, Kennewick Dialysis Center, Parkland Dialysis Center, and Whidbey Dialysis Center. Olympic View Dialysis Center is operational, but is owned by Group Health and managed by DaVita.

¹⁵ WAC 246-310-230(5)

¹⁶ States that did not provide responses are: Alaska, Alabama, Arkansas, Arizona, Florida, Georgia, Indiana, Louisiana, Massachusetts, Maryland, Michigan, Minnesota, Mississippi, North Carolina, North Dakota, New Jersey, New York, Oklahoma, Pennsylvanian, Rhode Island, North Carolina, South Dakota, Texas and Utah.

that considering that it own or operates more than 1,700 facilities, the number of out-of-state non-compliance surveys is acceptable.

For Washington State, since January 2008, The Department of Health's Investigations and Inspections Office has completed more than 30 compliance surveys for the operational facilities that FMC, or one of its subsidiaries, either owns or manages. Of the more than 30 surveys, one survey revealed potentially hazardous condition that was promptly corrected and nine surveys revealed no deficiencies. The remaining surveys revealed minor non-compliance issues and the facilities submitted plans of corrections for the non-compliance issues within the allowable response time. [source: facility survey data provided by the Investigations and Inspections Office]

For medical director services, FMC provided a copy of its existing medical director agreement with Mid-Columbia Medical Associates for services provided at Columbia Basin Dialysis Center located in Kennewick. The medical director agreement was executed on February 3, 2007. FMC also provided a draft "Amendment to the Medical Director Agreement" which incorporates RDC in Benton County. The initial contract and the draft amendment contract outline the roles and responsibilities of both FMC and the physicians associated with Mid-Columbia Medical Associates. The draft amendment outlines the compensation for medical director services. A review of the compliance history for all three physicians associated with Mid-Columbia Medical Associates revealed no recorded sanctions. [source: February 25, 2010, supplemental information, Attachment 1]

Neither applicant provided comments on this sub-criterion. Based on the above information, the department's conclusion regarding this sub-criterion follows.

DaVita-Chinook Dialysis Center

Given the compliance history of DaVita and that of the proposed medical director, the department concludes that there is reasonable assurance that the Benton County facility would operate in compliance with state and federal regulations. This sub-criterion is met.

FMC-Richland Dialysis Center

Given the compliance history of FMC and its subsidiaries, there is reasonable assurance that the Benton County facility would operate in compliance with state and federal regulations. The draft amendment to the Medical Director Agreement provided in the application also confirms this conclusion. If this project is approved, the department would include a term requiring FMC to provide a copy of the executed Amendment to the Medical Director Agreement. The costs and terms identified in the executed agreement must be consistent with the costs and terms identified in the draft agreement. If FMC agrees to this term, 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.*

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.

DaVita, Inc.

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, and monitors and evaluates all activities related to clinical outcomes, operations management, and process flow. Further, continuing education for both employees and patients are integral factors in the quality of care program. DaVita also provided examples of its quality index data and its physician, community, and patient services education offered through its quality of care program. [source: Application, p26, Appendices 17 & 18]

The department also considered DaVita's history of providing care to residents in Washington State. The department concludes that the applicant has been providing dialysis services to the residents of Washington State for several years and has been appropriately participating in relationships with community facilities to provide a variety of medical services. Nothing in the materials reviewed by staff suggests that approval of this project would change these relationships. [source: CN historical files]

Additionally, the department considers the results of the kidney disease treatment center numeric methodology and standards outlined in WAC 246-310-284. Application of the numeric methodology shows a surplus of 10 dialysis stations in Benton County. This project proposes to establish a 20-station facility in Richland, when 29 of the 42 stations in the county are not operating at or above the 4.8 patients per station standard outlined in WAC 246-310-284(5). Within the application, DaVita demonstrated it did not meet the standards to receive approval to establish a 20-station dialysis center in Richland.

Fresenius Medical Care

In response to this criterion, FMC identified the providers that it has already established long term relationships within Benton County and surrounding areas. Further, FMC provided an example of a transfer agreement with one of the local hospitals in the county. FMC intends to establish a transfer agreement with all three hospitals to ensure continuity and appropriate care of all dialysis patients. [source: Amendment Application, pp35-36, Exhibit 10; February 25, 2010, supplemental information, pp3-4]

The department also considered FMC's history of providing care to residents in Washington State. The department concludes that the applicant has been providing dialysis services to the residents of Washington State for several years and has been appropriately participating in relationships with community facilities to provide a variety of medical services. Nothing in the materials reviewed by staff suggests that approval of this project would change these relationships. [source: CN historical files]

Additionally, the department considers the results of the kidney disease treatment center numeric methodology and standards outlined in WAC 246-310-284. Application of the numeric methodology shows a surplus of 10 dialysis stations in Benton County. This project proposes to establish a 20-station facility in Richland, when 29 of the 42 stations in the county are not operating at or above the 4.8 patients per station standard outlined in WAC 246-310-284(5). Within the application, FMC demonstrated it did not meet the standards to receive approval to establish a 20-station dialysis center in Richland.

Neither applicant provided comments on this sub-criterion. Based on the above information, the department's conclusion regarding this sub-criterion follows.

DaVita-Chinook Dialysis Center

DaVita demonstrated it has, and will continue to have, appropriate relationships to the service area's existing health care system within the county. However, based on the results of the need criteria, approval of this project would not promote continuity in the provision of health care for the planning area and may result in an unwarranted fragmentation of services. This sub-criterion is not met.

FMC-Richland Dialysis Center

FMC demonstrated it has, and will continue to have, appropriate relationships to the service area's existing health care system within the county. However, based on the results of the need criteria, approval of this project would not promote continuity in the provision of health care for the planning area, and may result in an unwarranted fragmentation of services. This sub-criterion is not 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.

DaVita-Chinook Dialysis Center

This sub-criterion is addressed in sub-section (3) above and is considered met.

FMC-Richland Dialysis Center

This sub-criterion is addressed in sub-section (3) above and is considered met.

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

Based on the source information reviewed, the department concludes:

- DaVita, Inc.'s project has not met the cost containment criteria in WAC 246-310-240(1) and (2); and
- Fresenius Medical Care's project has not met the cost containment criteria in WAC 246-310-240(1) and (2).

- (1) Superior alternatives, 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 through 230 criteria, the department would move to step two 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 (tie-breaker) 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-Chinook Dialysis Center

DaVita's project did not meet the review criteria under WAC 246-310-210, 220, and 230. Therefore, the department must conclude that DaVita's project is not the best available alternative.

FMC-Richland Dialysis Center

FMC's project did not meet the review criteria under WAC 246-310-210, 220, and 230. Therefore, the department must conclude that FMC's project is not the best available alternative.

Both applicants provided extensive comments related to the tie-breaker criteria identified in WAC 246-310-288 and addressed in step three of this sub-criterion. Since both DaVita and FMC failed under step one above, steps two and three are not addressed in this evaluation. Based on the above information, the department's conclusion regarding this sub-criterion follows.

DaVita-Chinook Dialysis Center

Based on the results of step one above, DaVita's project does not meet this sub-criterion.

FMC-Richland Dialysis Center

Based on the results of step one above, FMC's project does not meet this sub-criterion.

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

(a) The costs, scope, and methods of construction and energy conservation are reasonable;

DaVita-Chinook Dialysis Center

As stated in the project description portion of this evaluation, this project involves construction. 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 not met.

FMC-Richland Dialysis Center

As stated in the project description portion of this evaluation, this project involves construction. 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 not 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.

DaVita-Chinook Dialysis Center

This sub-criterion is also evaluated within the financial feasibility criterion under WAC 246-310-220(2). Based on that evaluation, the department concludes that this sub-criterion is not met is met.

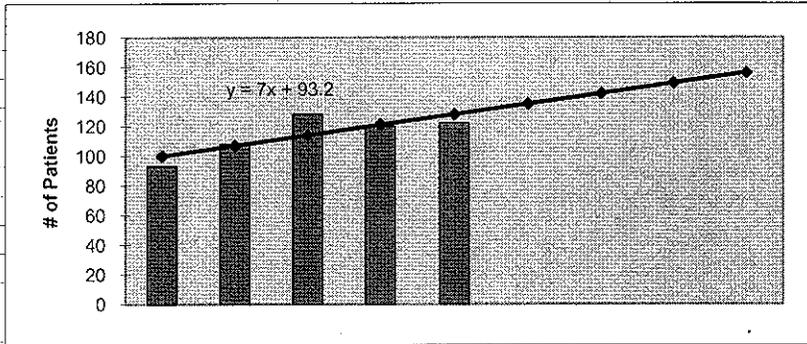
FMC-Richland Dialysis Center

This sub-criterion is also evaluated within the financial feasibility criterion under WAC 246-310-220(2). Based on that evaluation, the department concludes that this sub-criterion is not met.

Benton County							
ESRD Need Projection Methodology							
Planning Area		6 Year Utilization Data - Resident Incenter Patients					
Benton		2003	2004	2005	2006	2007	2008
Benton County		73	93	108	128	120	122
TOTALS		73	93	108	128	120	122
246-310-284(4)(a)	Rate of Change		27.40%	16.13%	18.52%	-6.25%	1.67%
	6% Growth or Greater?		TRUE	TRUE	TRUE	FALSE	FALSE
	Regression Method:	Linear					
246-310-284(4)(c)				Year 1	Year 2	Year 3	Year 4
				2009	2010	2011	2012
Projected Resident Incenter Patients	from 246-310-284(4)(b)			135.20	142.20	149.20	156.20
Station Need for Patients	Divide Resident Incenter Patients by 4.8			28.1667	29.6250	31.0833	32.5417
	Rounded to next whole number			29	30	32	33
246-310-284(4)(d)	subtract (4)(c) from approved stations						
Existing CN Approved Stations				42	42	42	42
Results of (4)(c) above				29	30	32	33
Net Station Need				13	12	10	9
Negative number indicates need for stations							
246-310-284(5)							
Name of Center	# of Stations	Patients	Utilization (Patients per Station)				
FMC Columbia Basin	13	75	5.77				
DaVita Kennewick	10	0	0.00				
DaVita Chinook	19	0	0.00				
Total	42	75					
Source: Northwest Renal Network data 2003-2008							
Most recent year-end data: 2008 year-end data as of 01/26/2009							
Most recent quarterly data as of the 1st day of application submission period: 4th quarter 2008 as of 01/26/2009							

Benton County
ESRD Need Projection Methodology

x	y	Linear
2004	93	100
2005	108	107
2006	128	114
2007	120	121
2008	122	128
2009		135.200
2010		142.200
2011		149.200
2012		156.200



SUMMARY OUTPUT

Regression Statistics	
Multiple R	0.796277572
R Square	0.634057971
Adjusted R Square	0.512077295
Standard Error	9.709102259
Observations	5

ANOVA

	df	SS	MS	F	Significance F
Regression	1	490	490	5.198019802	0.106943476
Residual	3	282.8	94.26666667		
Total	4	772.8			

	Coefficients	Standard Error	t Stat	P-value	Lower 95%	Upper 95%	Lower 95.0%	Upper 95.0%
Intercept	-13927.8	6158.998691	-2.26137408	0.108787784	-33528.48263	5672.882627	-33528.48263	5672.882627
X Variable 1	7	3.070287717	2.279916622	0.106943476	-2.771025801	16.7710258	-2.771025801	16.7710258

RESIDUAL OUTPUT

Observation	Predicted Y	Residuals
1	100.2	-7.2
2	107.2	0.8
3	114.2	13.8
4	121.2	-1.2
5	128.2	-6.2