



STATE OF WASHINGTON
DEPARTMENT OF HEALTH

October 31, 2011

CERTIFIED MAIL # 7009 2250 0001 8668 5982

Jason Bosh
DaVita, Inc., North Star, Region 1
1301 A Street, #400
Tacoma, Washington 98402

Re: CN11-25

Dear Mr. Bosh:

We have completed review of the Certificate of Need application submitted on behalf of DaVita, Inc. proposing to establish a 24 station dialysis center in Battle Ground within Clark County. For the reasons stated in this evaluation, the application submitted by DaVita is consistent with applicable criteria of the Certificate of Need Program, provided DaVita agrees to the following in its entirety.

Project Description:

Establish a 24-station facility providing hemodialysis, peritoneal dialysis, shifts after 5:00 p.m., and training/support for dialysis patients. At project completion, Battle Ground Dialysis Center would be approved to certify and operate a total of 24 dialysis stations. The stations are listed below.

Private Isolation Room	1
Permanent Bed Station	1
Other In-Center Stations	22
Total	24

Condition:

1. DaVita agrees with the project description above.
2. DaVita will provide the Department with an executed copy of a Patient Transfer Agreement for Department review and approval prior to commencement of services consistent with the draft agreement provided within the application.

Approved Costs:

The approved capital expenditure associated with this project is \$2,197,699.



Jason Bosh
DaVita, Inc.,
October 31, 2011
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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:

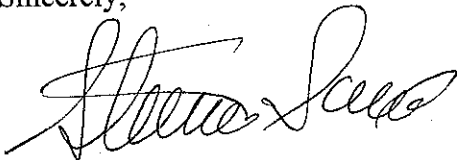
Department of Health
Certificate of Need Program
Mail Stop 47852
Olympia, WA 98504-7852

Other Than By Mail:

Department of Health
Certificate of Need Program
310 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.

Sincerely,



Steven M. Saxe, FACHE
Director, Health Professions and Facilities

Enclosure

EXECUTIVE SUMMARY

EVALUATIONS OF THE FOLLOWING CERTIFICATE OF NEED APPLICATIONS PROPOSING TO ADD DIALYSIS CAPACITY TO CLARK COUNTY:

- **FRESENIUS MEDICAL CENTER PROPOSING TO ESTABLISH A TWENTY-FOUR STATION DIALYSIS CENTER IN CLARK COUNTY**
- **DAVITA, INC. PROPOSING TO ESTABLISH A TWENTY-FOUR STATION DIALYSIS CENTER IN BATTLE GROUND**

BRIEF PROJECT DESCRIPTIONS

Pacific Northwest Renal Services

Fresenius Medical Care Holdings, Inc. is the parent corporation of Pacific Northwest Renal Services. PNRS proposes to establish a 24-station dialysis facility to be located on a parcel in Battle Ground, Washington. The new dialysis center would be known as PNRS Clark County Dialysis Center and would serve the residents of Clark County.

The capital expenditure associated with the establishment of the 24-station facility is \$2,953,931¹. If this project is approved, PNRS anticipates all 24 stations would become operational in October, 2012. Under this timeline, 2013 would be the facility's first full calendar year of operation. [PNRS Application, p9 & 10; April 29, 2011 Supplemental Information, p8]

DaVita, Inc.

DaVita is a private, not-for-profit corporation, incorporated in the State of Washington that provides dialysis services through its facilities. DaVita proposes to establish a 24-station facility to be located at 720 West Main in Battle Ground. The new dialysis center would be known as the Battle Ground Dialysis Center (Battle Ground) and would serve the residents of Clark County. [DaVita Application, p8]

The capital expenditure associated with the establishment of the 24-station facility is \$2,197,699. If this project is approved, DaVita anticipates all 24 stations would become operational mid to late 2012. Under this timeline, 2013 would be the facility's first full calendar year of operation. [DaVita Application, p12; Supplemental Information, Table 1A]

APPLICABILITY OF CERTIFICATE OF NEED LAW

Both of the 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).

¹ Table 5 of the screening responses details the estimated capital costs but totals a slightly lower total due to a calculation error. The correct total is cited here.

CONCLUSIONS

Pacific Northwest Renal Services

For the reasons stated in this evaluation, the application submitted on behalf of PNRS proposing additional dialysis capacity within Clark County is not sufficient to pass the applicable criteria of the Certificate of Need Program.

DaVita, Inc.

For the reasons stated in this evaluation, the application submitted by DaVita, Inc. proposing to establish a 24-station dialysis center in Battle Ground within Clark County is consistent with applicable criteria of the Certificate of Need Program, provided DaVita agrees to the following in its entirety:

Project Description:

Establish a 24-station facility providing hemodialysis, peritoneal dialysis, shifts after 5:00 p.m., and training/support for dialysis patients. At project completion, Battle Ground Dialysis Center would be approved to certify and operate a total of 24 dialysis stations. The stations are listed below.

Private Isolation Room	1
Permanent Bed Station	1
Other In-Center Stations	22
Total	24

Condition:

1. DaVita agrees with the project description above.
2. DaVita will provide the Department with an executed copy of a Patient Transfer Agreement for Department review and approval prior to commencement of services consistent with the draft agreement provided within the application.

Approved Costs:

The approved capital expenditure associated with this project is \$2,197,699.

**EVALUATIONS OF THE FOLLOWING CERTIFICATE OF NEED APPLICATIONS
PROPOSING TO ADD DIALYSIS CAPACITY TO CLARK COUNTY:**

- **FRESENIUS MEDICAL CENTER PROPOSING TO ESTABLISH A TWENTY-FOUR STATION DIALYSIS CENTER IN CLARK COUNTY**
- **DAVITA, INC. PROPOSING TO ESTABLISH A TWENTY-FOUR STATION DIALYSIS CENTER IN BATTLE GROUND**

APPLICANT DESCRIPTIONS

Pacific Northwest Renal Services

Pacific Northwest Renal Services (PNRS) is a joint venture between Oregon Health & Science University (OHSU) and Renal Care Group Northwest (RCG-NW). OHSU is a health and research university that works to combine patient care, research, and education to improve the delivery of health care services. RCG-NW is a legal entity of Fresenius Medical Care Holding, Inc (FMC), a for-profit organization and the parent corporation of the following five subsidiaries: [PNRC Application, p1; OHSU website]

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

In Washington State, FMC or one of its subsidiaries owns, operates, or manages 16 kidney dialysis facilities in twelve separate counties. Below is a listing of the 16 facilities in Washington, including the two Clark county facilities currently operated by PNRS.² [PNRC Application, p3; CN historical files]

Adams County Leah Layne Dialysis Center	Mason County Shelton Dialysis Facility
Gray Harbor County Aberdeen Dialysis Facility	Okanogan County Omak Dialysis Facility
Benton County Columbia Basin Dialysis Center	Spokane County Northpointe Dialysis Facility Spokane Kidney Center North Pines Dialysis Facility North Spokane Dialysis Center
Cowlitz County QualiCenters Longview	Stevens County Colville Dialysis Center
Clark County PNRS Fort Vancouver Dialysis Facility PNRS Salmon Creek Dialysis Facility	Thurston County Lacey Dialysis Facility
Lewis County Chehalis Facility	Walla Walla County QualiCenters Walla Walla

² One facility— North Spokane Dialysis Center—was recently approved by the department and is not yet operational.

DaVita, Inc.

DaVita, Inc. (DaVita) is a for-profit corporation that provides dialysis services in over 1,500 outpatient centers located in 43 states and the District of Columbia. DaVita also provides acute inpatient dialysis services in approximately 720 hospitals throughout the country.

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.³ [DaVita Applications, 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

PROJECT DESCRIPTIONS

Pacific Northwest Renal Services

This application proposes to establish a 24-station dialysis facility to be located on an identified parcel in Battle Ground, Washington. The new dialysis center would be known as PNRS Clark County Dialysis Center and would serve the residents of Clark County.

Services expected to be provided at the Clark County facility include hemodialysis, home and peritoneal dialysis, and training/support for dialysis patients. The 24-station facility would include a permanent bed station and an isolation station. [PNRS Application, p10 & 26]

The capital expenditure associated with the establishment of the 24-station facility is \$2,953,931⁴.

³ Three facilities—Whidbey Island Dialysis Center, Everett Dialysis Center, and Kennewick Dialysis Center—were recently approved by the department and are not yet operational.

Of that amount, 53% is related to construction; 22% for fixed/moveable equipment; and the remaining 25% is related to applicable fees, permits, and taxes. [April 29, 2011 Supplemental Information, p8]

If this project is approved, PNRS anticipates all 24 stations would become operational in October, 2012. Under this timeline, 2013 would be the facility's first full calendar year of operation. [PNRS Application, p9 & 10; April 29, 2011 Supplemental Information, p8]

DaVita, Inc.

DaVita proposes to establish a 24-station facility to be located at 720 West Main in Battle Ground. The new dialysis center would be known as the Battle Ground Dialysis Center (Battle Ground) and would serve the residents of Clark County. [DaVita Application, p8]

Services expected to be provided at Battle Ground include hemodialysis, home and peritoneal dialysis, and training/support for dialysis patients. Line drawings of the proposed facility detail the expected layout and identify a permanent bed station and an isolation station. [DaVita Application, p9 & Appendix 16]

The capital expenditure associated with the establishment of the 24-station facility is \$2,197,699. Of that amount 62% is related to building costs; 32% for fixed/moveable equipment; and the remaining 6% is related to professional fees. [DaVita Supplemental Information, Table 1A]

If this project is approved, DaVita anticipates all 24 stations would become operational mid to late 2012. Under this timeline, 2013 would be the facility's first full calendar year of operation. [DaVita Application, p12]

APPLICABILITY OF CERTIFICATE OF NEED LAW

These 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 the 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*

⁴ Table 5 of the screening responses details the estimated capital costs but totals a slightly lower total due to a calculation error. The correct total is cited here.

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

To obtain Certificate of Need approval, an 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, the applicant must demonstrate compliance with applicable kidney disease treatment center criteria outlined in WAC 246-310-280 through 284.⁵

APPLICATION CHRONOLOGY

As directed under WAC 246-310-282(1) the Department accepted this project under the year 2011 Kidney Disease Treatment Centers-Concurrent Review Cycle #1. Below is a chronologic summary of the project.

Action	PNRS	DaVita
Letter of Intent Submitted	January 31, 2011	January 31, 2011
Application Submitted	February 28, 2011	February 28, 2011
Department's pre-review Activities including screening and responses	March 1, 2011 through May 15, 2011	March 1, 2011 through May 15, 2011
Beginning of Review <ul style="list-style-type: none"> • public comments accepted throughout review • no public hearing conducted 	May 16, 2011	May 16, 2011
End of Public Comment	July 15, 2011	July 15, 2011

⁵ Each criterion contains certain sub-criteria. The following sub-criteria are not discussed in this evaluation because they are not relevant to this project: WAC 246-310-210(3), (4), (5), and (6); WAC 246-310-240(3), and WAC 246-310-287, 288, and 289.

Department's Anticipated Decision Date	September 30, 2011	September 30, 2011
Department's Updated Decision Date	October 31, 2011	October 31, 2011
Department's Actual Decision Date	October 31, 2011	October 31, 2011

CONCURRENT REVIEW AND AFFECTED PERSONS

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

“...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.”*

Under concurrent review, each applicant is an affected person for the other application. Throughout the review of this project, no other entities sought or received affected person status under WAC 246-310-010(2).

SOURCE INFORMATION REVIEWED

- Pacific Northwest Renal Services’ Certificate of Need application submitted February 28, 2011
- DaVita - Battle Ground Certificate of Need application submitted February 28, 2011
- Pacific Northwest Renal Services’ Supplemental Information submitted April 29, 2011
- DaVita - Battle Ground Supplemental Information submitted April 29, 2011
- Public comment was received during the review
- PNRS rebuttal comments submitted August 15, 2011
- DaVita rebuttal comments submitted August 12, 2011
- DaVita rebuttal supplemental submitted August 15, 2011
- Years 2004 through 2009 historical kidney dialysis data obtained from the Northwest Renal Network⁶
- Year 2010 Northwest Renal Network 3rd Quarter Data
- Licensing and survey data provided by the Department of Health’s Investigations and Inspections Office
- Certificate of Need historical files

PNRS LOCATION DISPUTE

PNRS’s application cover page states the proposed Clark County dialysis facility would be located in Vancouver. PNRS did not provide specific site information in its initial application. The information missing included:

- Site address
- Line drawings
- Any restricted uses of the property
- Documentation the site could be used for the proposed project and
- Site control documentation-i.e., lease or draft lease or purchase information

⁶ Modality reports for 2010 year-end and 4th quarter utilization did not become available until after the application submission period.

PNRS stated in its application that the above information would be “provided with our response to the request for supplemental information”. As a reminder, the department included references to the application sections PNRs stated they respond to with screening responses and asked them for that information. PNRs did provide the department with the information along with their other responses.

During the public comment portion of this review, DaVita argued PNRs had improperly amended its application by changing the proposed facility’s location from Vancouver to Battle Ground. Both of these locations are within Clark County. As part of its rebuttal, PNRs responded that its site information was not an un-timely amendment. PNRs referenced the department’s rules stating responses to screening questions, aren’t amendments.

Kidney dialysis projects are reviewed under a published concurrent review schedule. Both the applications were submitted on the last day of the application submission period, February 28, 2011. The department’s screening letters were sent to the applicants March 31, 2011. PNRs submitted their responses to the department April 29, 2011 or the last of the screening response time. Program rules⁷ outline the timeline for amending applications under a concurrent review. Amendments may be made through the first 45-days of the concurrent review process. That 45-day period is divided into two parts. During the first 30 days, an applicant or applicants may amend an application one or more times. When an amendment has been made to an application in the first 30 days, then all applicants may make one final amendment in the remaining 15-days of the 45-day period. If no amendment has been made to any application through the 30-day period, no amendments may be made during the last 15 day period⁸.

Using this timeline, one or more applicants would have had to amend their application by March 30, 2011 or 30 days after the start of the concurrent review process. Neither applicant clearly amended their respective application by the March 30, 2011 date.

What is at issue is whether PNRs amended its application when it submitted its site information with its responses to the department screening letter. If the department concludes the application was amended outside the strict timelines outlined in rule, the information would not be considered in the review of the PNRs application. However, if the department concludes the submitted information were responses to screening questions, then the review of both projects would continue concurrently.

To reach a conclusion on this matter, the department carefully reviewed its March 31, 2011 screening letter. Because the staff believed the project would be located in Vancouver, the questions in the March 31 letter did not specifically reference Vancouver when asking about site information. The department recognizes an argument can be made that the PNRs site information was in response to that letter and therefore not an untimely amendment. The department will include the site information in the review of the two kidney dialysis applications.

⁷ WAC 246-310-100(6)

⁸ *ibid*

CONCLUSIONS

Pacific Northwest Renal Services

For the reasons stated in this evaluation, the application submitted on behalf of PNRS proposing additional dialysis capacity within Clark County is not sufficient to pass the applicable criteria of the Certificate of Need Program.

DaVita, Inc.

For the reasons stated in this evaluation, the application submitted by DaVita, Inc. proposing to establish a 24-station dialysis center in Battle Ground within Clark County is consistent with applicable criteria of the Certificate of Need Program, provided DaVita agrees to the following in its entirety:

Project Description:

Establish a 24-station facility providing hemodialysis, peritoneal dialysis, shifts after 5:00 p.m., and training/support for dialysis patients. At project completion, Battle Ground Dialysis Center would be approved to certify and operate a total of 24 dialysis stations. The stations are listed below.

Private Isolation Room	1
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Other In-Center Stations	22
Total	24

Condition:

1. DaVita agrees with the project description above.
2. DaVita will provide the Department with an executed copy of a Patient Transfer Agreement for Department review and approval prior to commencement of services consistent with the draft agreement provided within the application.

Approved Costs:

The approved capital expenditure associated with this project is \$2,197,699.

A. Need (WAC 246-310-210)

Based on the source information reviewed, the department concludes:

- Pacific Northwest Renal Service's Clark County 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; and
- DaVita - Battle Ground 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; and 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 centers 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.⁹

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.¹⁰ 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,

⁹ 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]

¹⁰ 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 these projects, the base year is 2009.

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)]

Pacific Northwest Renal Services’ Application of the Numeric Methodology

PNRS proposes to establish a 24-station center in Battle Ground. Based on the calculation of the annual growth rate in the planning area as described above, PNRS used a linear regression to project need. Given that the Battle Ground facility would be located in Clark County Planning Area, the number of projected patients was divided by 4.8 to determine the number of stations needed in the planning area. [PNRS Application, p20]

DaVita, Inc.’s Application of the Numeric Methodology

DaVita also proposes a 24-station facility. Based on the calculation of the annual growth rate in the planning area as described above, DaVita used the same linear regression to determine planning are need. The number of projected patients was divided by 4.8 to determine the number of stations needed in the planning area. [DaVita Application, p19]

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 Clark County Planning Area. The Department also divided the projected number of patients by 4.8 to determine the number of stations needed as required under WAC 246-310-284(5).

Table 1 shows a summary of the projected net need provided by the applicants and the Department for the Clark County Planning Area.

**Table 1
Clark County Planning Area Numeric Methodology Summaries
of Projected Net Station Need**

	4.8 in-center patients per station		
	2013 Projected # of stations	Minus Current # of stations	2013 Net Need
PNRS	76	52	24
DaVita	76	52	24
DOH	76	52	24

When comparing the applicant’s and Department’s results shown in Table 1, it shows that the projections of the applicants match the Department’s figures. As a result, the net station need for Clark County Planning Area is twenty-four.

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 projects is February 1, 2011. [WAC 246-310-282] The quarterly modality report from NRN available at that time was September 30, 2010. For the Clark County planning area, there are 52 stations located in three separate facilities. Table 2 shows the utilization of the three existing dialysis centers.

Table 2
September 30, 2010 - Facility Utilization Data

Facility Name	# of Stations	# of Pts	Pts/Station
DaVita Vancouver	12	59	4.92
PNRS Ft. Vancouver	24	152	6.33
PNRS Salmon Creek	16	95	5.94

Table 2 above demonstrates that the current facilities satisfy this utilization requirement. **This sub-criterion 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. For Clark County Planning Area, the requirement is 4.8 in-center patients per approved station. [WAC 246-310-284(6)(a)] As a result, the applicants must demonstrate compliance with this criterion using the 4.8 in-center patient per station.

Pacific Northwest Renal Services

PNRS anticipates all 24 stations would become operational by the end of October 2012. Under this timeline, year 2013 would be the facility's first full calendar year of operation and 2015 would be year three. A summary of the applicant's projected utilization for the third year of operation is shown in Table 3 below. [PNRS Application, p21]

Table 3
PNRS - Third Year Projected Facility Utilization

Facility Name	Year 3	# of Stations	# of Pts	Pts/Station
PNRS-Battle Ground	2015	24	120	5.0

As shown in Table 3 above, PNRS's Clark County facility is expected to exceed this standard. Based on the above standards and criteria, the project is consistent with applicable criteria of the Certificate of Need Program. **This sub-criterion is met.**

DaVita, Inc.

DaVita anticipates all of the proposed stations would become operational by the end of 2012. Under this timeline, year 2013 would be each facility's first full calendar year of operation and 2015 would be year three. A summary of the applicant's projected utilization for the third year of operation is shown in Table 4 below. [DaVita Application, p17]

Table 4
DaVita - Third Year Projected Facility Utilization

Facility Name	Year 3	# of Stations	# of Pts	Pts/Station
DaVita-Battle Ground	2015	24	116	4.83

As shown above, the proposed DaVita project is expected to exceed this standard. Based on the above standards and criteria, the project is consistent with applicable criteria of the Certificate of Need Program. **This sub-criterion is met.**

(2) All residents of the service area, including low-income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly are likely to have adequate access to the proposed health service or services.

Pacific Northwest Renal Services

As previously stated, the applicant currently provides health care services to residents of Washington State. To determine whether all residents of the Clark County Planning Area 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.

To demonstrate compliance with this sub-criterion, PNRS provided a copy of its current Patient Admission Policy that is currently used within its Clark County facilities. The Patient Admission Policy outlines the process/criteria that the PNRS facility will use to admit patients for treatment, and ensures that patients will receive appropriate care at the dialysis center. The Patient 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, creed, or religion, color, age, sex, disability, national origin, and/or sexual orientation. [PNRS Application, Exhibit 5]

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.

PNRS currently provides services to Medicaid eligible patients at its existing dialysis centers. It expects to also provide services to these patients at the proposed new facility. A review of the anticipated revenue indicates that the new facility expects to receive Medicaid reimbursements. [PNRS Application, p31; April 29, 2011 Supplemental Information, Attachment 10]

PNRS currently provides services to Medicare eligible patients at its existing dialysis centers. It expects to also provide services to these patients at the proposed new facility. A review of the anticipated revenues indicates that the new facility also expects to receive Medicare reimbursements. [PNRS Application, p31; April 29, 2011 Supplemental Information, Attachment 10]

PNRS demonstrated its intent to provide charity care to Clark County Planning Area residents by submitting its current indigent waiver procedure that outlines the process one would use to access

services when they do not have the financial resources to pay for required treatments. PNRS also included a 'charity' line item as a deduction from revenue within the pro forma income statements documents. [PNRS Application, Exhibit 6; April 29, 2011 Supplemental Information, Attachment 10]

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

DaVita, Inc.

As previously stated, the applicant currently provides health care services to residents of Washington State. To determine whether all residents of the Clark County Planning Area 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.

To demonstrate compliance with this sub-criterion, DaVita provided a copy of its current policy for 'Accepting Patients for Treatment' that is currently used in its facilities. The policy outlines the process/criteria that the DaVita facilities will use to admit patients for treatment, and ensures that patients will receive appropriate care at the dialysis center. The policy also states that any patient with end stage renal disease needing chronic hemodialysis will be accepted for treatment at the facilities without regard to race, color, nation origin, sex, age, religion, or disability. [DaVita Application, Appendix 14]

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 currently provides services to Medicaid eligible patients at its existing dialysis centers. It expects to also provide services to these patients at the proposed new facility. A review of the anticipated revenue indicates that the new facility expects to receive Medicaid reimbursements. [DaVita Application, p24; Supplemental Information; Exhibit C]

DaVita currently provides services to Medicare eligible patients at its existing dialysis centers. It expects to also provide services to these patients at the proposed new facility. A review of the anticipated revenues indicates that the new facility also expects to receive Medicare reimbursements. [DaVita Application, p24; Supplemental Information; Exhibit C]

DaVita demonstrated its intent to provide charity care to Clark County residents by submitting the 'Indigent Care Policy' currently used within its facilities. It outlines the process one would use to access services when they do not have the financial resources to pay for required treatments. DaVita also included a 'charity' line item as a deduction from revenue within the pro forma income statements for each proposed facility. [DaVita Application, Appendix 14; Supplemental Information; Exhibit C]

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

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

Based on the source information reviewed, the department concludes:

- Pacific Northwest Renal Service’s Clark County project has met the financial feasibility criteria in WAC 246-310-220; and
- DaVita - Battle Ground 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.

Pacific Northwest Renal Service

PNRS anticipates the Clark County facility will become operational by October 2012. Based on this timeline, calendar year (CY) 2013 would be the facility’s first full year of operation. Using the financial information provided as part of the application, Table 5 illustrates the projected revenue, expenses, and net income for CY 2013 through 2015 for the Clark County facility. [PNRS April 29, 2011 Supplemental Information, Attachment 10]

**Table 5
PNRS-Clark County
Projected Revenue and Expenses Calendar Years 2013 - 2015¹¹**

	CY 1 - 2013	CY 2 - 2014	CY 3 - 2015
# of Stations	24	24	24
# of Treatments [1]	12,346	15,870	17,490
# of Patients [2]	86	110	120
Utilization Rate [2]	3.58	4.58	5.00
Net Revenue [1]	\$ 4,986,951	\$ 6,410,409	\$ 7,064,779
Total Expense [1,3]	\$ 3,576,285	\$ 4,461,073	\$ 4,885,762
Net Profit or (Loss) [1]	\$ 1,410,666	\$ 1,949,336	\$ 2,179,017

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

As shown in Table 5, at the projected volumes identified in the application, PNRS anticipates that the 24-station facility would be operating at a profit in each of the forecast years.

In response to screening, as detailed previously, PNRS selected a site for its new facility located on land plots identified by a tax parcel number in Battle Ground. The only address that has been referenced in property description records is 1109 SW 38th Circle in the city of Battle Ground. PNRS provided two separate documents to demonstrate site control and ‘sufficient interest in the

¹¹ Whole numbers may not add due to rounding.

site' as required in the application guidelines. A listing and description of the documents provided are below.

Letter of Intent between Camellia Subdivision, LLC and DDG Camellia One, LLC

[PNRS April 29, 2011 Supplemental Information, Attachment 2]

This document is a Real Estate Purchase and Sale agreement between Camellia Subdivision, LLC, as the seller, and DDG Camellia One, LLC, represented as the buyer. It confirms intent to purchase a particular set of parcels in Battle Ground. A map showing the location of the parcel is included along with signed amendments to establish DDG Camellia One, LLC as the Assignee Purchaser.

Lease Agreement between DDG Camellia One, LLC and PNRS

[PNRS April 29, 2011 Supplemental Information, Attachment 3 & 10]

This lease agreement between DDG Camellia One, LLC and PNRS identifies PNRS as the tenant for the rentable space to be built. The location of the site is identified by the parcel number shown in the Clark 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 April 29, 2011, 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, included in the lease agreement, is a map of the site and another printout from the Clark County Assessor Office website showing the parcel ID number.

Additionally, PNRS provided a copy of a Medical Director Agreement establishing a contract with Vancouver Clinic, Inc. The agreement identifies the member doctors, the terms, and compensation for the clinic to provide coverage within the dialysis facility. The medical director service costs appear to be accounted for in either the administration or overhead costs outlined in the pro forma documents. [PNRS April 29, 2011 Supplemental Information, Attachment 10]

Based on the above information, the Department concludes that PNRS's projected revenues and expenses are reasonable and can be substantiated. **This sub-criterion is met.**

DaVita

DaVita anticipates the Battle Ground facility will become operational by the end of calendar year (CY) 2012. Based on this timeline, CY2013 would be the facility's first full year of operation. Using the financial information provided as part of the application, Table 6 illustrates the projected revenue, expenses, and net income for CY 2013 through 2015 for the Battle Ground facility. [DaVita April 29 Supplemental Information, Exhibit C]

Table 6
DaVita-Battle Ground
Projected Revenue and Expenses Calendar Years 2013 - 2015¹²

	CY 1 - 2013	CY 2 - 2014	CY 3 - 2015
# of Stations	24	24	24
# of Treatments [1]	11,175	17,437	21,565
# of Patients [2]	75	116	144
Utilization Rate [2]	3.13	4.83	6.00
Net Revenue [1]	\$ 5,235,577	\$ 6,202,818	\$ 8,549,644
Total Expense [1,3]	\$ 2,883,183	\$ 4,193,855	\$ 5,409,718
Net Profit or (Loss) [1]	\$ 2,352,394	\$ 2,008,963	\$ 3,139,926

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

As shown above, at the projected volumes identified in the application, DaVita anticipates that the 24-station Battle Ground facility would be operating at a profit in each of the forecast years.

DaVita selected a site for its new facility located at 857 Roosevelt Avenue East in the city of Battle Ground. The executed letter of intent to lease provided in the application 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 6. [DaVita Application, pA12 & A19]

PNRS provided comments related to DaVita's lease. Specifically, PNRS contends that the lease submitted by DaVita is "unreliable for the purposes of financial projections". The comment expressed concerns regarding the reported 'out-clauses' that PNRS contends "are in addition to a typical contingency provisions" under which a typical lease may be terminated if a CN application were not approved. The contention is that DaVita has "no real intention of developing a facility in Battleground". (FMC/PNRS July 15, 2011 Comment, p3 & 9)

A review of the lease contents does identify terms that appear to be beneficial to a potential leasee. Concerns identified in comment relate to conditions that allow for a termination of the site lease brought about due to the termination of agreements that would affect the facility's operation. PNRS also identified terms that identify the costs that DaVita would be responsible for if they were to terminate the agreement. (Application, Exhibit 16, p33 & 35)

There is no process to allow the Department to critique many of the sections that are a result of negotiations for an applicant's facility lease. Sections regarding obligations of each party to the agreement that relate to periphery issues such as termination clauses, tenant improvements, sub-letting, and other components are a result of discussions between the parties involved and current market conditions. When the terms and conditions relevant to the application review are considered, it appears that the site is correctly cited, the term for the site is shown to extend for 10 years, and the rent is clearly identified and corresponds to the costs identified in the facility pro forma. In addition, the signature pages are complete and appear to hold each party to the negotiated terms of the lease and indicate a sincerity of intentions. As a result, PNRS's comments are outside the applicable review criteria and should not be used to fail the project.

¹² Whole numbers may not add due to rounding.

Additionally, DaVita provided a copy of a draft Medical Director Agreement expected to be used between itself and Majd Isreb, M.D. The medical director service costs are also substantiated in the pro forma documents. [DaVita Application, Appendix 3]

Based on the above information, the Department concludes that DaVita's projected revenues and expenses are reasonable and can be substantiated. **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 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.

Pacific Northwest Renal Service

The capital expenditure associated with the establishment of PNRS's proposed Clark County facility is \$2,953,931, of which 53% is related to leasehold improvements; 22% for both fixed and moveable equipment; and the remainder is related to fees, permits, and taxes. The capital cost breakdown is shown below. [PNRS April 29, 2011 Supplemental Information, p8]

**Table 7
Estimated Capitals Costs of Proposed PNRS Clark County**

Item	Cost	% of Total
Construction/Leasehold Improvements	\$ 1,562,966	53%
Fixed & Moveable Equipment	\$ 660,908	22%
Professional Fees	\$ 119,500	4%
Site, Permits, Interest	\$ 392,000	13%
Sales Tax & Other	\$ 218,557	7%
Total Estimated Capital Costs	\$ 2,953,931	100%

PNRS intends to finance the project entirely from available board reserves. A review of the financial statement provided in the application indicates that PNRS had sufficient cash assets and board approval to fund the project. [PNRS Application, p30 & Exhibit 7]

The Department recognizes that the majority of reimbursements for dialysis services are through Medicare ESRD entitlements. To further demonstrate compliance with this sub-criterion, PNRS also provided the sources of patient revenue shown in Table 8 below. [PNRS Application, p34]

**Table 8
PNRS-Clark County
Sources and Percentages of Revenue**

Source of Revenue	% of Revenue
Medicare	83.0%
Medicaid	4.2%
Commercial	11.5%
Other	1.3%
Total	100%

As shown above, the Medicare and State entitlements are projected to exceed 87% of the revenue at the facility. The Department concludes that since the majority of revenue is dependent upon entitlement sources that are not cost based reimbursement, they are not expected to have an unreasonable impact on charges for services. The remaining revenue will be derived through other or private insurance reimbursements.

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

DaVita

The capital expenditure associated with the establishment of DaVita's proposed Battle Ground facility is \$2,197,699, of which approximately 62% is related to leasehold improvements; 32% for both fixed and moveable equipment; and the remainder is related to applicable fees. The capital cost breakdown is shown below. [Battle Ground April 29, 2011 Supplemental Information, Table 1A]

**Table 9
Estimated Capitals Costs of Proposed DaVita – Brush Prairie**

Item	Cost	% of Total
Leasehold Improvements	\$ 1,355,002	62%
Fixed & Moveable Equipment	\$ 708,697	32%
Professional Fees	\$ 134,000	6%
Total Estimated Capital Costs	\$ 2,197,699	100%

DaVita intends to finance the project entirely from available board reserves. A review of the financial statement provided in the application indicates that DaVita had sufficient cash assets in both 2009 and 2010 to fund the project. [DaVita Application, Appendix 6]

The Department recognizes that the majority of reimbursements for dialysis services are through Medicare ESRD entitlements. To further demonstrate compliance with this sub-criterion, DaVita also provided the sources of patient revenue shown in Table 10 below. [DaVita Application, p24]

Table 10
DaVita – Battle Ground
Sources and Percentages of Revenue

Source of Revenue	% of Revenue
Medicare	59%
Medicaid / State	6%
Insurance / HMO	35%
Total	100%

As shown above, the Medicare and State entitlements are projected to equal 65% of the revenue at the facility. The Department concludes that since the majority of revenue is dependent upon entitlement sources that are not cost based reimbursement, they are not expected to have an unreasonable impact on charges for services. The remaining revenue will be derived through other or private insurance reimbursements.

Based on the information provided, the department concludes that the costs of this project would not result in an unreasonable impact to the costs and charges for health care services. **This sub-criterion 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.

Pacific Northwest Renal Service

As previously stated, the capital expenditure associated with the establishment of PNR's 24-station facility in Battle Ground is \$2,953,931. PNR states that the project will be funded from PNR's available board reserves. A review of PNR's statements of financial position show the funds necessary to finance the project are available. [PNR Application, p30 & Exhibit 7]

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

DaVita

As previously stated, the capital expenditure associated with the establishment of DaVita's 24-station facility in Battle Ground is \$2,197,699. DaVita states that the project will be funded from DaVita's available board reserves. A review of DaVita's statements of financial position show the funds necessary to finance the project are available. [DaVita Application, pA31]

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.**

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

Based on the source information reviewed, the department concludes that the DaVita - Battle Ground project has met the structure and process of care criteria in WAC 246-310-230; and

(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.

Pacific Northwest Renal Service

To staff its proposed 24-station facility, PNRS intends to have 17.25 FTEs in full year one and increase the FTEs to 22.75 by the end of full calendar year three (2015). A breakdown of the proposed FTEs is shown in Table 11 below. [PNRS Application, p32, April 29, 2011 Supplemental Information, p9]

**Table 11
PNRS 2012 – 2015 Projected Total FTEs**

Staff/FTEs	2012 Current	2013 Total	2014 Total	2015 Total
Medical Director	Professional Services Contract			
Nurse Mgr	1.00	1.00	1.00	1.00
RNs	2.50	3.75	4.00	4.25
Patient Care Tech	6.50	9.75	11.25	12.75
Equip Tech	0.50	0.50	0.75	0.75
Social Worker	0.50	0.75	0.85	1.00
Dietician	0.50	0.75	0.85	1.00
Secretary	0.50	0.75	1.00	1.00
Total FTE's	12.00	17.25	19.70	21.75

After the initial recruitment of 12 FTEs in 2013, PNRS plans for annual increases. PNRS states that it does not anticipate any difficulty in recruiting staff for the Battle Ground facility due to its location and past success in attracting qualified health personnel. Further, PNRS states that a high employee retention rate¹³ supports this assertion and that “PNRS is confident that we will be successful in putting into place a qualified core staff to provide and promote continuity of care at the new facility”. [PNRS Application, p33]

PNRS identified the Vancouver Clinic to provide medical director coverage for the proposed facility and provided a copy of the executed medical director’s agreement. The draft agreement outlines the roles and responsibilities of the clinic doctors and the PNRS facility. The agreement also identifies the annual compensation for the medical director services. [PNRS April 29, 2011 Supplemental Information, Attachment 4]

Based on the information reviewed, the Department concludes adequate staffing for the 24-station facility is available or can be recruited. **This sub-criterion is met.**

¹³ Fresenius Medical Care reports a current average employee retention rate of 85%

DaVita

To staff its proposed 24-station Battle Ground facility, DaVita intends to hire 7.60 FTEs in full year one (2013) and increase the FTEs steadily through full calendar year three (2015) and beyond. Breakdowns of the incremental increases are shown in Table 12 below. [Supplemental Information, Exhibit D]

Table 12
Battle Ground 2013 – 2015 Projected Incremental FTEs

Staff/FTEs	2013 Addition	2014 Addition	2015 Addition	2016 Addition	Total
Medical Director	Professional Services Contract				
Administrator	1.00	0.00	0.00	0.00	1.00
RNs	1.80	1.20	1.00	1.00	5.00
Patient Care Tech	2.60	3.60	2.80	2.00	11.00
Biomedical Tech	0.60	0.00	0.00	0.00	0.60
Admin Asst	0.80	0.40	0.80	1.20	3.20
Social Wk	0.40	0.30	0.40	0.30	1.40
Dietician	0.40	0.30	0.40	0.30	1.40
Total FTE's	7.60	5.80	5.40	4.80	23.60

After the initial recruitment in 2013, DaVita expects to add to the FTE totals in each of the following years. DaVita states that it does not anticipate any difficulty in recruiting staff for the Battle Ground facility due to its location and past success in attracting qualified health personnel. Further, DaVita states that this is aided by their wage and benefit package and that “DaVita has an extensive employee-traveling program guaranteeing all appropriate staff”. [DaVita Application, p25]

DaVita identified Majd Isreb, M.D. as the medical director for the proposed facility and provided a copy of the executed medical director's agreement. The agreement outlines the roles and responsibilities of Dr. Isreb and the DaVita facility. The agreement also identifies the annual compensation for the medical director. [DaVita Application, Appendix 3]

Based on the information reviewed, the Department concludes adequate staffing for the 24-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(2) criteria as identified in WAC 246-310-200(2)(a)(i). There are no 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.

Pacific Northwest Renal Service

Information provided in the application confirms that PNRS maintains the appropriate relationships with ancillary and support services for its two existing dialysis centers in Clark County. For this new Clark County facility, ancillary and support services, such as lab services, pharmaceutical,

radiology will continue through the existing relationships within the service area. Regular social services and dietary support will be available within the proposed facility. [PNRS Application, p34]

Since this would be a new facility in Clark County Planning Area, transfer agreements would need to be established. PNRS provided a copy of the transfer agreement currently maintained with Southwest Washington Medical Center as an example of the transfer agreements the existing PNRS facilities use. [PNRS Application, Exhibit 9]

Based on this information, the Department concludes PNRS 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 PNRS 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.**

DaVita

Information provided in the application confirms that DaVita currently maintains the appropriate relationships with ancillary and support services for its existing dialysis center in Clark County. For its proposed Battle Ground 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. [DaVita Application, p25]

DaVita acknowledges that since this would be a new facility in Clark County, transfer agreements would have to be established. To further demonstrate compliance with this sub-criterion, DaVita provided an example of a draft transfer agreement. [Brush Prairie Application, p25 & 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 no 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.

Pacific Northwest Renal Service

As stated earlier, PNRS is currently a provider of dialysis services within Washington State, and operates two kidney dialysis treatment centers in Clark County. 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.¹⁴

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 states¹⁵ and the 2 non-state entities surveyed, the department received 26 responses or 55% of those surveyed¹⁶.

Six of the 26 states responding to the survey indicated that non-compliance deficiencies were cited at FMC facilities in the past three years, but none was reported to have resulted in fines or enforcement action. FMC submitted and implemented acceptable plans of correction. Given the results of the out-of-state compliance history of the facilities own or operated by FMC, the department concludes that considering that it owns or operates more than 1,700 facilities; the number of out-of-state non-compliance surveys is acceptable. [Licensing and/or survey data provided by out of state health care survey programs]

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. [Facility survey data provided by the Investigations and Inspections Office]

For medical director services, PNRS intends to contract with the Vancouver Clinic. A review of the compliance history of the doctor's identified within the Vancouver Clinic revealed no recorded sanctions. [PNRS April 29, 2011 Supplemental Information, Attachment 4]

Given the compliance history of PNRS and that of the proposed clinic, the Department concludes that there is reasonable assurance that the PNRS facility would operate in compliance with state and federal regulations. **This sub-criterion is met.**

DaVita

DaVita owns or operates twenty-three kidney dialysis treatment centers in eleven 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.¹⁷ 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 the states, District of Columbia, and San Juan Puerto Rico where DaVita, Inc. or any subsidiaries have health care facilities.

¹⁴ WAC 246-310-230(5).

¹⁵ This figure excludes Washington. The department did not send a survey to itself for compliance.

¹⁶ Those not responding were: Alabama, Arkansas, District of Columbia, Georgia, Indiana, Louisiana, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Nebraska, New Jersey, New York, Oklahoma, Pennsylvanian, Rhode Island, Texas, Vermont, Wisconsin, and Puerto Rico.

¹⁷ WAC 246-310-230(5).

Of the 42 state and entities, the department received responses from 21 states or 50% of the 42 states.¹⁸ The compliance history of the remaining 19 states, and 2 non-state entities Puerto Rico and the District of Columbia is unknown.¹⁹

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 re-opened, none of the deficiencies reported to have resulted in fines or enforcement action. All other facilities comply with applicable regulations. The Iowa facility chose voluntary 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. [Compliance history from state licensing and/or surveying entities]

The department concludes that considering the more than 1,500 facilities owned/managed by DaVita, only one out-of-state facility 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 manages²⁰. Of the compliance surveys completed, there were some 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. [DOH Investigations and Inspections Office records]

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. 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. [Facility survey data provided by the Investigations and Inspections Office]

For medical director services, DaVita provided a copy of its executed agreement with Majd Isreb, M.D. Under the contract, Dr. Isreb is designated as medical director for the Battle Ground facility. A review of the compliance history for Dr. Isreb revealed no recorded sanctions. [DaVita Application, p6 & Exhibit 3]

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

¹⁸ 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, Washington and West Virginia

¹⁹ 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 and Puerto Rico did not respond to the survey.

²⁰ As of the writing of this evaluation, three facilities—Whidbey Island Dialysis Center, Everett Dialysis Center, and Kennewick Dialysis Center—were recently approved by the department and are not yet operational. Olympic View Dialysis Center is operational, but is owned by Group Health and managed by DaVita.

(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.

Pacific Northwest Renal Service

The Department considered PNRS'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. [PNRS Application, p33; 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 need for 24 dialysis stations in Clark County Planning Area. This project proposes to establish a 24 station facility in Clark County.

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.**

DaVita

The Department 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. [DaVita Application, p25; 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 need for 24 dialysis stations in Clark County Planning Area. This project proposes to establish a 24 station facility in Clark County.

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.

Pacific Northwest Renal Service

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

DaVita

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

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

Based on the source information reviewed, the department concludes that the DaVita - Battle Ground project has met the cost containment criteria in WAC 246-310-240(1) and (2); and

(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 (tie-breaker) criteria contained in WAC 246-310. The tie-breaker 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

Both proposed projects meet the review criteria under WAC 246-310-210, 220, and 230. Therefore, the Department moves to step two below.

Step Two

Pacific Northwest Renal Service

Within the application, PNRS identified and rejected two alternatives before submitting this application. A summary of each is below. [PNRS Application, p36]

Alternative 1-Add no new facility

PNRS states it rejected this option because of increased volumes at the two PNRS facilities. Both facilities have added a 4th shift. PNRS states that both facilities are struggling to be able to accommodate the entire patient needing care.

Alternative 2-Establish a 12-station facility

PNRS states that “a 12-station facility is not nearly as efficient to build and operate”. Further, based on the projected need, PNRS determined that it was not a reasonable option to address the needs of the patients in the planning area.

DaVita

Within the application, DaVita identified and rejected two alternatives before submitting this application. A summary of each is below. [DaVita Application, p27]

Alternative 1-Add no new facility

DaVita states it rejected this option because all three existing facilities in the Greater Vancouver area are operating at over 80% of 3-shift capacity and there is a projected need in 2013 of 24 stations.

Alternative 2-Establish a 12-station facility in Battle Ground

DaVita states that this option was rejected when the projected need exceeded the 12-station capacity. Thus, access and availability issues would soon arise at a smaller 12-station facility.

Both applicants outlined the same options for consideration and rejected them for similar reasons. In the end, each determined that a 24-station facility was the preferred alternative.

Step Three

WAC 246-310-288 identifies specific tie-breaker criteria that must be applied if two or more applications meet all applicable review criteria and there is not enough station need projected for all applications to be approved. Under this tie-break criteria, the department will approve the application accumulating the largest number of points. If sufficient additional stations remain after approval of the first application, the department will approve the application accumulating the next largest number of points, not to exceed the total number of stations projected for a planning area. If the applications remain tied after applying all the tie-breakers, the department will award stations as equally as possible among those applications, without exceeding the total number of stations projected for a planning area.

Below is an evaluation of the tie-breaker criteria under WAC 246-310-288(1) and (2).

WAC 246-310-288(1)

(1) The department will award one point per tie-breaker to any applicant that meets a tie-breaker criteria in this subsection.

(a) Training services (1 point):

(i) The applicant is an existing provider in the planning area and either offers training services at the facility proposed to be expanded or offers training services in any of its existing facilities within a thirty-five mile radius of the existing facility; or

(ii) The applicant is an existing provider in the planning area that offers training services in any of its existing facilities within thirty-five miles of the proposed new facility and either intends to offer training services at the new facility or through those existing facilities; or

(iii) The applicant, not currently located in the planning area, proposes to establish a new facility with training services and demonstrates a historical and current provision of training services at its other facilities; and

- (iv) Northwest Renal Network's most recent year-end facility survey must document the provision of these training services by the applicant.
- (b) Private room(s) for isolating patients needing dialysis (1 point).
- (c) Permanent bed stations at the facility (1 point).
- (d) Evening shift (1 point): The applicant currently offers, or as part of its application proposes to offer at the facility a dialysis shift that begins after 5:00 p.m.
- (e) Meeting the projected need (1 point): Each application that proposes the number of stations that most closely approximates the projected need.

Pacific Northwest Renal Service

A total of five points is possible. Table 13 shows the distribution of tie-breaker points under this sub-criterion for PNRS.

**Table 13
WAC 246-310-288(1)
PNRS Tie-Breaker Review**

WAC 246-310-288(1)	Point	Source
(a) Training services	1	Application, p10
(b) Private room(s) for isolating patients	1	Screening, p149
(c) Permanent bed stations at the facility	1	Screening, p149
(d) Evening shift	1	Application, p26
(e) Meeting the projected need	1	Application, p20
Total Points	5	

DaVita

A total of five points is possible. Table 14 shows the distribution of tie-breaker points under this sub-criterion for DaVita.

**Table 14
WAC 246-310-288(1)
DaVita Tie-Breaker Review**

WAC 246-310-288(1)	Point	Source
(a) Training services	1	Application, p9
(b) Private room(s) for isolating patients	1	Screening, Exhibit B
(c) Permanent bed stations at the facility	1	Screening, Exhibit B
(d) Evening shift	1	Application, p9
(e) Meeting the projected need	1	Application, p19
Total Points	5	

Under WAC 246-310-288(1) where each applicant could receive a maximum of 5 points, both PNRS and DaVita received the maximum number of points.

WAC 246-310-288(2)

- (2) Only one applicant may be awarded a point for each of the following four tie-breaker criteria:
 - (a) Economies of scale (1 point): Compared to the other applications, an applicant demonstrates its proposal has the lowest capital expenditure per new station.
 - (b) Historical provider (1 point)

- (i) The applicant was the first to establish a facility within a planning area; and
 - (ii) The application to expand the existing facility is being submitted within five years of the opening of its facility; or
 - (iii) The application is to build an additional new facility within five years of the opening of its first facility.
- (c) Patient geographical access (1 point): The application proposing to establish a new facility within a planning area that will result in services being offered closer to people in need of them. The department will award the point for the facility located farthest away from existing facilities within the planning area provided:
- (i) The facility is at least three miles away from the next closest existing facility in planning areas that qualify for 4.8 patients per station; or
 - (ii) The facility is at least eight miles from the next closest existing facility in planning areas that qualify for 3.2 patients per station.
- (d) Provider choice (1 point):
- (i) The applicant does not currently have a facility located within the planning area;
 - (ii) The department will consider a planning area as having one provider when a single provider has multiple facilities in the same planning area;
 - (iii) If there are already two unrelated providers located in the same planning area, no point will be awarded.

Only one applicant may receive a point for each of the four tie-breaker criteria under this section. Table 15 below shows the distribution of tie-breaker points under this sub-criterion for PNRS.

Table 15
WAC 246-310-288(2)
PNRS Tie-Breaker Review

WAC 246-310-288(2)	Point	Source
(a) Economies of Scale	0	Screening, p8 [\$2,953,931]
(b) Historical Provider	0	
(c) Patient Geographical Access	0	
(d) Provider Choice	0	
Total Points	0	

Table 16 below shows the distribution of tie-breaker points under this sub-criterion for DaVita.

Table 16
WAC 246-310-288(2)
DaVita Tie-Breaker Review

WAC 246-310-288(2)	Point	Source
(a) Economies of Scale	1	Screening, Table 1A [\$2,197,699]
(b) Historical Provider	0	
(c) Patient Geographical Access	1	MapQuest Mileage Estimates
(d) Provider Choice	0	
Total Points	2	

Table 17 below shows the total accumulation of tie-breaker points for both PNRS and DaVita.

Table 17
WAC 246-310-288 – Tie-Breaker Summary Table

	Tie-Breaker Point Distribution	
	PNRS	DaVita
1(a) – Training services	1	1
1(b) – Private Room	1	1
1(c) – Permanent Bed Station	1	1
1(d) – Evening Shift	1	1
1(e) – Meets Need	1	1
2(a) – Economies of Scale	0	1
2(b) – Historical Provider	0	0
2(c) – Geographical Access	0	1
2(d) – Provider Choice	0	0
Cumulative Total	5	7

At the completion of the tie-breaker point allocations, DaVita accumulated a total of five (5) points and DaVita accumulated a total of seven (7) points. Due to the results outlined in this section, the department concludes that DaVita’s project is the application accumulating the largest number of points and is the first application to be considered in the allocation of stations to meet the projected need.

Since the DaVita project accounts for all 24 of the stations projected for the planning area, there are no stations remaining to award to PNRS as the application earning the next highest point total.

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

Pacific Northwest Renal Service

Based on the results of the tie-breaker criteria above, PNRS’s project does not meet this sub-criterion. **This project is denied.**

DaVita

Based on the results of the tie-breaker criteria above, DaVita’s project meets this sub-criterion. **This project is approved.**

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

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

WAC 246-310 does not contain specific WAC 246-310-240(2)(a) criteria as identified in WAC 246-310-200(2)(a)(i). There are known minimum building and energy standards that healthcare facilities must meet to be licensed or certified to provide care. If built to only the minimum standards all construction projects could be determined to be reasonable. However, the department, through its experience knows that construction projects are usually built to exceed these minimum standards. Therefore, the department considered information in the applications that addressed the reasonableness of their construction projects that exceeded the minimum standards.

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). **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.

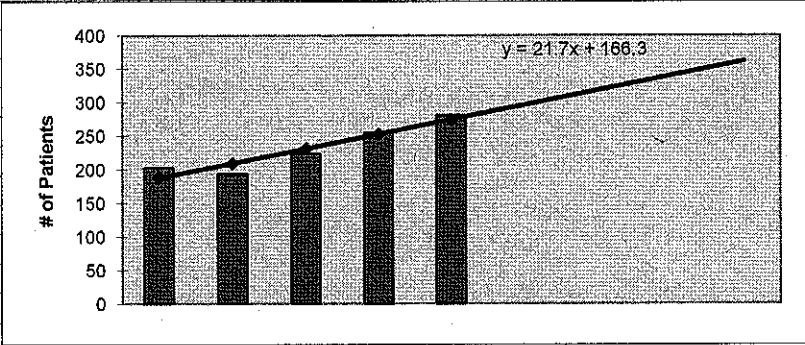
This sub-criterion is also evaluated within the financial feasibility criterion under WAC 246-310-220(2). **This sub-criterion is met.**

Appendix A

Clark County ESRD Need Projection Methodology							
	Planning Area	6 Year Utilization Data - Resident Incenter Patients					
	Clark	2004	2005	2006	2007	2008	2009
	Clark County	219	203	194	224	255	281
	TOTALS	219	203	194	224	255	281
246-310-284(4)(a)	Rate of Change		-7.31%	-4.43%	15.46%	13.84%	10.20%
	6% Growth or Greater?		FALSE	FALSE	TRUE	TRUE	TRUE
	Regression Method:	Linear					
246-310-284(4)(c)				Year 1 2010	Year 2 2011	Year 3 2012	Year 4 2013
Projected Resident Incenter Patients	from 246-310-284(4)(b)			296.50	318.20	339.90	361.60
Station Need for Patients	Divide Resident Incenter Patients by 4.8			61.7708	66.2917	70.8125	75.3333
	Rounded to next whole number			62	67	71	76
246-310-284(4)(d)	subtract (4)(c) from approved stations						
Existing CN Approved Stations				52	52	52	52
Results of (4)(c) above				62	67	71	76
Net Station Need				-10	-15	-19	-24
Negative number indicates need for stations							
246-310-284(5)							
Name of Center	# of Stations	Patients	Utilization (Patients per Station)				
DaVita Vancouver	12	59	4.92				
PNRS Ft. Vancouver	24	152	6.33				
PNRS Salmon Creek	16	95	5.94				
Total	52	306					
Source: Northwest Renal Network data 2004-2009							
Most recent year-end data: 2009 year-end data as of 01/26/2010							
Most recent quarterly data as of the 1st day of application submission period: 3rd quarter 2010 as of 11/09/2010							

Clark County
ESRD Need Projection Methodology

x	y	Linear
2005	203	188
2006	194	210
2007	224	231
2008	255	253
2009	281	275
2010		296.500
2011		318.200
2012		339.900
2013		361.600



SUMMARY OUTPUT

Regression Statistics	
Multiple R	0.944621785
R Square	0.892310316
Adjusted R Square	0.856413755
Standard Error	13.76347824
Observations	5

ANOVA					
	df	SS	MS	F	Significance F
Regression	1	4708.9	4708.9	24.85782157	0.015513203
Residual	3	568.3	189.4333333		
Total	4	5277.2			

	Coefficients	Standard Error	t Stat	P-value	Lower 95%	Upper 95%	Lower 95.0%	Upper 95.0%
Intercept	-43320.5	8735.256881	-4.959270299	0.015741204	-71119.98598	-15521.014	-71119.98598	-15521.014
X Variable 1	21.7	4.352393977	4.985761885	0.015513203	7.84873987	35.55126013	7.84873987	35.55126013

RESIDUAL OUTPUT

Observation	Predicted Y	Residuals
1	188	15
2	209.7	-15.7
3	231.4	-7.4
4	253.1	1.9
5	274.8	6.2