



STATE OF WASHINGTON  
DEPARTMENT OF HEALTH  
*Olympia, Washington 98504*

August 1, 2019

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RE: CN Application #19-20 – FMC Leah Layne Dialysis Center

Dear Mr. Chiastra:

We have completed review of the Certificate of Need application submitted by Fresenius Medical Care. The application proposes the addition of one dialysis station to FMC Leah Layne Dialysis Center located in Adams County. The station is added under the special circumstance provisions of Washington Administrative Code 246-310-818. Enclosed is a written evaluation of the application.

For the reasons stated in the enclosed decision, the application is consistent with the applicable criteria of the Certificate of Need Program, provided FMC agrees to the following in its entirety.

**Project Description:**

This certificate approves the addition of one dialysis station to the nine-station FMC Leah Layne, for a facility total of 10 dialysis stations. Services provided at FMC Leah Layne include in-center hemodialysis, peritoneal dialysis support for dialysis patients, and shifts beginning after 5:00 pm.

The table below provides a breakdown of the total number of stations at FMC Leah Layne, which includes one additional station approved under the special circumstance criterion outlined in Washington Administrative Code 246-310-818.

	CMS Certified Stations	Stations Counted in Methodology
General Use In-Center Stations	8	8
Permanent Bed Station	1	1
Private Isolation Station	1	0
<b>Total Stations</b>	<b>10</b>	<b>9</b>

As required under Washington Administrative Code 246-310-818(10), the additional station must be operational within six months of approval, otherwise this Certificate of Need is revoked.

**Conditions:**

1. Approval of the project description as stated above. Fresenius Medical Care further agrees that any change to the project as described in the project description is a new project that requires a new Certificate of Need.
2. Fresenius Medical Care shall finance this project using existing capital reserves, as described in the application.

**Approved Costs:**

The approved capital expenditure for this one-station addition is \$604. This amount represents the costs for moveable equipment. All costs will be paid by Fresenius Medical Care.

Please notify the Department of Health within 20 days of the date of this letter whether you accept the above project description, conditions, and capital costs for your project. If you accept these in their entirety, your application will be approved and a Certificate of Need sent to you.

If you reject any of the above provisions, your application will be denied. The department will send you a letter denying your application and provide you information about your appeal rights.

Send your written response 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

Physical Address:

Department of Health  
Certificate of Need Program  
111 Israel Road SE  
Tumwater, WA 98501

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

Sincerely,



Nancy Tyson, Executive Director  
Health Facilities and Certificate of Need

Enclosure

**2019 CYCLE 1 SPECIAL CIRCUMSTANCE EVALUATION DATED AUGUST 1, 2019, FOR THE CERTIFICATE OF NEED APPLICATION SUBMITTED BY FRESENIUS MEDICAL CARE PROPOSING TO ADD ONE DIALYSIS STATION TO LEAH LAYNE DIALYSIS CENTER LOCATED IN ADAMS COUNTY**

**APPLICANT DESCRIPTION**

**Fresenius Medical Care.**

Renal Care Group Northwest (RCGNW) is one of three entities owned by Renal Care Group, Inc. (RCG). RCGN is responsible for the operation of facilities under three separate legal entities. These entities include Pacific Northwest Renal Services (PNRS), Renal Care Group Northwest (RCGNW), and Inland Northwest Renal Care Group (IN-RCG). In March of 2006, Fresenius Medical Care Holdings (FMC) became the sole owner of RCG. In addition to the three entities listed above, FMC also operates two other entities, including QualiCenters, Inc. and National Medical Care, Inc. As all of these subsidiaries are owned by one parent corporation, this evaluation shall refer to the applicant and all subsidiaries as Fresenius, or FMC. FMC operates outpatient dialysis centers in 48 states, the District of Columbia, and Puerto Rico through these subsidiaries. In Washington State, FMC owns, operates, or manages 23 kidney dialysis facilities. These facilities are listed below. [source: Application pp4-8, CMS Dialysis Facility Compare website]

**Adams County**

FMC Leah Layne Dialysis Center

**Benton County**

FMC Columbia Basin

**Clark County**

PNRS Fort Vancouver

PNRS Clark County Dialysis Clinic

PNRS Salmon Creek

**Grant County**

FMC Moses Lake Dialysis Unit

**Grays Harbor County**

FMC Aberdeen

**Lewis County**

FMC Chehalis

**Mason County**

FMC Shelton

**Okanogan County**

FMC Omak Dialysis Center

**Pierce County**

Fresenius Kidney Care Mt. Rainier

Fresenius Kidney Care South Tacoma

Fresenius Kidney Care Tacoma East

Fresenius Kidney Care Gig Harbor

Fresenius Kidney Care Puyallup

**Spokane County**

FMC Spokane Kidney Center

FMC Northpointe Dialysis Unit

Panorama Dialysis

FMC North Pines Dialysis Unit

**Stevens County**

FMC Colville

**Thurston County**

FMC North Thurston County Dialysis Center

FMC Lacey

**Walla Walla County**

Qualicenters – Walla Walla LLC

**PROJECT DESCRIPTION**

This project focuses on Fresenius Kidney Care Leah Layne (FMC Leah Layne) located at 530 South 1<sup>st</sup> Avenue in Othello [99344] within Adams County. Currently, FMC Leah Layne is approved to be a 9-station facility as shown in Table 1 below.<sup>1</sup>

**Department’s Table 1  
FMC Leah Layne**

<b>Station Type</b>	<b>CMS Certified Stations</b>	<b>Station Counted for Station Use and Methodology</b>
General Use In-Center Stations	7	7
Permanent Bed Station	1	1
Isolation Station	1	0
<b>Total Stations</b>	<b>9</b>	<b>8</b>

This application proposes to add one additional station at FMC Leah Layne, resulting in nine in-center stations and one isolation station. FMC Leah Layne would remain at its current location in Othello and would continue to provide the following services.

- Hemodialysis patients who dialyze in the chronic setting,
- Hemodialysis patients requiring isolation,
- Hemodialysis patients requiring dialysis in a permanent bed station,
- Hemodialysis patients requiring treatment shifts that begin after 5:00 PM.

The capital expenditure associated with the addition of one station is \$604 and all costs are associated with the equipment including sale tax. All costs would be paid by FMC Leah Layne. [source: Application, p17]

Within this application, FMC Leah Layne determined this evaluation would be released in in February 2019. Using that timeline, FMC Leah Layne estimated the additional station would be operational in March 1 2019. [source: Application, p10] Under this timeline, full year one is 2020 and full year three is 2022.

**Department Information on Timelines for Completion of the Projects**

FMC Leah Layne identified a timeline for completion of this project based on a February 2019 evaluation release date. Due to delays in releasing this evaluation, FMC Leah Layne’s timeline may not be achievable or accurate. If this project is approved, the department will adjust the operational timeline to account for the additional days of delay of the release of this evaluation.

**APPLICABILITY OF CERTIFICATE OF NEED LAW**

FMC Leah Layne’s application proposes to add one dialysis station to an existing dialysis center. This application is subject to review as an increase in the number of dialysis stations in a kidney disease center under provisions of RCW 70.38.105(4)(h) and WAC 246-310-020(1)(e).

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<sup>1</sup> Effective January 1, 2018, FMC Leah Layne was issued CN #1679 allowing the addition of one station consistent with WAC 246-310-809(3). To date, FMC Leah Layne has not activated and certified this station.

**EVALUATION CRITERIA**

WAC 246-310-200(1)(a)-(d) identifies the four determinations that the department must make for each application. WAC 246-310-200(2) provides additional direction on how the department is to make its determination. 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 services 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 service or facilities for health services proposed, the department may consider standards not in conflict with those standards in accordance with subsection (2)(b) of this section; and*
  - (iii) The relationship of the proposed project to the long-range plan (if any) of the person proposing the project.”*

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

- (b) 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.*

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).

FMC Leah Layne must also demonstrate compliance with applicable kidney disease treatment center criteria outlined in WAC 246-310-800 through 833. For ESRD applications submitted under WAC 246-310-818 ‘Special Circumstance One- or Two-Station Expansion,’ the following review criteria do not apply and will not be discussed in this evaluation.

WAC 246-310-809	One-time exempt isolation station reconciliation
WAC 246-310-812	Kidney disease treatment facilities—Methodology
WAC 246-310-821	Kidney disease treatment facilities—Standards for planning areas without an existing facility
WAC 246-310-830	Kidney disease treatment facilities—Relocation of facilities
WAC 246-310-833	One-time state border kidney dialysis facility station relocation

### **WAC 246-310-803**

WAC 246-310-803 requires an applicant to submit specific data elements to the Certificate of Need Program. For the 2018 concurrent review cycle, the data must be received before February 16, 2018. Fresenius submitted the data elements on February 15, 2018. This data is used to calculate superiority in the event that more than one application meets the applicable review criteria. Consistent with WAC 246-310-827, these data elements are the only means by which two or more applications may be compared to one another.

### **TYPE OF REVIEW**

As directed under WAC 246-310-806, the department accepted this application under the Kidney Disease Treatment Centers-Special Circumstances Concurrent Review Cycle #2 for calendar year 2018. Even though applications submitted under WAC 246-310-806 are reviewed under a concurrent review cycle, the applications are not reviewed competitively. Below is the chronologic summary of the application's review.

### **APPLICATION CHRONOLOGY**

<b>Action</b>	<b>FMC</b>
Letter of Intent Submitted	October 1, 2018
Application Submitted	October 31, 2018
Department's Pre-review Activities including <ul style="list-style-type: none"><li>• DOH 1<sup>st</sup> Screening Letter</li><li>• Applicant's 1st Screening Responses Received</li></ul>	November 15, 2018 December 17, 2018
Beginning of Review	December 26, 2018
End of Public Comment <sup>2</sup> <ul style="list-style-type: none"><li>• Public comments accepted through the end of public comment</li><li>• No public hearing requested or conducted</li></ul>	January 25, 2019
Rebuttal Comments Received	February 1, 2019
Department's Anticipated Decision Date	February 18, 2019
Department's Anticipated Decision Date with a 180-day extension <sup>3</sup>	July 19, 2019
Department's Actual Decision Date	August 1, 2019

### **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."*

<sup>2</sup> Public comments were accepted through January 25, 2019, however no public comments were submitted for this project. As a result, FMC Leah Layne did not provide rebuttal comments.

<sup>3</sup> Thirty-day extension letters were sent to FMC Leah Layne on February 21, 2019, May 3, 2019, May 29, 2019, June 18, 2019 and July 19, 2019.

As noted above, WAC 246-310-010(2) requires an affected person to first meet the definition of an ‘interested person.’ WAC 246-310(34) defines “interested person” as:

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

For this project, no entity requested interested or affected person status.

### **SOURCE INFORMATION REVIEWED**

- Fresenius Medical Care’s Certificate of Need application received November 1, 2018
- Fresenius Medical Care 1<sup>st</sup> screening response received December 17, 2018
- Years 2015 through 2017 historical kidney dialysis data obtained from the Northwest Renal Network
- Department of Health’s ESRD Need Projection Methodology for Adams County posted to its website March 2018
- Licensing data provided by the Medical Quality Assurance Commission, Nursing Quality Assurance Commission, and Health Systems Quality Assurance Office of Customer Service
- Compliance history obtained from the Washington State Department of Health Office of Health Systems Oversight
- Fresenius Medical Care website at [www.fmcna.com](http://www.fmcna.com)
- Northwest Renal Network website at [www.nwrn.org](http://www.nwrn.org)
- Centers for Medicare and Medicaid website at [www.medicare.gov/dialysisfacilitycompare](http://www.medicare.gov/dialysisfacilitycompare)
- Certificate of Need historical files

### **CONCLUSION**

#### **Fresenius Medical Care.**

For the reasons stated in this evaluation, the application submitted by Fresenius Medical Care proposing to add one dialysis station to FMC Leah Layne located in Adams County is consistent with applicable criteria of the Certificate of Need Program, provided that the applicant agrees to the following in its entirety.

#### **Project Description:**

This certificate approves the addition of one dialysis station to the nine-station FMC Leah Layne, for a facility total of 10 dialysis stations.<sup>4</sup> Services provided at FMC Leah Layne include in-center hemodialysis, peritoneal dialysis support for dialysis patients, and shifts beginning after 5:00 pm.

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<sup>4</sup> Certificate of Need #1679 was issued to Fresenius Medical Care approving the one-time addition of an isolation station to FMC Leah Layne consistent with Washington Administrative Code 246-310-809(3). The certificate was effective on January 1, 2018. As of the writing of this evaluation, FMC has not yet added the one adjustment station, however they are approved to do so.

The table below provides a breakdown of the total number of stations at FMC Leah Layne, which includes one additional station approved under the special circumstance criterion outlined in Washington Administrative Code 246-310-818.

	<b>CMS Certified Stations</b>	<b>Stations Counted in Methodology</b>
General Use In-Center Stations	8	8
Permanent Bed Station	1	1
Private Isolation Station <sup>5</sup>	1	0
<b>Total Stations</b>	<b>10</b>	<b>9</b>

As required under Washington Administrative Code 246-310-818(10), the additional station must be operational within six months of approval, otherwise this Certificate of Need is revoked.

Conditions:

1. Approval of the project description as stated above. Fresenius Medical Care further agrees that any change to the project as described in the project description is a new project that requires a new Certificate of Need.
2. Fresenius Medical Care shall finance this project using existing capital reserves, as described in the application.

Approved Capital Expenditure:

The approved capital expenditure for this one-station addition is \$604. This amount represents the costs for moveable equipment. All costs will be paid by Fresenius Medical Care.



## **CRITERIA DETERMINATIONS**

### **A. Need (WAC 246-310-210)**

Based on the source information reviewed and agreement to the conditions identified in the conclusion section of this evaluation, the department concludes that the Fresenius Medical Care Leah Layne project has met the need criteria in WAC 246-310-210, which includes the applicable kidney disease treatment facility criteria in WAC 246-310-800 through 833.

- (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 246-310-818**

WAC 246-310-818(1) - (13) outline the review requirements for dialysis projects submitted under the special circumstance review criteria. For this project, Fresenius Medical Care must demonstrate compliance with the following sub-sections of WAC 246-310-818.

*WAC 246-310-818(1) The department will approve one or two additional special circumstance stations for an existing kidney dialysis facility (facility) if it meets the following criteria, regardless of whether the need methodology in WAC 246-310-812 projects a need for additional stations in the planning area:*

- (a) *For 3.2 planning areas, the facility has operated at or above an average of 3.5 patients per station for the most recent six consecutive month period preceding the letter of intent submission date for which data is available. Data used to determine patients per station must be obtained from the Northwest Renal Network; or*
- (c) *The facility can accommodate one or two additional stations within its existing building, which may include shelled space. If renovation is needed to accommodate the additional station(s), renovation must be within the existing building.*

### **Fresenius Medical Care**

To demonstrate compliance with this sub-criterion, Fresenius Medical Care provided the following documents:

- Six month utilization data from Northwest Renal Network.; and
- Single line drawing showing the stations and support areas of the dialysis center both before and after the station addition.

[source: Application, Exhibit 5 and December 17, 2018, screening response, p2]

### **Public Comment**

None

### **Rebuttal Comment**

None

### **Department Evaluation**

For this project, the six months preceding the letter of intent submission period for the Special Circumstance submission cycle #2 for Adams County is April 2018 through September 2018. The data to be used by Fresenius Medical Care for this project is the same time frame. The data provided in the application shows that FMC Leah Layne was operating at an average of approximately 4.2 patients per station, not counting the exempt isolation station.

The single line drawing shows the one additional station will be set up in existing space within the facility. Based on the information reviewed the department concludes the **sub-criterion is met**.

WAC 246-310-818(5) For 3.2 planning areas, a facility is ineligible for a special circumstance one- or two-station expansion if the owner or affiliate has approved certificate of need stations in the planning area that have operated below an average of 3.5 patients per station for the most recent six consecutive month period preceding the letter of intent submission date. Data used to calculate patients per station must be obtained from the Northwest Renal Network.

**Fresenius Medical Care**

To demonstrate compliance with this sub-criterion, FMC Leah Layne provided the following documents:

- Six month utilization data from Northwest Renal Network. This data focuses on FMC Leah Layne located in Adams County.

[source: Application, p11]

Public Comment

None

Rebuttal Comment

None

**Department Evaluation**

For this project, the six months preceding the letter of intent submission period for the Special Circumstance submission cycle #2 for Adams County is April 2018 through September 2018. The data to be used by Fresenius Medical Care for this project is the same time frame. Adams County has one facility—FMC Leah Layne—is operated by Fresenius Medical Care. The data provided in the application shows that FMC Leah Layne operated at approximately 4.2 patients per station, not counting the exempt isolation station. **This sub-criterion is met.**

WAC 246-310-818(7) For 3.2 planning areas, a special circumstance one- or two-station expansion will not be approved if, with the requested new station(s), the applicant's kidney dialysis facility would fall below a calculated 3.5 patients per station. Data used to make this calculation is the average patients per station from subsection (1)(a) of this section.

**Fresenius Medical Care**

To demonstrate compliance with this sub-criterion, FMC Leah Layne provided the following documents:

- Six month utilization data from Northwest Renal Network. This data focuses on FMC Leah Layne located in Adams County.

[source: Application, p11]

Public Comment

None

Rebuttal Comment

None

**Department Evaluation**

For this project, the six months preceding the letter of intent submission period for the Special Circumstance submission cycle #2 for Adams County is April 2018 through September 2018. The data to be used by Fresenius Medical Care for this project is the same time frame. If this project is approved, FMC Leah Layne would be operating 9 counted in center dialysis stations, not counting the exempt isolation station. The data provided in the application shows that the 9-station center would be operating at an average of 3.75 patients per station. **This sub-criterion is met.**

*WAC 246-310-818(10) Station(s) approved under this section must be operational within six months of approval, otherwise the approval is revoked.*

**Fresenius Medical Care**

To demonstrate compliance with this sub-criterion, FMC Leah Layne provided the following table showing the projected timeline for operation of the additional station. [source: Application, p9]

*Applicant's Table*

Table 1 FMC Leah Layne Anticipated Dates of Commencement & Completion of Project	
Design Complete	NA
Construction Commenced	NA
Construction Completed	NA
Facility Prepared for Survey	03/07/19

**Public Comment**

None

**Rebuttal Comment**

None

**Department Evaluation**

The timeline identified in Fresenius Medical Care's Table 1 above projects the new dialysis station would be operational at FMC Leah Layne within approximately one month of approval. Fresenius Medical Care identified a timeline for completion of this project based on a February 2019 evaluation release date. Due to delays in releasing this evaluation, Fresenius Medical Care's timeline could not be achievable, so the department recalculated an operational date for this project. Using the actual July 2019 decision date, plus one month would be late August or early September 2019. Given that WAC 246-310-818(10) requires additional stations to be operational within six months of approval, **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.

To evaluate this sub-criterion, the department evaluates an applicant's admission policies, willingness to serve Medicare and Medicaid patients, and to serve patients that cannot afford to pay for services.

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 assurances regarding access to treatment. The admission policy must also include language to ensure all residents of the planning area would have access to the proposed services. This is accomplished by providing an admission policy that states patients would be admitted without regard to race, ethnicity, national origin, age, sex, pre-existing condition, physical, or mental status.

Medicare certification is a measure of an agency's willingness to serve the elderly. With limited exceptions, Medicare is coverage for individuals age 65 and over. It is also well recognized that women live longer than men and therefore more likely to be on Medicare longer. One of the exceptions is Medicare coverage for patients with permanent kidney failure. Patients of any age with permanent kidney failure are eligible for Medicare coverage.

Medicaid certification is a measure of an agency's willingness to serve low income persons and may include individuals with disabilities.

A facility's charity care policy should show a willingness of a provider to provide services to patients who have exhausted any third-party sources, including Medicare and Medicaid, and whose income is equal to or below 200% of the federal poverty standards, adjusted for family size or is otherwise not sufficient to enable them to pay for the care or to pay deductibles or coinsurance amounts required by a third-party payer.<sup>6</sup> With the passage of the Affordable Care Act (ACA), the amount of charity care is expected to decrease, but not disappear. The policy should also include the process one must use to access charity care at the facility.

### **Fresenius Medical Care**

FMC Leah Layne provided the following statement related to this sub-criterion:

*"Fresenius Medical Care's history of providing dialysis services at numerous locations throughout Washington State provides evidence that all ESRD patients have access to Fresenius Medical Care's facilities, including members of the under-served groups referenced in WAC 246-310-210(2).*

[source: Application, p14]

Fresenius Medical Care provided copies of the following policies used at all Fresenius Medical Care dialysis centers, including the existing FMC Leah Layne. [source: Application, Exhibits 6 and 7]

- Admission Policy
- Charity care or financial assistance policy

### **Medicare and Medicaid Programs**

FMC Leah Layne is currently Medicare and Medicaid certified and provided the facility's Medicare and Medicaid provider numbers. FMC Leah Layne also included a table showing the current

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<sup>6</sup> WAC 246-453-010(4).

percentages of revenues by payer and revenues by patient for the facility. The information is summarized below. [source: Application, p10 and pp19]

Medicare Provider Number: 502558  
 Medicaid Provider Number: 1295987493

*Applicant Table*

<b>Current FMC Leah Layne</b>		
<b>Source</b>	<b>Percentage of Patients by Payer</b>	<b>Percentage of Revenue by Payer</b>
Medicare	55.0%	18.8%
Commercial	10.1%	70.5%
Medicaid	29.1%	8.7%
Medicare Adv	3.4%	1.6%
Medicare Risk	0.0%	0.0%
Misc Insurance	0.1%	0.0%
Self Pay	2.4%	0.4%
<b>Total</b>	<b>100.00%</b>	<b>100.00%</b>

Public Comment

None

Rebuttal Comment

None

**Department Evaluation**

Fresenius Medical Care has been providing dialysis services to the residents of Washington State for many years. The Accepting End Stage Renal Disease Patients for Treatment provides the assurance that FMC Leah Layne would accept patients for treatment without regard to “*race, color, national origin, gender, sexual orientation, age, religion, or disability...*” provided that the patient is a candidate for dialysis services.

All Fresenius Medical Care dialysis centers are Medicare and Medicaid certified. Documentation provided in the application demonstrates that FMC Leah Layne would continue both Medicare and Medicaid certifications. Fresenius Medical Care projected the Medicare and Medicaid revenues for FMC Leah Layne to be 29.1% of total revenues. Pro forma financial data provided in the application shows Medicare and Medicaid revenue.

The charity care policy provides the necessary information and process a patient would use to obtain charity care at a FMC Leah Layne facility. FMC Leah Layne further demonstrated its intent to provide charity care for patients by including a ‘charity’ line item as a deduction from revenue within the pro forma income statement. Furthermore, this policy is already in place

Given that Fresenius Medical Care currently operates dialysis centers in Washington State and uses the same policies and procedures at each center, the policies provided in the application are executed policies used by Fresenius Medical Care in its Washington State facilities. The department concludes FMC Leah Layne’s project **meets this sub-criterion.**

- (3) The applicant has substantiated any of the following special needs and circumstances the proposed project is to serve.
- (a) The special needs and circumstances of entities such as medical and other health professions schools, multidisciplinary clinics and specialty centers providing a substantial portion of their services or resources, or both, to individuals not residing in the health service areas in which the entities are located or in adjacent health service areas.
  - (b) The special needs and circumstances of biomedical and behavioral research projects designed to meet a national need and for which local conditions offer special advantages.
  - (c) The special needs and circumstances of osteopathic hospitals and non-allopathic services.
- (4) The project will not have an adverse effect on health professional schools and training programs. The assessment of the conformance of a project with this criterion shall include consideration of:
- (a) The effect of the means proposed for the delivery of health services on the clinical needs of health professional training programs in the area in which the services are to be provided.
  - (b) If proposed health services are to be available in a limited number of facilities, the extent to which the health professions schools serving the area will have access to the services for training purposes.
- (5) The project is needed to meet the special needs and circumstances of enrolled members or reasonably anticipated new members of a health maintenance organization or proposed health maintenance organization and the services proposed are not available from nonhealth maintenance organization providers or other health maintenance organizations in a reasonable and cost-effective manner consistent with the basic method of operation of the health maintenance organization or proposed health maintenance organization.

### **Department Evaluation**

WAC 246-310-210(3), (4), and (5) do not apply to this dialysis project under review.

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

Based on the source information reviewed and agreement to the conditions identified in the conclusion section of this evaluation, the department concludes that the FMC Leah Layne project has met the financial feasibility criteria in WAC 246-310-220 and WAC 246-310-815.

- (1) The immediate and long-range capital and operating costs of the project can be met.
- WAC 246-310-815 outlines the financial feasibility review requirements for dialysis projects. For this project, Fresenius Medical Care must demonstrate compliance with the following sub-sections of WAC 246-310-815(1). 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.

**WAC 246-310-815(1)**

*(1) The kidney dialysis facility must demonstrate positive net income by the third full year of operation.*

- (a) The calculation of net income is subtraction of all operating and non-operating expenses, including appropriate allocated and overhead expenses, amortization and depreciation of capital expenditures from total revenue generated by the kidney dialysis facility.*
- (b) Existing facilities. Revenue and expense projections for existing facilities must be based on that facility's current payer mix and current expenses.*
- (c) New facilities.*
  - (i) Revenue projections must be based on the net revenue per treatment of the applicant's three closest dialysis facilities.*
  - (ii) Known expenses must be used in the pro forma income statement. Known expenses may include, but are not limited to, rent, medical director agreement, and other types of contracted services.*
  - (iii) All other expenses not known must be based on the applicant's three closest dialysis facilities.*
  - (iv) If an applicant has no experience operating kidney dialysis facilities, the department will use its experience in determining the reasonableness of the pro forma financial statements provided in the application.*
  - (v) If an applicant has one or two kidney dialysis facilities, revenue projections and unknown expenses must be based on the applicant's operational facilities.*

Given that FMC Leah Layne is currently operational, sub-sections (1)(a) and (b) above apply to this project.

**Fresenius Medical Care**

As previously stated, FMC Leah Layne proposes the one additional station would be operational March 2019 based on a February 2019 evaluation release date. [source: Application, p9] Under this timeline, calendar year one of this project is 2019 and full year one is 2020; calendar year three is 2022.

Once the additional station is added, FMC Leah Layne would be operating with 10 total in center dialysis stations including one isolation station. Fresenius Medical Care provided the assumptions used to project in-center and home treatments and patients for calendar year 2019, referenced as the 'expansion year' and full calendar years 2020 through 2022. The assumptions are restated below. [source: Application, p13]

- ***First Full Year:*** 2020, based on a first patient date in March 2019 for the expansion.
- ***Total Stations:*** CON Approved stations. One CON-exempt isolation station is also included in driving relevant category calculations (bio-med FTE, overall existing facility depreciation).
- ***Total Chronic Capacity:*** 6 shift capacity of CON-approved stations is assumed to be 100% utilization.
- ***Patient Census Projections:*** Census projections are based on a 5-year projection of planning area patients using a regression of 5 years historical data and Fresenius Medical Care's own experience and expertise. This is the same trend line (based on the Department's methodology as applied through 2022), but extended out through 2024 to project planning area census through the projection period. Fresenius Medical Care uses projected planning area census, existing

planning area capacity, and additional market and experiential knowledge to project new facility census. Peritoneal dialysis patients are projected as a constant ratio to in-center patients

- **Total Treatments:** Total Treatment Volume is assumed to be based on average yearly census, a 5% missed treatment rate consistent with Fresenius Medical Care’s own experience and expertise, and three treatments weekly for 52 weeks per year.

Using the assumptions stated above, Fresenius Medical Care’s projected number of in-center dialyses and patients for the 10-station facility in years 2019 through 2022 is shown in Table 2. [source: Application, p 13]

**Department’s Table 2**  
**FMC Leah Layne**  
**Projected Patients and Dialyses for Years 2019 – 2022**

	CY 2019	CY 2020	CY 2021	CY 2022
Number of Stations	9	9	9	9
Total In center Patients	31	33	35	35
Total In center Treatments	3,720	4,752	5,040	5,040

Fresenius Medical Care provided the following assumptions used for its projected financial statements. [source: December 17, 2018, screening response, Exhibit 8B]

- **Revenue per treatment:** No inflation is applied to revenue per treatment, which is based on the last full year of operation for the facility, 2017, and its payor mix.
- **Charity Care:** estimated at 1% of gross revenue, consistent with Fresenius Medical Care’s historical experience.
- **General expenses:** Based on cost per treatment for the last full calendar year (2017) by category. This excludes lease expenses (noted below), depreciation expense (based on projected capital expenditures and existing depreciation), medical director expense (noted below), and labor costs (noted below).
- **Cost inflation:** Fresenius Medical Care does not assume inflation in any expense category – no current contract cost increases are known, and thus none are included, except for the lease, noted below.
- **Medical Director Expense:** based on contracted, known expenses in latest medical director agreements that run through the extent of the three-year projection window.
- **Lease Expense:** base rent is directly pulled from the lease contract for each calendar year and the lease term and rent tables. Tax & CAM are calculated based on actual 2017 tax and CAM per square foot. The lease terms call for inflation in base rent expense of 10% per year, which is included.
- **Labor Assumptions:** Based on safe, fair, and efficient staffing ratios for projected census and required staff type. Benefits, taxes, and non-base pay are assumed at a rate of 69% of base salaries and wages based on 2017 facility data.

Specific to various line items in the revenue and expense statement, Fresenius Medical Care provided the following clarification. [source: December 17, 2018, screening response, pdf7]



- *Other Purchased Services includes (1) pre-employment screening and time keeping services and (2) employment advertising. It is projected based on a cost-per-treatment basis from FMC Leah Layne data in 2017.*
- *Depreciation is straight-line; assumes 10 years on the leaseholds and 8 years on equipment*
- *Expenses have been calculated on a per treatment basis for variable expenses from FMC Leah Layne*

Specific to the lease expense category, Fresenius Medical Care provided the following clarification. [source: Application, Exhibit 10]

*“Please see the table below. The “Total” row matches Exhibit 10 to the dollar.”*

***FMC Leah Layne’s Base Rent Table***

	<b><i>Yearly Rate</i></b>	<b><i>Monthly Rate</i></b>
<b><i>Years 1-5</i></b>	<b><i>\$108,216.00</i></b>	<b><i>\$9,018.00</i></b>
<b><i>Years 6-10</i></b>	<b><i>\$119,037.60</i></b>	<b><i>\$9,919.80</i></b>

Based on the assumptions above, Fresenius Medical Care projected the revenue, expenses, and net income for years 2019 through 2022. A summary of the projections are shown in Table 3. [source: December 17, 2018, screening response, pdf6]

**Department’s Table 3  
FMC Leah Layne  
Projected Revenue and Expenses for Years 2019 - 2022**

	<b>CY 2019</b>	<b>CY 2020</b>	<b>CY 2021</b>	<b>CY 2022</b>
Net Revenue	\$1,896,901	\$2,382,534	\$2,585,613	\$2,585,613
Total Expenses	\$1,361,667	\$1,663,742	\$1,696,568	\$1,698,579
<b>Net Profit / (Loss)</b>	<b>\$535,234</b>	<b>\$718,792</b>	<b>\$889,045</b>	<b>\$887,034</b>

The ‘Net Revenue’ line item is gross in-center and training revenue, minus deductions for bad debt and charity care.

The ‘Total Expenses’ line item includes all expenses related to the projected operation of the 9-station facility in years 2019 through 2022. The expenses also include allocated costs as described above. Medical director costs are split between the Leah Lane facility and the Colville facility, and were allocated in the pro forma on a per treatment basis.

Public Comment

None

Rebuttal Comment

None

**Department Evaluation**

FMC Leah Layne is currently operating with eight dialysis stations. Fresenius Medical Care based its projected utilization of FMC Leah Layne on its current utilization, plus one additional station. This approach for an existing facility is reasonable.

As a special circumstance application, WAC 246-310-815(1)(b) requires an applicant to base its revenue projections on the current payer mix and base its expense projections on current expenses. Fresenius Medical Care provided both revenue and expense projections and based them on current operations.

Since FMC Leah Layne is currently operational, the facility has both an existing lease agreement and an existing medical director agreement. The lease agreement was executed in July 2009 and is valid for twelve years. The costs identified in the lease agreement can be substantiated in the revenue and expense statement.

Fresenius Medical Care provided a copy of the initial Medical Director Agreement among Inland Northwest Renal Care Group, LLC dba Rockwood Clinical P.S., and individual physician Constance Christ, MD. The agreement is currently effective and includes automatic annual renewals. The costs identified in the medical director agreement can be substantiated in the revenue and expense statement.

Based on the above information provided in the application, the department concludes that Fresenius Medical Care’s projected revenue and expense statement is reasonable. **This sub-criterion is met.**

(2) The costs of the project, including any construction costs, will probably not result in an unreasonable impact on the costs and charges for health services.

WAC 246-310-815 outlines the financial feasibility review requirements for dialysis projects. For this project, Fresenius Medical Care must demonstrate compliance with the following sub-sections of WAC 246-310-815(2). Using its experience and expertise the department compared the proposed project’s costs with those previously considered by the department.

**WAC 246-310-815(2)**

*An applicant proposing to construct finished treatment floor area square footage that exceeds the maximum treatment floor area square footage defined in WAC 246-310-800(11) will be determined to have an unreasonable impact on costs and charges and the application will be denied. This does not preclude an applicant from constructing shelled space.*

**Fresenius Medical Care**

For this sub-criterion, Fresenius Medical Care states that this project requires equipment, but no construction, to add a station to FMC Leah Layne. FMC Leah Layne provided its capital cost breakdown shown below. [source: Application, p17]

**Department’s Table 4  
Estimated Capital Costs  
FMC Leah Layne**

<b>Item</b>	<b>Total</b>
Moveable Equipment (dialysis machines)	\$604
<b>Total Estimated Capital Costs</b>	<b>\$604</b>

Specific to costs and charges for health services, Fresenius Medical Care provided the following statements. [source: Application, p18]

*“WAC 246-310-815(2) requires that applicants limit the costs of facility projects by creating a test of reasonableness in the construction of finished treatment floor area square footage. The treatment*

*floor area must not exceed the maximum treatment floor area square footage defined in WAC 246-310-800(11). As outlined in response to Question Eleven under the Project Description, Fresenius Medical Care does not propose to construct treatment floor space in excess of the maximum treatment floor area square footage, and thus, under the WAC 246-310-815(2) test, this project does not have an unreasonable impact on costs and charges.*

*Additionally, as noted in response to question seven, reimbursements for dialysis services are not subject to or affected by capital improvements and expenditures by providers; the proposed project will have no impact on increases in charges for services within the ESRD planning area.”*

Public Comment

None

Rebuttal Comment

None

Department Evaluation

The costs for adding one station to FMC Leah Layne is \$604. The costs are comparable to those reviewed in past applications for similar size station addition without construction. The department does not consider the capital expenditure to be excessive for this project.

Documentation provided in the application shows that FMC Leah Layne currently has Medicare and Medicaid reimbursements that equal 29.1% of the revenue at the dialysis center. This amount is reasonable and consistent with percentages reviewed and approved in past Fresenius Medical Care projects.

The department notes that Medicare and Medicaid patients typically make up the largest percentage of patients served by a dialysis facility. CMS implemented an ESRD Prospective Payment System (PPS). Under the new ESRD PPS, Medicare pays dialysis facilities a bundled rate per treatment. The rate is not the same for each facility.

Each facility, within a given geographic area, may receive the same base rate. However, there are a number of adjustments both at the facility and at patient-specific level that affects the final reimbursement rate each facility will receive. What a dialysis facility receives from its commercial payers will also vary. Even if two different dialysis providers billed the same commercial payer the same amount, the actual payment to each facility will depend on the negotiated discount rate obtained by the commercial payer from each individual provider. The department does not have an adopted standard on what constitutes an unreasonable impact on charges for health services. Based on department's understanding of how dialysis patients may qualify for Medicare payments, the department concludes that the information presented by Fresenius Medical Care about its revenue indicates this project may not have an unreasonable impact on charges for Medicare and Medicaid, since that revenue is dependent upon cost based reimbursement. The remaining 70.9% of revenue is combined commercial and other revenues.

Based on the above information provided in the application, the department concludes that Fresenius Medical Care's projected costs associated with the addition of one station to FMC Leah Layne would probably not have an unreasonable impact on the costs and charges for healthcare services in Adams County. **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.

**Fresenius Medical Care**

Fresenius Medical Care identified a capital expenditure of \$604 to add one station to FMC Leah Layne. Fresenius Medical Care intends to fund the project using corporate reserves. Fresenius Medical Care provided a letter from its corporate chief operating officer for kidney care to demonstrate an operational and financial commitment to the project. [source: Application, p19-20]

Fresenius Medical Care also provided a copy of its audited financial statements for years 2015 and 2016 to demonstrate sufficient reserves to finance the project. [source: Application, Exhibit 12]

Public Comment

None

Rebuttal Comment

None

**Department Evaluation**

Fresenius Medical Care intends to finance the project with reserves and demonstrated the funds are available. If this project is approved, the department would attach a condition requiring Fresenius Medical Care to finance the project consistent with the financing description provided in the application.

With a financing condition, the department concludes the Fresenius Medical Care project **meets this sub-criterion.**

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

Based on the source information reviewed and agreement to the conditions identified in the conclusion section of this evaluation, the department concludes that the Fresenius Medical Care project has 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 full time equivalents (FTEs) that should be employed for projects of this type or size. Therefore, using its experience and expertise the department determined whether the proposed staffing would allow for the required coverage.

**Fresenius Medical Care**

If this project is approved, Fresenius Medical Care expects the additional station would be operational by the end of March 2019. Year 2020 would be the facility's first full calendar year of operation and 2022 would be year three. Table 5 provides a breakdown of projected FTEs for current

year 2018, and projected years 2019 through 2022. [source: Application, p21 and screening response December 17, 2018 pdf 8]

**Department’s Table 5**  
**FMC Leah Layne**  
**Current Year 2018 and Projected Years 2019 – 2022**

<b>FTE by Type</b>	<b>CY 2019 Increase</b>	<b>CY 2020 Increase</b>	<b>CY 2021 Increase</b>	<b>CY 2022 Increase</b>
Nurse Manager	1.0	1.0	1.0	1.0
Outpatient RN	2.0	2.0	2.0	2.0
Patient Care Technician	4.25	4.25	4.38	4.38
Equipment Technician	0.50	0.50	0.50	0.50
Social Worker	0.25	0.26	0.28	0.28
Dietician	0.25	0.26	0.28	0.28
Secretary	0.25	0.26	0.28	0.28
<b>Total FTEs</b>	<b>8.50</b>	<b>8.54</b>	<b>8.72</b>	<b>8.72</b>

Fresenius Medical Care’s medical director is under contract at \$99,969 annual, but is not an employee and is not included in the table above. Fresenius Medical Care also provided the following clarifications related to the staffing table above. [source: December 17, 2018, screening response, pdf3]

*Fresenius Medical Care projects FTEs based on staffing ratios for patients per shift, FTE, or station count (including any exempt isolation station, in the case of biomed)*

Fresenius Medical Care provided a copy of the initial Medical Director Agreement among Inland Northwest Renal Care Group, LLC. dba Rockwood Clinic, PS, and individual physician Constance Christ, MD. The agreement was executed in year 2012. Fresenius Medical Care also provided a copy of the First Amendment to the Medical Director Agreement among the same entities. The agreement is currently effective and includes automatic annual renewals. [source: Application, Exhibit 9 and December 17, 2018, screening response, pdf7]

Fresenius Medical Care provided the following statements related to recruitment and retention of staff. [source: Application, p23]

*“FMC Leah Layne is an operational dialysis facility, which is staffed with qualified clinical and support personnel. By virtue of our geographic location, we anticipate recruiting additional staff from Adams County as well as from neighboring counties in the region. To be effective in staff recruitment and retention, IN-RCG offers competitive wage and benefit packages. Further, to ensure that we have adequate staff across all our facilities in Washington, we have built a local float pool of WA Licensed Patient Care Techs and RN’s to ensure we have coverage for patient care. Fresenius also has an internal staffing agency, Fresenius Travel, in which we request assistance. We also have the capability of using outside staffing agencies to fill critical needs.*

Public Comment

None

Rebuttal Comment

None

**Department Evaluation**

Information provided in the application demonstrates that Fresenius Medical Care is a well-established provider of dialysis services in Washington State and in Adams County. Its FMC Leah Layne has been operational since July 2009.

For this project, Fresenius Medical Care is proposing to one station to the existing center. The one station increase will require addition of approximately 0.22 FTES by the end of the third full year of operation—2022.

Based on the above information, the department concludes that Fresenius Medical Care has the ability and expertise to recruit and retain a sufficient supply of qualified staff for this project. **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) as identified in WAC 246-310-200(2)(a)(i). There are also no known recognized standards as identified in WAC 246-310-200(2)(a)(ii) and (b) that directs what relationships, ancillary and support services should be for a project of this type and size. Therefore, using its experience and expertise the department assessed the materials contained in the application.

**Fresenius Medical Care**

Fresenius Medical Care provides dialysis services throughout Washington State, including its FMC Leah Layne in Adams County. If this project is approved, FMC Leah Layne’s in-center stations will increase by one station. Fresenius Medical Care states that the following ancillary and support services would be provided on site: social services, nutrition, financial counseling, pharmacy access, patient and staff education, human resources, material management, administration and biomedical technical services.

Additional services are coordinated through Fresenius Medical Care’s corporate offices in Greenwood Village, Colorado and support offices in Moses Lake and Kennewick, Washington. [source: Application, p23]

Fresenius Medical Care also provided a listing of the entities it currently has working relationships with for its FMC Leah Layne. [source: Application, p23 and Exhibit 13]

Fresenius Medical Care provided the following statement related to the existing working relationships for FMC Leah Layne. [source: Application, p27]

*“FMC Leah Layne has an established relationship with the community and other health care providers in the area. The additional station will not only ensure timely access to dialysis services, but it will also realize increased efficiency and economies of scale. FMC Leah Layne’s transfer agreement with Providence Holy Family Hospital, Othello Community Hospital, Providence Sacred Heart Medical Center, and Valley Hospital.*

**Public Comment**

None

Rebuttal Comment

None

**Department Evaluation**

FMC Leah Layne has been operating in Adams County since the year 2009. All ancillary and support services have been established for the dialysis center since that time. Fresenius Medical Care states that no new agreements or revisions to existing agreements are necessary for this project.

The department also concludes that all other required ancillary and support agreements and relationships are already in place. **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.

The evaluation of WAC 246-310-230(5) is also evaluated under this sub-criterion, as it relates to facility compliance history. Compliance history is factored into the department’s determination that an applicant’s project would be operated in compliance with WAC 246-310-230(3).

**Fresenius Medical Care**

Fresenius Medical Care provided the following statements in response to this sub-criterion. [source: Application p27]

*“Both IN-RCG and Fresenius have proven track records in complying with applicable state and federal rules and regulations.”*

Public Comment

None

Rebuttal Comment

None

**Department Evaluation**

The department reviews two different areas when evaluating this sub-criterion. One is the conformance with Medicare and Medicaid standards and the other is conformance with state standards. To accomplish this task for this project, the department first reviewed the quality of care compliance history for all healthcare facilities operated outside of Washington State using the ‘star rating’ assigned by Centers for Medicare & Medicaid Services (CMS). Then the department focused on the CMS ‘star ratings’ for Washington State facilities.

CMS Star Rating for Out-of-State Centers

In the application, FMC states that it provides outpatient dialysis centers and services all across the United States and worldwide. FMC reports dialysis services to CMS for approximately 2,579

facilities. Of the 2,728 facilities reporting to CMS by FMC, 549 do not have the necessary amount of data to compile a star rating. For the remaining 2,357 facilities with a star rating, the national average rating is 3.87.

#### CMS Star Rating for Washington State Centers

For Washington State, FMC owns, operates, or manages 23 facilities in 12 separate counties. All of the 23 centers are operational. The Washington State average rating is 3.65.

The department also focused on its own state survey data performed by the Department of Health's Office of Health Systems Oversight.

#### Washington State Survey Data

While all 23 of FMC's facilities are operational, in the most recent three years, not all facilities have been surveyed. All surveys that did take place resulted in no significant non-compliance issues. [source: DOH OHSO survey data]

In this application, Fresenius Medical Care provided its initial Medical Director Agreement with Inland Northwest Renal Care Group, LLC. dba Rockwood Clinic, PS. The agreement identifies Dr. Christ as the medical director, and RN, Brenda Britos as the director of operations. Using data from the Medical Quality Assurance Commission, the department found that both professionals are compliant with state licensure and have no enforcement actions on the license.

The department also reviewed the compliance history of all known staff working at FMC Leah Layne which includes seven registered nurses, four dialysis technicians, a dietician, and a medical social worker. All known staff are compliant with state licensure and have no enforcement actions on the license

In review of this sub-criterion, the department considered the total compliance history of the dialysis facilities owned and operated by Fresenius Medical Care. The department concludes that Fresenius Medical Care has been operating in compliance with applicable state and federal licensing and certification requirements. The department also conclude there is reasonable assurance that the addition of one new station to FMC Leah Layne would not cause a negative effect on Fresenius Medical Care's compliance history. The department concludes that FMC Leah Layne's project **meets this sub-criterion.**

- (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.

#### Fresenius Medical Care

Fresenius Medical Care provided statements and supporting documentation to demonstrate compliance with this sub-criterion. [source: Application, p27]



*“The proposed project promotes continuity of care as it seeks to expand FMC Leah Layne’s existing dialysis care services.”*

Public Comment

None

Rebuttal Comment

None

**Department Evaluation**

Fresenius Medical Care has been a provider of dialysis services in Washington State for many years. FMC Leah Layne also has a history of establishing relationships with existing healthcare networks in Adams County. Additionally, Fresenius’s project would promote continuity in the provision of healthcare services in the Adams County planning area by increasing the number of stations at FMC Leah Layne.

FMC provided documentation in the application to demonstrate that the project would promote continuity in the provision of health care services in the community and not result in unwarranted fragmentation.

Based on the information above, the department concludes that Fresenius Medical Care’s project **meets this sub-criterion.**

- (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.*

**Department Evaluation for Fresenius Medical Care**

This sub-criterion was evaluated in conjunction with WAC 246-310-230(3) above and is considered met.

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

Based on the source information reviewed and agreement to the conditions identified in the conclusion section of this evaluation, the department concludes that the FMC project has met the cost containment criteria in WAC 246-310-240.

- (1) *Superior alternatives, in terms of cost, efficiency, or effectiveness, are not available or practicable.*  
To 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 has met the applicable criteria in WAC 246-310-210 through 230 criteria, in step two, the department assesses the other options considered by the applicant. If the department determines the proposed project is better or equal to other options considered by the applicant and the department has not identified any other better options this criterion is determined to be met unless there are multiple applications.

If there are multiple applications, the department's assessment is to apply any service or facility superiority criteria contained throughout WAC 246-310 related to the specific project type in Step three. Under WAC 246-310-818(11) this step does not to apply Special Circumstance applications.

### **Step One**

For this project, Fresenius Medical Care met the applicable review criteria under WAC 246-310-210, 220, and 230. Therefore, the department moves to step two for this project.

### **Step Two**

For this sub-criterion, Fresenius Medical Care considered and discussed two options before submitting this application. Below is Fresenius Medical Care's discussion related to both options. [source: Application, p28]

#### **Do nothing**

*“Currently, FMC Leah Layne is a very busy facility, with utilization of 3.75 patients per station in the latest monthly data available from the NWRN, and thus has little additional capacity to provide access to Adams County patients. With strong and consistent demand for access to FMC Leah Layne's services and without expansion, patients will be forced to dialyze at less convenient times, locations, or even out of the planning area entirely. This alternative was rejected.”*

#### **Add two stations to FMC Leah Layne, rather than one station**

*“While FMC Leah Layne would have loved to have been able to pursue the option of adding two stations, rather than one, this option was not legally feasible per WAC 246-310-828(7), which requires that “for 3.2 planning areas, a special circumstance one- or two-station expansion will not be approved if, with the requested new station(s), the applicant's kidney dialysis facility would fall below a calculated 3.5 patients per station. Data used to make this calculation is the average patients per station from subsection (1)(a) of this section.”*

*In this case, the addition of two (2) stations would mean that FMC Leah Layne would have had 4.28 patients per station over the previous six (6) month period, per the patient census data provided by the NWRN in Table 10. Operationally, FMC Leah Layne would have no difficulty accommodating an additional two stations, rather than one, and patients would be well-served by the access provided, but given the WAC 246-310-828(7) threshold was not met FMC Leah Layne rejected that option.”*

#### **Public Comment**

None

#### **Rebuttal Comment**

None

### **Department Evaluation**

Fresenius Medical Care provided a comprehensive discussion of the “do nothing” alternative before submitting this application. Specifically, Fresenius Medical Care operates only one center in Adams County and asserts it is a highly utilized facility. Fresenius Medical Care appropriately rejected the ‘do nothing’ alternative.

Fresenius Medical Care's rationale for rejecting the option of adding two stations to FMC Leah Layne is reasonable because it is consistent with the standard outlined in WAC 246-310-828(7).

Special circumstance applications are designed to quickly bring stations online in highly utilized facilities. The department is satisfied that the applicant appropriately chose to submit a special circumstance application for FMC Leah Layne in order to promote immediate access to services.

The department concludes that the project submitted by Fresenius Medical Care is the best available alternative for the community. **This sub-criterion is met.**

- (2) In the case of a project involving construction:
  - (a) The costs, scope, and methods of construction and energy conservation are reasonable;
  - (b) The project will not have an unreasonable impact on the costs and charges to the public of providing health services by other persons.

**Department Evaluation**

Since Fresenius Medical Care’s capital expenditure is solely related to dialysis equipment, this sub-criterion does not apply to this project.

- (3) The project will involve appropriate improvements or innovations in the financing and delivery of health services which foster cost containment and which promote quality assurance and cost effectiveness.

**Fresenius Medical Care**

Fresenius Medical Care provided the following information for this sub-criterion. [source: Application, p27]

*“The approval of the expansion project request will allow for the facility to optimize its capacity and achieve corresponding economies of scale.”*

**Public Comment**

None

**Rebuttal Comment**

None

**Department Evaluation**

Fresenius Medical Care’s project could have the potential to improve delivery of dialysis services to the residents of Adams County with the addition of another station in the planning area. Consistent with the special circumstance rules, FMC Leah Layne would be operating the additional station within six months of approval. **This sub-criterion is met.**