STATE OF WASHINGTON

DEPARTMENT OF HEALTH

Olympia, Washington 98504

July 28, 2020

Luca Chiastra, Regional Vice President – Rocky Mountain Region
Fresenius Medical Care
5251 DTC Parkway, Suite 500
Greenwood Village, CO 80111

Sent via email: Luca.Chiastra@fmc-na.com

RE: Certificate of Need Application #20-16, Fresenius Kidney Care Leah Layne

Dear Mr. Chiastra:

We have completed review of the Certificate of Need application submitted by Fresenius Medical Care Holdings, Inc. The application proposes to expand Fresenius Kidney Care Leah Layne by adding two general use dialysis stations, for a facility total of 12 stations which includes one Certificate of Need-exempt isolation station. Fresenius Kidney Care Leah Layne is located in the Adams County ESRD Planning Area. 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 Fresenius Medical Care Holdings, Inc. agrees to the following in its entirety.

Project Description:

This certificate approves the addition of two general use dialysis stations to the ten-station Fresenius Kidney Care Leah Layne, for a facility total of twelve dialysis stations. Services provided at Fresenius Kidney Care Leah Layne include in-center hemodialysis, home hemodialysis, home peritoneal dialysis, training and support for dialysis patients, an isolation dialysis station, a bed dialysis station, and shifts beginning after 5:00 pm.

Station Type	CMS Certified Stations	Station Counted for Station Use and Methodology
General Use In-Center Stations	10	10
Permanent Bed Station	1	1
Exempt Isolation Station	1	0
Isolation Station	0	0
Total Stations	**12**	**11**

Conditions:

1. Approval of the project description as stated above. Fresenius Medical Care Holdings, Inc. 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 Holdings, Inc. shall finance this project using corporate reserves, as described in the application.

Approved Costs:

The approved capital expenditure for this two-station addition is $138,787. This amount represents costs of construction, fees, equipment, and applicable sales tax. All costs will be paid by Fresenius Medical Care Holdings, Inc.

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:	Physical Address:
Department of Health	Department of Health
Certificate of Need Program	Certificate of Need Program
Mail Stop 47852	111 Israel Road SE
Olympia, WA 98504-7852	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,

Eric Hernandez, Program Manager
Certificate of Need
Office of Community Health Systems

Enclosure

CC: Frank Fox, PhD, frankgfox@comcast.net

YEAR 2019 CYCLE TWO NON-SPECIAL CIRCUMSTANCE EVALUATION DATED JULY 28, 2020 FOR INLAND NORTHWEST RENAL CARE GROUP, LLC A SUBSIDIARY OF FRESENIUS MEDICAL CARE HOLDINGS, INC. DBA FRESENIUS KIDNEY CARE LEAH LAYNE PROPOSING TO ADD DIALYSIS STATION CAPACITY IN ADAMS COUNTY

APPLICANT DESCRIPTION

Fresenius Medical Care Holdings, Inc.

Inland Northwest Renal Care Group, LLC is one of many subsidiaries owned by Renal Care Group, Inc. (RCG). RCG is responsible for the operation of facilities under its subsidiaries which are separate legal entities. In March of 2006, Fresenius Medical Care Holdings, Inc. (FMC) became the sole owner of RCG. In addition to the entities listed above, FMC also owns and operates two other entities, QualiCenters, Inc. and National Medical Care, Inc.

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 25 kidney dialysis facilities. [Source: Application, Exhibit 2, and CMS dialysis facility compare, updated April 22, 2020

For ease of reference in this evaluation, Fresenius Medical Care Holdings, Inc. is referred to as "FMC", and the dialysis facility, Fresenius Kidney Care Leah Layne is referred to as "FKC Leah Layne". For the purpose of this application, the department recognizes Fresenius Medical Care Holdings, Inc. as the applicant.

PROJECT DESCRIPTION

This project focuses on a specific FMC dialysis facility, Fresenius Kidney Care Leah Layne (FKC Leah Layne), located at 530 South 1st Avenue, Othello [99344] in the Adams County ESRD Planning Area. Currently, FKC Leah Layne has eight general use dialysis stations, one permanent bed station, and one exempt isolation station, see the following table. [Source: CN historical files, CN1802]

Station Type	CMS Certified Stations	Station Counted for Station Use and Methodology
General Use In-Center Stations	8	8
Permanent Bed Station	1	1
Exempt Isolation Station	1	0
Isolation Station	0	0
Total Stations	**10**	**9**

This application proposes to add two general use stations to FKC Leah Layne, resulting in ten general use in-center dialysis stations, for a facility total of 12 stations. FKC 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,
- Home hemodialysis patients,
- Continuous cycle peritoneal dialysis patients,

Additional services provided will include:

- Training and support for home hemodialysis patients, and
- Training and support for peritoneal hemodialysis patients.

[Source: Application, p7]

FMC's estimated capital expenditure for this proposal is $138,787 and all costs are associated with construction, fees, equipment and applicable sales tax. All costs would be paid by FMC, using its corporate reserves. [Source: Application, pp 15-16 and Exhibit 13]

Within the application materials, FMC estimated the additional stations would be operational in May 2021. [Source: February 13, 2020 screening response, p2] Under this timeline, full calendar year one is 2022 and full calendar year three is 2024.

APPLICABILITY OF CERTIFICATE OF NEED LAW

FMC's application proposes to add two dialysis stations 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).

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.

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 must also demonstrate compliance with applicable kidney disease treatment center criteria outlined in WAC 246-310-800 through 833. For this application submitted under WAC 246-310-806 Nonspecial Circumstance, 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 246-310-818	Special circumstances one- or two-station expansion—Eligibility criteria and application process
WAC 246-310-821	Kidney disease treatment facilities—Standards for planning areas without an existing facility
WAC 246-310-824	Kidney disease treatment centers—Exceptions
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 2019 concurrent review cycle, the data must be received before February 16, 2019. FMC submitted the data elements on February 7, 2019. 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.

WAC 246-310-803 and WAC 246-310-827 allow for public review and correction to data submissions prior to any concurrent review cycle. Therefore, if the department receives public comments related to data submission under WAC 246-310-803 or WAC 246-310-827 during a review, the comments will not be considered and discussed.

TYPE OF REVIEW

As directed under WAC 246-310-806, the department accepted this application under the Kidney Disease Treatment Centers-Nonspecial Circumstances Concurrent Review Cycle Two for calendar year 2019. FMC's application was the only project submitted for Adams County. Consistent with sub-section WAC 246-310-806(8), the department converted the review to a regular review timeline. Below is the chronological summary of the review timelines.

APPLICATION CHRONOLOGY

Action	FMC
Letter of Intent Submitted	October 31, 2019
Application Submitted	December 2, 2019
Department's Pre-review Activities including • DOH First Screening Letter • Applicant's First Screening Responses Received • DOH Second Screening Letter • Applicant's Second Screening Responses Received	 December 31, 2019 February 13, 2020 March 3, 2020 April 17, 2020
Beginning of Review	April 29, 2020
End of Public Comment[1] • Public comments accepted through the end of public comment • No public hearing requested or conducted	June 3, 2020
Rebuttal Comments Deadline	June 17, 2020
Department's Anticipated Decision	August 3, 2020
Department's Actual Decision	July 28, 2020

AFFECTED PERSONS

Affected persons are defined under WAC 246-310-010(2). In order to qualify as an affected person, someone must first qualify as an "interested person," defined under WAC 246-310-010(34). For this project, no entities sought affected person status.

SOURCE INFORMATION REVIEWED

- FMC's Certificate of Need application received December 2, 2019
- FMC's first screening response received February 13, 2020
- FMC's second screening response received April 17, 2020
- Historical kidney dialysis utilization data from the Northwest Renal Network
- Department of Health's ESRD Need Projection Methodology for the Adams County ESRD planning area posted to its website in March of 2019
- Licensing data provided by the Medical Quality Assurance Commission, Nursing Quality Assurance Commission, and Health Systems Quality Assurance Office of Customer Service

[1] No public comments were submitted for this project by the public comment deadline, June 3, 2020. As a result, FMC did not provide rebuttal comments.

- Compliance history obtained from the Washington State Department of Health Office of Health Systems Oversight
- Fresenius' website at https://fmcna.com/
- Northwest Renal Network website at www.nwrn.org
- Centers for Medicare and Medicaid website at www.medicare.gov/dialysisfacilitycompare
- Certificate of Need historical files

CONCLUSION

Fresenius Medical Care Holdings, Inc.

For the reasons stated in this evaluation, the application submitted by FMC proposing to add two dialysis stations to FKC Leah Layne located in the Adams County ESRD Planning Area, 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 two general use dialysis stations to the ten-station Fresenius Kidney Care Leah Layne, for a facility total of 12 dialysis stations. Services provided at Fresenius Kidney Care Leah Layne include in-center hemodialysis, home hemodialysis, home peritoneal dialysis, training and support for dialysis patients, an isolation dialysis station, a bed dialysis station, and shifts beginning after 5:00 pm.

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1. Approval of the project description as stated above. Fresenius Medical Care Holdings, Inc. 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 Holdings, Inc. shall finance this project using corporate reserves, as described in the application.

Approved Costs:

The approved capital expenditure for this two-station addition is $138,787. This amount represents costs of construction, fees, equipment, and applicable sales tax. All costs will be paid by Fresenius Medical Care Holdings, Inc.

CRITERIA DETERMINATIONS

A. Need (WAC 246-310-210)

Fresenius Medical Care Holdings, Inc.

Based on the source information reviewed, the department concludes that FMC has met the need criteria in WAC 246-310-210. The kidney disease treatment facility numeric methodology applied is detailed under WAC 246-310-812(4). WAC 246-310-210(1) criteria is also identified in WAC 246-310-812(6).

(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 246-310-812 requires the department to evaluate kidney disease treatment facility applications based on the population's 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 facility numeric methodology is applied and detailed under WAC 246-310-812(4). WAC 246-310-210(1) criteria and also identified in WAC 246-310-812(5) and (6).

WAC 246-310-812 Kidney Disease Treatment Facility Numeric Methodology

WAC 246-310-812 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 (NWRN).[2]

The first step in the methodology calls for the determination of the type of regression analysis to be used to project resident in-center station need. [WAC 246-310-812(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.[3]

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 NWRN data, again concluding with the base year. [WAC 246-310-812(4)(b) and (c)]

[2] NWRN 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]

[3] WAC 246-310-800(2) defines base year as "the most recent calendar year for which December 31 data is available as of the letter of intent submission date from the *Northwest Renal Network's Modality Report*." For this project, the base year is 2018.

WAC 246-310-812(5) identifies that for all planning areas except Adams, Columbia, Douglas, Ferry, Garfield, Jefferson, Kittitas, Klickitat, Lincoln, Okanogan, Pacific, Pend Oreille, San Juan, Skamania, Stevens, and Wahkiakum counties, the number of projected patients is divided by 4.8 to determine the number of stations needed in the planning area. WAC 246-310-812(6) states 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 246-310-812(4)(d)] The department calculates the numeric methodology for each of the 57 planning areas and posts the results to its website. Below is a discussion of the numeric methodology submitted by FMC.

Fresenius Medical Care Holdings, Inc.
FMC proposes to expand FKC Leah Layne by two stations. FMC provided a numeric methodology that matches the numeric methodology authored by the department and posted to the department's website for Adams County. Both methodologies projected need for four stations in projection year 2023 in Adams County.

Public Comment
None

Rebuttal Comment
None

Department Evaluation of the Numeric Methodology for Adams County
The department calculates the numeric methodology for each of the 57 ESRD planning areas in Washington and posts each of the results to its website. The department's year 2019 numeric methodology was posted in March 2019. This methodology will be used for evaluating this project.

Based on the calculation of the annual growth rate in the planning area, the department used the linear regression to determine numeric need. The number of projected patients was divided by 3.2 to determine the number of stations needed in Adams County. A summary of the department's numeric methodology is shown in the table below.

Department's Table 1
Adams County DOH Numeric Methodology Summary

3.2 in-center patients per station		
2023 Projected # of stations	**Minus Current # of stations**	**2023 Net Need or (Surplus)**
13	9	4

As shown in the table, once the nine existing stations are subtracted from the projected need, the result is a net need of four stations. The department's methodology is included in this evaluation as Appendix A. The department concludes that **this sub-criterion is met**.

In addition to the numeric need, the department must determine whether other services and facilities of the type proposed are not or will not be sufficiently available or accessible to meet the dialysis

station need.[4] The department uses the standards in WAC 246-310-812(5) and WAC 246-310-812(6).

WAC 246-310-812(6)

Before the department approves new in-center kidney dialysis stations in a 3.2 planning area, all certificate of need counted stations at each facility in the planning area must be operating at or above 3.2 in-center patients per station. If the certificate of need approval is contested, the eight months would start from the date of the final department or judicial order. However, when a planning area has facilities with stations not meeting the in-center patients per station standard, the department will consider the 3.2 in-center patients per station standard met for those facilities when:

(a) All stations for a facility have been in operation for at least three years; or

(b) Certificate of need approved stations for a facility have not become operational within the timeline as represented in the approved application.

...Both resident and nonresident patients using the kidney dialysis facility are included in this calculation. Data used to make this calculation must be from the most recent quarterly modality report from the Northwest Renal Network as of the letter of intent submission date.

For Adams County, WAC 246-310-812(6) requires all CN approved stations in the planning area be operating at or above 3.2 in-center patients per station. There is one dialysis center operating, or approved to operate, in Adams County. It is FKC Leah Layne, FMC provided the following table showing that its facility was operating at or above the 3.2 standard. [Source: Application, p8]

Applicant's Table 2

Table 2. Adams County Dialysis Planning Area Provider Utilization – 2Q2019

Facility	Number of Stations	06/30/19 Number of Patients Per Quarterly In-Center Data	06/30/19 Patients/ Station
FKC Leah Layne	9	30	3.33

*Station count excludes 1 isolation station

Source: Northwest Renal Network Modality Reports, 06/30/19

Public Comment

None

Rebuttal Comment

None

Department Evaluation

WAC 246-310-812(6) states that the "*data used to make this calculation must be from the most recent quarterly modality report from the Northwest Renal Network as of the letter of intent submission date."* The date of the relevant letter of intent is October 31, 2019. The data available as of October 31, 2019, is September 30, 2019. The utilization of FKC Leah Layne is shown in the following table.

[4] WAC 246-310-210(1)(b).

Department's Table 2
FKC Leah Layne
September 30, 2019, Utilization Data for Adams County

Facility Name	# of Stations	# of Patients	Patients/Station
FKC Leah Layne	9	34	3.78

As shown in the table, the existing facility meets this standard.

Based on the information above, the department concludes that **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.[5] 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 Holdings, Inc.

FMC provided the following information for this sub-criterion. [Source: Application, p12]

"All individuals identified as needing dialysis services will continue having access to FKC Leah Layne. FKC Leah Layne's admission policies prohibits discrimination on the basis of race, income, ethnicity, sex or handicap. A copy of the admission policy is contained in Exhibit 7.

[5] WAC 246-453-010(4).

A copy of our charity care policy is contained in Exhibit 6"

FMC also provided the following policies for this facility. [Source: Application, Exhibits 6 and 7]

- Charity Care/Indigence Policy
- Patient Admission Policy
- Patient Rights and Responsibilities Policy
- Patient Rights and Responsibilities List
- Patient Acknowledgement of Receipt of Rights and Responsibilities

Public Comment
None

Rebuttal Comment
None

Department Evaluation

FMC provided copies of the necessary policies used at all FMC dialysis centers, including the Adams County facility. The policies reflect FMC's commitment to provide adequate access to all residents of the service area. They are consistent with those reviewed and approved by the department in the past.

Medicare and Medicaid Programs

FMC currently participates in Medicare and Medicaid programs at its dialysis facilities. As directed by WAC 246-310-815(1)(b) and since it is an existing facility, FMC provided a table showing the historical and projected percentages of revenues by payer and revenues by patient. Following is a table summarizing the historical and projected revenues of FKC Leah Layne. [Source: April 17, 2020, screening response, p5]

Department's Table 3
FKC Leah Layne
Payer Mix

Source	Historical Percentages		Projected Percentages	
	% of Patients	% of Revenue	% of Patients	% of Revenue
Medicare	52.8%	15.1%	52.8%	15.1%
Commercial	9.3%	78.4%	9.3%	78.4%
Medicaid	26.5%	2.5%	26.5%	2.5%
Medicare Advantage	3.3%	1.4%	3.3%	1.4%
Medicaid Risk	2.9%	1.0%	2.9%	1.0%
Miscellaneous Insurance	2.0%	0.9%	2.0%	0.9%
Self Pay	3.2%	0.8%	3.2%	0.8%
Old Revenue Accounts	0.0%	0.1%	0.0%	0.1%
Total*	**100.0%**	**100.2%**	**100.0%**	**100.2%**

*Totals may not add to 100% based on rounding

Based on the information above, the department concludes that **this sub-criterion is met**.

(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)

Fresenius Medical Care Holdings, Inc.
Based on the source information reviewed the department concludes that FMC 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, each applicant must demonstrate compliance with the following sub-sections of WAC 246-310-815(1).

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.*

Fresenius Medical Care Holdings, Inc.
For FMC's project, sub-sections (a) and (b) of WAC 246-310-815(1) apply. FMC provided the following information related to this sub-criterion.

"*May 2021 is also the revised timeline Leah Layne anticipates to first treat patients in the expansion stations.*" [Source: February 13, 2020, screening response, p2]

"*It is assumed the number of treatments per patient is 144 treatments per year.*" [Source: Application, p 12]

"*In-Center Forecast Methodology*
The time periods preceding project completion are based on the 2019 patient counts (31 patients) given the existing facility is at full capacity. Incremental growth for in-center patients is assumed to begin when the new stations become operational (May 2021) and is based on the incremental growth featured in step (b) of the need methodology which is added to the 4Q2018 FKC Leah Layne volumes.

It is assumed the number of treatments per patient is 153.5 treatments per year based on Leah Layne 2019 actuals.

Home Forecast Methodology
Please note that Leah Layne does not currently have home dialysis patients but is capable to provide such care." [Source: April 17, 2020, screening response, pp4-5]

"*Information and assumptions used to prepare Table 11 include:*
・The wage and salary figures are based on FKC Leah Layne current actuals. They are held constant over the forecast period.
・It is assumed a FTE ("full time equivalent") employee works 2,080 hours per year.
・Non-productive hours are estimated at 10% of productive hours, based on FMC experience.
・Benefits are calculated at 22.1% of wages and salaries based on FKC Leah Layne 2018 actuals.
・The staff to patient ratio matrix below was used to construct minimum FTE counts for the projection years based on future patient counts presented in Table 7." [Source: Application, p19]

"*The staff to patient ratio matrix below was used to construct minimum FTE counts for the projection years based on future patient counts. Except for the position 'Secretary', Leah Layne's 2019 FTE counts were higher than the minimum FTEs projected according to the staff to patient ratios. Therefore, the FTE counts for non-secretary positions are kept at their 2019 values. The projected secretary FTEs are based on the staff to patient ratios identified below.*" [Source: April 17, 2020, screening response, p6]

Applicant's Table

	Staff to Patient Ratios (FTE Staff)
PCT (1)	1:8
RN (2)	1:20
Equipment Technician (3)	1:125
Social Worker (3)	1:125
Dietician (3)	1:125
Secretary (3)	1:125
Nurse Manager (4)	1

(1) A PCT works two shifts of patients each day, with 4 patients per shift.
(2) A RN works two shifts of patients per day, with 10 patients per shift.
(3) These FTEs are staffed based on staff-to-patient ratios identified in the table.
(4) The Center for Medicare and Medicaid ("CMS") requires that a dialysis facility be staffed with one FTE manager, irrespective of size of the facility or number of patients.

[Source: April 17, 2020, screening response, p6]

"'*Admin Expenses' includes: taxes, transportation/lodging/misc. travel – mileage, telephone, recruiting, printing, meals, internet, bank charges, office supplies, professional development, promotion, postage, and freight. It is held constant based on 2018 actuals.*

'G&A' includes: administrative allocations, which in turn is comprised of the expected contribution from FKC Leah Layne toward billing, computer costs, regional administration, finance center & financial coordinators, sales & account management, people management, and strategic business

operations. It is held constant based on 2018 actuals." [Source: February 13, 2020, screening response, p7]

Applicant's Table

FKC Leah Layne *Pro Forma Assumptions*
Patient Volumes
Utilization projections, including the assumptions used to derive the forecasts, are presented in Appendix A of April 2020 screening response text.
It is assumed the number of treatments per patient is 153.5/year based on Leah Layne full year 2019 actuals. There is an adjustment in 2021 to reflect only partial year utilization.
Revenues
In-center revenues are based on CY2019 FKC Leah Layne data ("actuals"), given it is an existing facility. Payer mix statistics have also been obtained from FKC Leah Layne actuals for the most recent calendar year. Revenues are calculated by payer and treatment. Bad debt and charity care are subtracted from revenues to yield net revenue figures.
Charity Care
Calculated at 0.88% of revenue based on the experience of Fresenius' facilities in Washington State.
Bad Debt
Calculated on a per treatment basis from FKC Leah Layne actuals.
Expenses
Unless otherwise noted, expenses have been calculated based on CY2019 FKC Leah Layne actuals.
Medical supplies, ancilliary, and 'other med' expenses have been calculated on a per treatment basis from FKC Leah Layne actuals.
Personnel expenses are based on identified patient to staff ratios and incorporates a 10% non-productive factor. Wage figures have been compiled from current rates at the FKC Leah Layne facility.
Rent Expense is based on 2nd Amendment to the Lease. Renewal terms (i.e. Fair Market Value) is assumed to equal Lease Years 11-12 base rent given inflation is excluded from model
Existing depreciation/amortization, other property expenses (property taxes, CAM), and interest expense are based on full year 2019 Moses Lake actuals, including accounting adjustments applicable under International Financial Reporting Standards (IFRS).
Project-related Depreciation is straight-line; assumes 10 years on leaseholds and 8 years on equipment.
Physician Compensation: Page 2 from the 2nd amendment to the Medical Director Agreement (MDA) sets fees at $99,968.61 as of the commencement date (August 24, 2015) and increases by 3% each year thereafter. The $99,968.61 fee represents a lump sum for both Fresenius' Leah Layne and Colville facilities. Fresenius allocates the MDA fee based on a treatment basis. Projected physician compensation fees are based on (1) calculating the physician compensation fees per treatment from 2019 actuals, (2) applying a 3% year-over-year fee escalator, and (3) multiplying by the number of treatments in the applicable forecast period.

[Source: April 17, 2020, screening response, p11]

Additionally, FMC provided historical and projected revenue information.

Applicant's Table

Table 3. FKC Leah Layne Dialysis Center, Projected Payer Mix, by Revenue and by Patient

Payor Class	Mix Based on Treatments	Mix based on Revenue
Medicare	52.8%	15.1%
Commercial	9.3%	78.4%
Medicaid	26.5%	2.5%
Medicare Adv	3.3%	1.4%
Medicaid Risk	2.9%	1.0%
Misc. Ins	2.0%	0.9%
Self Pay	3.2%	0.8%
Old Revenue Accounts	0.0%	0.1%
TOTAL	**100%**	**100%**

*Based on FKC Leah Layne CY2019 actuals

[Source: April 17, 2020, screening response, p5]

Using the assumptions stated earlier, FMC projected the end-of-year number of in-center dialyses and patients for years 2022 through 2024, which are shown in following table. [Source: Application and April 17, 2020, screening responses, revised Exhibit 8B]

Department's Table 4
FKC Leah Layne
Projected Utilization for 2022 – 2024

	2022 Full Year 1	2023 Full Year 2	2024 Full Year 3
Number of Stations	11	11	11
Total In-center Treatments	5,527	5,834	5,987
Average In-center Patient Count	36	38	39
Average Treatment per In-center Patient	153.5	153.5	153.5

FMC also projected the revenue, expenses, and net income for 2022 through 2024, which are shown in following table. [Source: April 17, 2020, screening responses, revised Exhibit 8B]

Department's Table 5
FKC Leah Layne
Projected Revenue and Expenses for 2022- 2024

	2022 Full Year 1	2023 Full Year 2	2024 Full Year 3
Net Revenue	$2,729,162	$2,956,763	$3,069,281
Total Expenses	$1,797,551	$1,821,434	$1,834,658
Net Profit / (Loss)	$931,611	$1,135,329	$1,234,623

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

The 'Total Expenses' line item includes all projected expenses related to the operation of the 12-station (including the exempt, uncounted isolation station) facility in years 2022 through 2024. The expenses also include allocated costs consistent with historical FMC percentages.

Medical director costs vary from year to year with a three percent year-over-year increase and allocation between two facilities (FKC Leah Layne and Colville) based on treatments. The forecast statement amounts are consistent with the executed agreement in the application. [Source: April 17, 2020, screening response, Revised Exhibit 8B]

Public Comment
None

Rebuttal Comment
None

Department Evaluation
FMC proposes to expand FKC Leah Layne by two dialysis stations. FMC based its projected utilization on the historical utilization of FKC Leah Layne consistent with WAC 246-310-815(1)(a) and (b). Based on a review of the assumptions used for projecting utilization of the 12-station (including the exempt, uncounted isolation station) dialysis center, the department concludes they are reasonable.

FMC provided a copy of the executed lease agreement for the site to demonstrate site control. Since FMC will be leasing the site, lease costs were included in pro forma revenue and expense statement. FMC provided corrections to the pro forma revenue and expense statement in screening.

FMC also provided a copy of the executed Medical Director Agreement that substantiates the costs identified in the pro form revenue and expense statement.

For FMC's project, the department concludes that **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, FMC must demonstrate compliance with the following sub-sections of WAC 246-310-815(2).

WAC 246-310-815(2)
An applicant proposing to construct a 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 Holdings, Inc.
FMC provided the following tables under this sub-criterion. [Source: Application, Exhibit 5]

Applicant's Tables from Exhibit 5

MAXIMUM ALLOWABLE TREATMENT AREA SQUARE FOOTAGE CALCULATION			
WAC 246-310-800 (11)			
AREA	**MAX. ALLOWABLE SF**	**# STATIONS**	**CALCULATED SF**
GENERAL USE/NON-ISOLATION	150 SF/STATION	10	1,500
ISOLATION STATION	200 SF/STATION	1	200
BED STATION	200 SF/STATION	1	200
FUTURE EXPANSION STATIONS	150 SF/STATION	2	300
SUBTOTAL			2,200
OTHER TREATMENT	75% SUBTOTAL		1,650
TOTAL MAXIMUM SF - TREATMENT FLOOR AREA			3,850

ACTUAL SQUARE FOOTAGE			
WAC 246-310-800 (11)			
AREA	**ACTUAL UNIT SF**	**# STATIONS**	**CALCULATED SF**
GENERAL STATION	80 SF/STATION	10	800
ISOLATION STATION	120 SF/STATION	1	120
BED STATION	80 SF/STATION	1	80
FUTURE EXPANSION STATIONS	80 SF/STATION	0	0
SUBTOTAL			1,000
OTHER TREATMENT FLOOR AREA			796
TOTAL ACTUAL SF - TREATMENT FLOOR AREA			1,796
NON-TREATMENT FLOOR AREA			3,325
TOTAL ACTUAL SF - CLINIC AREA			5,121

TOTAL MAXIMUM SF - TREATMENT FLOOR AREA		TOTAL ACTUAL SF - TREATMENT FLOOR AREA
3,850 SF	>	1,796 SF

FMC provided a copy of its existing and proposed line drawings for its dialysis center. Consistent with WAC 246-310-800(11), FKC Leah Layne's allowable maximum treatment floor area square footage for 12 stations is 3,850 square feet. FMC's project will use 1,796 square feet. [Source: Application, Exhibit 5 and February 13, 2020 screening response, Exhibit 16]

Specific to the costs and charges for health services, FMC provided the statements below. [Source: Application, p16]

"This project has no impact on either charges or payment, as reimbursement for kidney dialysis services is based on a prospective composite per diem rate. In the case of government payers, reimbursement is based on CMS (Center for Medicaid and Medicare) fee schedules which have

nothing to do with capital expenditures by providers such as Fresenius. In the case of private sector payers, Fresenius negotiates national, state, and regional contracts with payers. These negotiated agreements include consideration/negotiation over a number of variables, including number of covered lives being negotiated; the provider's accessibility, including hours of operation; quality of care; the provider's patient education and outreach; its performance measures such as morbidity and/or mortality rates; and increasingly, consideration of more broad performance/quality measures, such as the CMS Quality Incentive Program ('QIP') Total Performance Score ('TPS').

Fresenius does not negotiate any of its contracts at the facility-level, thus, the capital costs associated with the proposed FKC Leah Layne expansion would have no impact on payer negotiations or levels of reimbursement. In this regard, facility-level activities, such as number of FTEs, operating expenses or capital expenditures have no effect on negotiated rates, since such negotiations do not consider facility-level operations. As such, the proposed FKC Leah Layne expansion will have no effect on rates Fresenius would receive in the Adams County Dialysis Planning Area."

Public Comment
None

Rebuttal Comment
None

Department Evaluation
The estimated cost for this project is $138,787, which includes all costs associated with the two station expansion. The costs are comparable to those reviewed and approved in past applications for similar type projects and similar sized facilities. The department does not consider the capital expenditure to be excessive for this project.

FKC Leah Layne's projected combined Medicare and Medicaid reimbursements is 20.0% of revenue. Combined commercial, miscellaneous insurance, and self-pay is 80.0% of revenue. Although the majority of dialysis payments are by Medicare and Medicaid reimbursement, this demonstrates that even having a small percentage of commercial payers (FKC Leah Layne's percent of historical commercial patients is 9.3%) can impact a facility's bottom line. The projected figures although atypical appear reasonable since they are based on the existing facility's actual historical amounts.

Regardless of FMC's projections, under the new ESRD PPS payment system, Medicare pays dialysis facilities a bundled rate per treatment and that 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 the department's understanding of how dialysis patients may qualify for Medicare payments, the department concludes that the information provided by FMC indicates that this project would not have an unreasonable impact on charges for Medicare and Medicaid, since that revenue is dependent upon cost based reimbursement.

To be compliant with WAC 246-310-800(11), FMC's allowable maximum treatment floor area square footage for 12-station facility is 3,850. FMC's project will use 1,796 square feet. FMC's project does not exceed the maximum treatment floor area square footage allowable.

Based on the above information provided in the application, the department concludes that FMC's projected costs associated with the this project would not have an unreasonable impact on the costs and charges for healthcare services in Adams County, the department concludes that **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 applicant's projected source of financing to those previously considered by the department.

Fresenius Medical Care Holdings, Inc.

FMC provided the following statement about financing the $138,787 estimated capital expenditure costs for this project. *"Fresenius is the sole applicant and entity responsible for the estimated capital costs identified above."* [Source: Application, p16] FMC also provided a letter signed by an FMC Senior Vice President & Treasurer committing corporate reserves needed to fund this project. [Source: Application, Exhibit 13]

Department's Table 6
FKC Leah Layne
Capital Expenditure Breakdown

Item	Amount	% of Total
Building Construction (includes sales tax)	$102,250	73.7%
Fixed Equipment	$18,049	13.0%
Moveable Equipment	$6,010	4.3%
Architect and Engineering Fees	$10,505	7.6%
Washington State Sales Tax (for equipment)	$1,973	1.4%
Total Capital Expenditure	**$138,787**	**100.0%**

Public Comment
None

Rebuttal Comment
None

Department Evaluation

FMC intends to finance this project with corporate reserves and demonstrated the funds are available. If this project is approved, the department would attach a condition requiring FMC to finance the project consistent with the financing description provided in the application. With a financing condition, the department concludes that **this sub-criterion is met**.

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

Fresenius Medical Care Holdings, Inc.
Based on the source information reviewed, the department concludes that FMC 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 the number 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 Holdings, Inc.
FMC provided the following staffing table showing the planned staffing changes for the dialysis center expansion. [Source: February 13, 2020, screening response, p6]

Applicant's Table 3 (Revised Application Table 11)

Table 3 (Revised App Table 11). FKC Leah Layne, Historical and Proposed Staffing, by FTE and Position

Productive FTEs, by Type	Current (2019)	2020	Jan–Apr 2021	May-Dec 2021	2022	2023	2024
In-Center FTE's							
Nurse Manager	1.0	1.0	1.0	1.0	1.0	1.0	1.0
Outpatient RN	2.0	2.0	2.0	2.0	2.0	2.0	2.0
Patient Care Technician	6.0	6.0	6.0	6.0	6.0	6.0	6.0
Equipment Technician	0.4	0.4	0.4	0.4	0.4	0.4	0.4
Social Worker	0.5	0.5	0.5	0.5	0.5	0.5	0.5
Dietitian	0.5	0.5	0.5	0.5	0.5	0.5	0.5
Secretary	0.0	0.0	0.0	0.3	0.3	0.3	0.3
Total	**10.4**	**10.4**	**10.4**	**10.7**	**10.7**	**10.7**	**10.7**

FMC provided the following assumptions and clarification regarding the preceding staffing table.

"Please see Table 3 below. January to April 2021 and May to December 2021 have been separated to reflect pre- and post-project completion (i.e. when the new stations are anticipated to become operational)." [Source: February 13, 2020, screening response, p6]

"Information and assumptions used to prepare Table 11 include:
- *The wage and salary figures are based on FKC Leah Layne current actuals. They are held constant over the forecast period.*
- *It is assumed a FTE ("full time equivalent") employee works 2,080 hours per year.*
- *Non-productive hours are estimated at 10% of productive hours, based on FMC experience.*
- *Benefits are calculated at 22.1% of wages and salaries based on FKC Leah Layne 2018 actuals.*

- *The staff to patient ratio matrix below was used to construct minimum FTE counts for the projection years based on future patient counts presented in Table 7.*

	Staff to Patient Ratios (FTE Staff)
PCT (1)	1:8
RN (2)	1:20
Equipment Technician (3)	1:125
Social Worker (3)	1:125
Dietician (3)	1:125
Secretary (3)	1:125
Nurse Manager (4)	1

(1) A PCT works two shifts of patients each day, with 4 patients per shift.
(2) A RN works two shifts of patients per day, with 10 patients per shift.
(3) These FTEs are staffed based on staff-to-patient ratios identified in the table.
(4) The Center for Medicare and Medicaid ("CMS") requires that a dialysis facility be staffed with one FTE manager, irrespective of size of the facility or number of patients."
[Source: Application, pp19-20]

Focusing on the recruitment and retention of necessary staff, FMC provided the following information.

"FKC Leah Layne is an operational dialysis facility, which is staffed with qualified clinical and support personnel. Table 11 provides the number of current and proposed FTEs, by type. By virtue of our geographic location, any additional staff would be expected to principally come 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 can request assistance. We also have the capability of using outside staffing agencies to fill critical needs." [Source: Application, p21]

"To ensure that we have adequate staff in Washington we have built a local float pool of Washington licensed patient care technicians and RN's to ensure we have proper coverage for patient care. Fresenius also has an internal staffing agency, Fresenius Travel, in which we can request assistance, if needed. We also have the capability of using outside staffing agencies to fill critical needs." [Source: February 13, 2020, screening responses, p6]

Public Comment
None

Rebuttal Comment
None

Department Evaluation

Information provided in the application demonstrates that FMC is a well-established provider of dialysis services in Washington State and Adams County.

Because FKC Leah Layne is an operational facility that is currently staffed, FMC anticipates increasing staff by approximately 0.3 FTE by project completion. This is in line with staffing increases for projects of this size approved by the department in the past.

For this project, FMC intends to rely on successful recruitment and retention strategies it has used in the past. This approach is reasonable.

Based on the above information, the department concludes that FMC has the ability and expertise to recruit and retain qualified staff for this project. The department concludes that **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 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 Holdings, Inc.

FMC provided the following information for this sub-criterion.

"All patient care and support services except senior management, financial, legal, planning, marketing, architectural/construction and research and development are provided on-site at each clinic." [Source: Application, p22]

"FKC Leah Layne has working relationships with the following facilities: Providence Holy Family Hospital, Othello Community Hospital, Providence Sacred Heart Medical Center, Valley Hospital, Avalon Health Care, Coventry House, and Gevalia Hope." [Source: February 13, 2020 screening responses, p6]

FMC provided a list of FKC Leah Layne's existing ancillary and support vendors. [Source: Application, p21]

Applicant's Table 13

Table 13. List of vendors for FKC Leah Layne

Clinic Vendor List	Service
Dell Marketing	computers, etc.
Oxarc	fire extinguishers
Dura Shine	Janitorial Services
Basin Refrigeration, Heating, Plumbing	hvac repair
Moon Security Services	OCTV monitor and camera install
UPS	delivery service
Cintas	Linens
Health Trends	Consulting
First Choice Services	Coffee/Bev service
Oxarc	Oxygen cyl rental/O2
Joes Tree & Landscape Service	landscape maintenance
Jims Lock Service LLC	lock repair, rekey, etc.
Susan Hickok	Janitorial Services
Mountain West Polymers, INC	Floor epoxy for water room
ASD	Meds
Henry Schein	meds/supplies
metro Medical	meds/supplies

Additionally FMC stated, *"There are no anticipated changes to the existing ancillary or support agreements as a result of this project."* [Source: Application, p22]

FMC provided several executed patient transfer agreements for the dialysis center. The first is effective April 10, 2014, and signed by Providence Holy Family Hospital's Chief Executive, Alexander M. Jackson. The agreement states that it is effective until terminated. The second is effective July 3, 2009, and signed by Othello Community Hospital's Administrator, Harold S. Geher. This agreement states that it will automatically renew annually until terminated. The third is effective September 2, 2009, and signed by Providence Sacred Heart Medical Center's Chief Operating Officer, Elaine Couture. This agreement states that it will automatically renew annually until terminated. The forth is effective April 10, 2014, and signed by Valley Hospital's administrator, Gregory Repetti. This agreement states that it is effective until terminated. [Source: Application, Appendix 15]

Additionally FMC stated in reference to existing working relationships that, *"There are no anticipated changes expected as a result of this project."* [Source: Application, p22]

FMC also provided a copy of its executed Medical Director Agreement that identifies Member Physicians associated with Rockwood Clinic, P.S. located in Spokane. The physician identified in the application as contracting for medical director services is Constance Christ MD. In addition to Dr. Christ, the following physicians are identified in the application as current Member Physicians: Satinder Singh, MD, Sean Sanchez, MD, John Musa, MD, Richard Carson, MD, Brenden Mielke, MD, Emily Petersen, MD, and Kristie E. Jones, MD. The agreement provided in the application states, the listed Member Physicians can provide medical director services. Four of the Member Physicians identified in the agreement have expired Washington State credentials, the applicant's February 13, 2020 screening responses state that Dr. Wickre and Dr. Benedetti have retired, and Dr. Jones and Dr. Petersen have moved out of state; thus these four Member Physicians are not expected

to renew their credentials. The agreement identifies roles and responsibilities for both FMC and all Member Physicians and all costs are identified in the agreement. [Source: Application, p20, Exhibit 9, and February 13, 2020 screening responses, p8]

Public Comment
None

Rebuttal Comment
None

Department Evaluation
For this project, FMC provided a listing of the ancillary and support services currently used at the existing dialysis center.

Additionally, FMC provided executed and evergreen Patient Transfer Agreements between itself and Providence Holy Family Hospital, Othello Community Hospital, Providence Sacred Heart Medical Center, and Valley Hospital.

FMC also provided a copy of an executed Medical Director Agreement for the dialysis center. The agreement is between Inland Northwest Renal Care Group, LLC (a subsidiary of FMC) and Rockwood Clinic, P.S. The agreement outlines all roles and responsibilities for each entity, includes all costs associated with the agreement, and is effective until at least December 31, 2025. This agreement is acceptable.

Based on the information above, FMC demonstrated that it would have the necessary ancillary and support services at FKC Leah Layne. The department concludes that **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 Medicare and Medicaid certified. 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 Holdings, Inc.
FMC provided the following statement related to this sub-criterion. [Source: Application, p23]

"Fresenius is committed to conduct its business activities in compliance with applicable law. The company has long maintained a corporate compliance program which includes a Code of Ethics and Business Conduct, ongoing compliance related education and training for employees, a Compliance Department to support the company and its employees with compliance concerns, including a compliance line for anonymous reporting, and monitoring and auditing of business activities.

Fresenius, as one of the largest dialysis providers in the country, is routinely involved in claims, lawsuits, regulatory matters and investigations in the ordinary course of business. As for matters responsive to the application questions, Fresenius has no history of criminal convictions relating to the ownership or operation of a health care facility within the United States within the past 10 years. Fresenius also has no history of license revocations or decertifications for facilities in Washington State. In the past 10 years, a dialysis facility located in New York (Lindenhurst Dialysis Center), for which Fresenius provided management services, and a Fresenius facility located in San Francisco (RAI – Cesar Chavez), were decertified."

FMC also provided the following Table 12 with a listing of current credentialed staff at FKC Leah Layne. [Source: Application, p20]

Applicant's Table 12

Table 12. Names and License Numbers of Current Staff at FKC Leah Layne

Name	License Number
Kristina Barber	RN60919604
Liz Irene Barros	RN60742105
Leah Dawn Erban	DI00000668
Andrew J Holmes	SC60684795
Heather Tabor	HT60760037
Gabriela Villegas	LP60929916
Kassandra Garza	HT60990314
Matthew Mancao	HT60888751
Noe Puente	HT60972579

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
FMC reports dialysis services to CMS for approximately 2,658 facilities nationwide. Of the 2,658 facilities reporting to CMS by FMC, 239 do not have the necessary amount of data to compile a star rating. For the remaining 2,419 facilities with a star rating, the national average rating is 3.85 out of five stars. [Source: CMS, dialysis facility compare, updated April 22, 2020]

CMS Star Rating for Washington State Centers

For Washington State, FMC owns, operates, or manages 25 operational facilities. The Washington State average rating is 4.17 out of five stars. [Source: CMS, dialysis facility compare, updated April 22, 2020].

CMS Survey Data

While 25 FMC facilities are operational in Washington State, 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]

FMC provided an executed Medical Director Agreement with Rockwood Clinic, P.S. The agreement identifies Member Physicians which includes Constance Christ, MD, who the application identifies as the current contracted Medical Director. There are six additional physicians identified as Member Physicians that can serve as back-up for medical director services at FKC Leah Layne:

Satinder Singh, MD	Sean Sanchez, MD	John Musa, MD
Richard Carson, MD	Brenden Mielke, MD	

Using data from the Medical Quality Assurance Commission, the department found that all six Member Physicians associated with the Rockwood Clinic, P.S. agreement are compliant with state licensure and have no enforcement actions on their licenses.

FMC provided a listing of credentialed staff, which includes: one dietician, four hemodialysis technicians, one licensed practical nurse, two registered nurses, and one advanced associate social worker. Using data from the DOH Office of Customer Service, the department found that of the nine credentialed staff, one hemodialysis technician is working on renewing.

In review of this sub-criterion, the department considered the total compliance history of the dialysis facilities owned and operated by FMC. And although two facilities affiliated with FMC had in the past 10 years, lost certification this is a minority of the over two thousand facilities owned and managed by FMC.

The department also considered the compliance history of the certified staff who are currently associated with the facility. All of which have no documented enforcement actions.

Based on the information reviewed, the department concludes that FMC has been operating in substantial compliance with applicable state and federal licensing and certification requirements. The department also concludes there is reasonable assurance that the expansion of this dialysis center would not have a negative impact on FMC's compliance.

Based on the information above, FMC demonstrated that this proposed expansion project would be in conformance with the applicable state licensing requirements; and that it would likely continue to meet conditions of participation required by Medicaid and Medicare. The department concludes that **this sub-criterion is met.**

(4) The proposed project will promote continuity in the provision of health care, not result in an unwarranted fragmentation of services, and have an appropriate relationship to the service area's existing health care system.

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

Fresenius Medical Care Holdings, Inc.
FMC provided the following statements for this sub-criterion. [Source: Application, p23]

"The proposed project promotes continuity of care as it seeks to expand FKC Leah Layne's existing dialysis care services. Further, we have provided documentation that FKC Leah Layne has met all standards contained in WAC 246-310-812, demonstrating net need that fully supports the requested project.

As an existing facility, FKC Leah Layne has an established relationship with the community. Additional stations will not only ensure timely access to dialysis services, but it will also realize increased efficiency and economies of scale."

Public Comment
None

Rebuttal Comment
None

Department Evaluation
FMC has been a provider of dialysis services in Washington State for many years. FMC also has a history of established relationships with existing healthcare networks in Adams County. Additionally, FMC's project would promote continuity in the provision of healthcare services in the planning area by expanding its existing facility in a planning area where additional dialysis stations are needed.

FMC provided documentation in its 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 **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.

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

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

Fresenius Medical Care Holdings, Inc.
Based on the source information reviewed, 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. Since FMC submitted the only application for Adams County for year 2019 Cycle 2, step three does not apply to this project.

Step One

Department Evaluation
FMC's application met the review criteria under WAC 246-310-210, 220, and 230. The department will review this application under step two below.

Step Two

Fresenius Medical Care Holdings, Inc.
FMC identified the following two options considered before submitting this application. [Source: Application, p25]

"The following two options were evaluated in the alternatives analysis:
- *Option One: Add two (2) stations to existing facility —The Project*
- *Option Two: Postponing the request—Do Nothing*

Please see Tables 14-17, respectively. They provide a summary of advantages and disadvantages of each of the two options based on the following evaluative criteria: Promoting availability, or access to healthcare services; Promoting Quality of Care; Promoting Cost and Operating Efficiency; and Legal Restrictions."

FMC provided the following tables to demonstrate its analysis.

Applicant's Tables 14 – 17

Table 14. Alternatives Analysis: Promoting Access to Healthcare Services.

Option:	Advantages/Disadvantages:
Option One Add two (2) stations to existing facility —The Project	• Adds additional dialysis stations to the Planning Area, as warranted by the department's dialysis forecast model. (Advantage ("A")). • Residents of the Adams County Dialysis Planning Area will be better able to access needed facility dialysis services and would not be forced to out-migrate to other facilities outside the planning area--improves access (A).
Option Two Do nothing	• Would do nothing to improve access (Disadvantage ("D")). • Outmigration would increase (D).

Table 15. Alternatives Analysis: Promoting Quality of Care.

Option:	Advantages/Disadvantages:
Option One Add two (2) stations to existing facility —The Project	• Adds additional dialysis station capacity as warranted by the station forecast model (A). • This promotes access, reduces fragmentation, thus, promotes quality (A). • Residents of Adams County Planning Area would have increased dialysis station capacity--this improves quality of care inasmuch as it improves continuity of care (A).
Option Two Do nothing	• Planning Area residents will need to out-migrate to receive care, and do so in increasing numbers without added capacity. As such, patient care will be fragmented, which harms access and quality of care (D)

Table 16. Alternatives Analysis: Promoting Cost and Operating Efficiency.

Option:	Advantages/Disadvantages:
Option One Add two (2) stations to existing facility —The Project	• Approval of the current project request will allow for the facility to optimize its capacity and achieve corresponding economies of scale. (A) • Would require limited re-location of supplies and equipment, minimizing impact on existing operations and capital expenditures associated with the project. (A)
Option Two Do nothing	• Capital and operating costs would be least under this option, since there would be none (A). • Suffers from significant disadvantages by not promoting access and continuity of care. Forces patients to continue to out-migrate, which is inefficient and costly for planning area residents (D).

Table 17. Alternatives Analysis: Legal Restrictions.

Option:	Advantages/Disadvantages:
Option One Add two (2) stations to existing facility —The Project	• This option requires certificate-of-need approval.
Option Two Do nothing	• There are no legal implications with this option.

Public Comment
None

Rebuttal Comment
None

Department Evaluation
FMC currently operates one dialysis center in Adams County. FMC provided a discussion of options considered, including not submitting this application. After reviewing the information, the department concludes that FMC appropriately rejected the other option before submitting its application.

(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
This sub-criterion was evaluated in conjunction with WAC 246-310-220 above and is considered met.

(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 Holdings, Inc.
FMC provided the following information related to this sub-criterion. [Source: Application, p27]

"Any proposed changes would meet IN-RCG and Fresenius internal standards which have been engineered and tested to ensure that they support our high quality, efficient and patient-focused standards. Our standards also meet and or exceed all applicable state and local codes, including compliance with the State Energy Code, latest edition."

Public Comment
None

Rebuttal Comment
None

Department Evaluation
FMC's project is likely to improve delivery of dialysis services to the residents of Adams County with the addition of dialysis stations in the planning area. The department concludes that **this sub-criterion is met.**

APPENDIX A

2019
Adams County
ESRD Need Projection Methodology

	Planning Area	**6 Year Utilization Data - Resident Incenter Patients**					
	Adams	**2013**	**2014**	**2015**	**2016**	**2017**	**2018**
	Adams County	**16**	**15**	**18**	**21**	**26**	**25**
	TOTALS	**16**	**15**	**18**	**21**	**26**	**25**
246-310-812(4)(a)	**Rate of Change**		**-6.25%**	**20.00%**	**16.67%**	**23.81%**	**-3.85%**
	6% Growth or Greater?		**FALSE**	**TRUE**	**TRUE**	**TRUE**	**FALSE**
	Regression Method:	**Linear**					
246-310-812(4)(c)			Year 1	Year 2	Year 3	Year 4	**Year 5**
			2019	2020	2021	2022	**2023**
Projected Resident Incenter Patients	from 246-310-812(4)(b)		29.40	32.20	35.00	37.80	**40.60**
Station Need for Patients	**Divide Resident Incenter by 3.2**		9.19	10.06	10.94	11.81	**12.69**
	Rounded to next whole number		**10**	**11**	**11**	**12**	**13**
246-310-812(4)(d)	subtract (4)(c) from approved stations						
Existing CN Approved Stations		Total	9	9	9	9	**9**
Results of (4)(c) above			10	11	11	12	**13**
Net Station Need			-1	-2	-2	-3	**-4**
Negative number indicates need for stations							

Planning Area Facilities

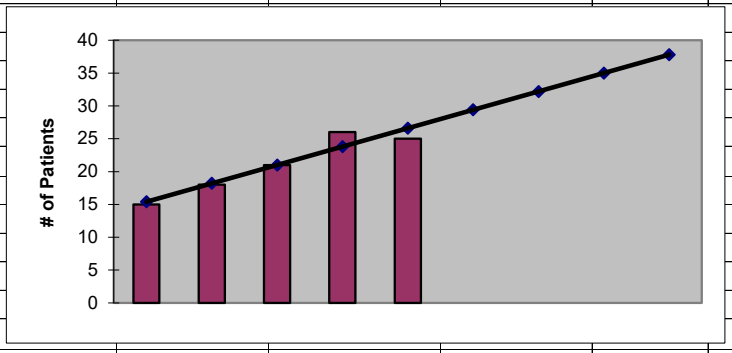
Name of Center	**# of Stations**
FMC Leah Layne Dialysi	**9**
Total	**9**

Source: Northwest Renal Network data 2013-2018

Most recent year-end data: 2018 posted 02/15/2019

2019
Adams County
ESRD Need Projection Methodology

x	y	Linear
2014	15	**15**
2015	18	**18**
2016	21	**21**
2017	26	**24**
2018	25	**27**
2019		**29.40**
2020		**32.20**
2021		**35.00**
2022		**37.80**
2023		**40.60**



SUMMARY OUTPUT

Regression Statistics	
Multiple R	0.954792075
R Square	0.911627907
Adjusted R Square	0.882170543
Standard Error	1.591644852
Observations	5

ANOVA

	df	*SS*	*MS*	*F*	*Significance F*
Regression	1	78.4	78.4	30.94736842	0.011460104
Residual	3	7.6	2.533333333		
Total	4	86			

	Coefficients	*Standard Error*	*t Stat*	*P-value*	*Lower 95%*	*Upper 95%*	*ower 95.0%*	*Upper 95.0%*
Intercept	-5623.8	1014.697998	-5.542338718	0.011579735	-8853.021894	-2394.57811	-8853.02	-2394.58
X Variable 1	2.8	0.503322296	5.5630359	0.011460104	1.19820382	4.40179618	1.198204	4.401796