



STATE OF WASHINGTON
DEPARTMENT OF HEALTH
Olympia, Washington 98504

February 27, 2020

CERTIFIED MAIL # 7019 1640 0000 8194 1168

Casey Stowell, Regional VP
Fresenius Medical Care
20900 SW 115th Avenue, Suite 190
Tualatin, OR 97062

RE: Certificate of Need Application #19-74

Dear Mr. Stowell:

We have completed review of the Certificate of Need application submitted by Fresenius Medical Care. The application proposes to add four dialysis stations to Fresenius Kidney Care Columbia Basin located in Kennewick within Benton County. 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 agrees to the following in its entirety.

Project Description:

This certificate approves the addition of four dialysis stations to the 14-station Fresenius Kidney Care Columbia Basin, for a facility total of 18-dialysis stations. At project completion, Fresenius Kidney Care Columbia Basin is approved to certify and operate 18 dialysis stations. The table below provides a breakdown of the total number of stations at Fresenius Kidney Care Columbia Basin.

	CMS Certified Stations	Stations Counted in Methodology
General Use In-Center Stations	16	16
Permanent Bed Station	1	1
Exempt Isolation Station	1	0
Private Isolation Station	0	0
Total Stations	18	17

Services provided at Fresenius Kidney Care Columbia Basin include in-center hemodialysis, home hemodialysis and peritoneal dialysis training and support for dialysis patients, a dedicated isolation area, and a dedicated bed station. Fresenius Kidney Care Columbia Basin will also offer an evening shift beginning after 5:00 pm.

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 existing corporate reserves, as described in the application.

Approved Capital Expenditure:

The approved capital expenditure for the four station addition is \$245,289. This amount represents the costs for moveable equipment. Fresenius Medical Care Holdings, Inc. will pay all costs

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:

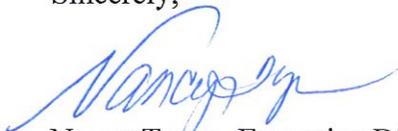
Department of Health
Certificate of Need Program
Mail Stop 47852
Olympia, WA 98504-7852

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

YEAR 2019 CYCLE 1 NON-SPECIAL CIRCUMSTANCE EVALUATION DATED FEBRUARY 27, 2020 FOR THE CERTIFICATE OF NEED APPLICATION SUBMITTED BY QUALICENTERS INLAND NORTHWEST, LLC. A SUBSIDIARY OF FRESENIUS MEDICAL CARE HOLDINGS, INC. TO EXPAND FRESENIUS KIDNEY CARE COLUMBIA BASIN LOCATED IN BENTON COUNTY.

APPLICANT DESCRIPTION

QualiCenters Inland Northwest, LLC.

QualiCenters Inland Northwest, LLC is a limited liability company and its parent company is Fresenius Medical Care Holdings, Inc. is a profit corporation. QualiCenters Inland Northwest, LLC UBI number is 601-638-504. Fresenius Medical Care Holdings, Inc. operates outpatient dialysis centers in 48 states, the District of Columbia, and Puerto Rico through these subsidiaries.

In Washington State, Fresenius Medical Care Holdings, Inc. owns, operates, or manages 25 kidney dialysis facilities. Some facilities operate under the name of Fresenius Medical Care or FMC, other operate under the name of Fresenius Kidney Care or FKC. [Source: Application, Exhibit 2, CMS Dialysis Facility Compare website]

For ease of reference in this evaluation, QualiCenters Inland Northwest, LLC would be referred to as “QualiCenters” and Fresenius Medical Care Holdings, Inc. would be referred to as “Fresenius”, and the 18-station Fresenius Kidney Care Columbia Basin would be referred to as “FKC Columbia Basin”. For the purpose of this application, the Department will recognize Fresenius Medical Care Holdings, Inc. as the applicant.

PROJECT DESCRIPTION

Fresenius.

Fresenius proposes to expand the fourteen station Fresenius Kidney Care Columbia Basin by four in-center stations. Fresenius Kidney Care Columbia Basin is located at 6600 West Rio Grande Avenue, in Kennewick [99336]. [Source: Application, page 6]

Currently, Fresenius Kidney Care Columbia Basin is certify to operate 14 stations shown in Table 1A is a breakdown of the stations operational at the facility.

**Department’s Table 1A
Fresenius Kidney Care Columbia Basin**

Station Type	CMS Certified Stations	Station Counted for Station Use and Methodology
General Use In-Center Stations	12	12
Permanent Bed Station	1	1
Exempt Isolation Station	1	0
Isolation Station	0	0
Total Stations	14	13

If this project is approvable, when the four stations are added Fresenius Kidney Columbia Basin, the facility would be operating 18 stations. Table 1B below provides a breakdown of the total number of the dialysis stations that would be operational at Fresenius Kidney Columbia Basin.

**Department's Table 1B
Fresenius Kidney Care Columbia Basin**

Station Type	CMS Certified Stations	Station Counted for Station Use and Methodology
General Use In-Center Stations	16	16
Permanent Bed Station	1	1
Exempt Isolation Station	1	0
Isolation Station	0	0
Total Stations	18	17

Services provided at Fresenius Kidney Care Columbia Basin include in-center hemodialysis, home hemodialysis and peritoneal dialysis training and support for dialysis patients, a dedicated isolation area, and a dedicated bed station. Fresenius Kidney Care Columbia Basin Columbia Basin will also offer an evening shift beginning after 5 pm. [Source: Application, page 7, and Screening response received August 12, 2019, page 2]

The total capital expenditure for this project is \$245, 289. Of that amount 80% or \$197,438 is related to building construction improvement; 13% or \$30,920 is for fixed and moveable equipment, 1%, or \$2,659; is for taxes and consulting fees. [Source: Application Page 16]

The applicant anticipates that the decision for this project would be released in April 2020. Using that timeline, Fresenius estimated that the four new dialysis stations facility would be operational at the center in December 2020. [Source: Application, page 6] Under this timeline, year 2020 is a partial year of operation, full calendar year one is 2021, and full calendar year three is 2023.

APPLICABILITY OF CERTIFICATE OF NEED LAW

Fresenius application proposes to add four-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).

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).

Fresenius must also demonstrate compliance with applicable kidney disease treatment center criteria outlined in WAC 246-310-800 through 833. The following review criteria do not apply to applications submitted under WAC 246-310-806 Nonspecial Circumstance. These criteria 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. Fresenius 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 WAC 246-310-803 or WAC 246-310-827 during a review; these 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 #1 for calendar year 2019. Fresenius application was the only project submitted for Benton County planning area. 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 application review timeline.

APPLICATION CHRONOLOGY

Action	RCG
Letter of Intent Submitted	May 1, 2019
Application Submitted	May 31, 2019
Department’s pre-review activities <ul style="list-style-type: none"> • DOH 1st Screening Letter • Applicant's Responses Received • DOH 2nd Screening Letter • Applicant’s Responses Received 	June 28, 2019 August 12, 2019 September 3, 2019 November 19, 2019
Beginning of Review	November 27, 2019
End of Public Comment <ul style="list-style-type: none"> • Public comments accepted through the end of public comment • No public hearing requested or conducted 	December 31, 2019 N/A
Rebuttal Comments Submitted ¹	January 15, 2020
Department's Anticipated Decision Date	March 2, 2020
Department's Actual Decision Date	February 27, 2020

¹ The Department did not receive public any comments; as a result, the applicant did not submit any rebuttal comments.

AFFECTED PERSONS

“Affected persons” are defined under WAC 246-310-010(2). In order to qualify as an affected person, the entity or person must first qualify as an “interested person,” defined under WAC 246-310-010(34). For this project, DaVita, Inc., an existing dialysis provider in the Benton County planning area requested interested and affected person status. However, DaVita, Inc. did not provide public comment on this project and does not qualify for affected person in this review.

SOURCE INFORMATION REVIEWED

- Fresenius Medical Care Holdings, Inc. Certificate of Need application received May 31, 2019
- Fresenius Medical Care Holdings, Inc. 1st responses received August 12, 2019, and 2nd responses received November 19, 2019.
- Years 2013 through 2018 historical kidney dialysis data obtained from the Northwest Renal Network
- Department of Health’s ESRD Need Projection Methodology for Benton County posted to its website February 15, 2019
- 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 and Oversight
- Fresenius Medical Care website at www.fmcna.com
- Centers for Medicare and Medicaid Services website at www.medicare.gov/dialysisfacilitycompare
- Northwest Renal Network website at www.nwrn.org
- Northwest Renal Network modality data

CONCLUSION

Fresenius Medical Care

For the reasons stated in this evaluation, the application submitted by Fresenius Medical Care Holdings, Inc. proposing to add four-dialysis station to Fresenius Kidney Care Columbia Basin located in Kennewick within Benton 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 four dialysis stations to the 14-station Fresenius Kidney Care Columbia Basin, for a facility total of 18-dialysis stations. At project completion, Fresenius Kidney Center Columbia Basin is approved to certify and operate 18 dialysis stations. The table below provides a breakdown of the total number of stations at Fresenius Kidney Care Columbia Basin.

	CMS Certified Stations	Stations Counted in Methodology
General Use In-Center Stations	16	16
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Services provided at Fresenius Kidney Care Columbia Basin include in-center hemodialysis, home hemodialysis and peritoneal dialysis training and support for dialysis patients, a dedicated isolation area, and a dedicated bed station. Fresenius Kidney Care Columbia Basin will also offer an evening shift beginning after 5:00 pm.

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 existing corporate reserves, as described in the application.

Approved Capital Expenditure:

The approved capital expenditure for the four station addition is \$245,289. This amount represents the costs for moveable equipment. Fresenius Medical Care Holdings, Inc. will pay all costs.

CRITERIA DETERMINATIONS

A. Need (WAC 246-310-210)

Based on the source information reviewed, the department concludes that Fresenius Medical Care Holdings, Inc. **met** the need criteria in WAC 246-310-210. The kidney disease treatment center specific 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(5) and (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 centers 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 center specific 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 Center 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)]

[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

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]

³WAC 246-310-812 defines base year as the most recent calendar year for which December 31 data is available as of the first day of the application submission period from the *Northwest Renal Network's Modality Report* or successor report." For this project, the base year is 2018.

to determine the number of stations needed in the planning area. For the specific counties listed above, the number of projected patients is divided by 3.2 to determine needed stations. Additionally, the number of stations projected as needed in the target year is rounded up to the nearest whole number.

Finally, once station need has been calculated for the project years, the number of CN approved in-center stations are then subtracted from the total need, resulting in a net need for the planning area. [WAC 246-310-812(4)(d)] The department calculates the numeric methodology for each of the 57 planning areas and posts the results to its website. Below is the discussion of the applicants' numeric methodologies.

Fresenius

Fresenius proposes to expand the 14-station FKC Columbia Basin located in Kennewick within Benton County by adding four new in-center stations for a total of 18-stations. Of the 18-stations, only 17 stations will be counted in the methodology. Fresenius provided a numeric methodology that matches the department's numeric methodology posted to its website for Benton County. Both methodologies projected need for four stations in projection year 2023 in Benton County.

Public Comment

None

Rebuttal Comment

None

Department Evaluation of the Numeric Methodology for Benton 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 4.8 to determine the number of stations needed in Benton County. A summary of the department's numeric methodology is shown in the table below.

**Department's Table 1
Benton County Numeric Methodology Summary**

	4.8 in-center patients per station		
	2023 Projected # of stations	Minus Current # of stations	2023 Net Need or (Surplus)
DOH Methodology Post to Website	46	42	4

As shown in the table, once the 42 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(5)

Before the department approves new in-center kidney dialysis stations in a 4.8 planning area, all certificate of need counted stations at each facility in the planning area must be operating at 4.5 in-center patients per station. However, when a planning area has one or more facilities with stations not meeting the in-center patients per stations standard, the department will consider the 4.5 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. For example, an applicant states the stations will be operational within eight months following the date of the certificate of need approval. The eight months would start from the date of an uncontested certificate of need approval. If the certificate of need approval is contested, the eight months would start from the date of the final department or judicial order. However, the department, at its sole discretion, may approve a one-time modification of the timeline for purposes of this subsection upon submission of documentation that the applicant was prevented from meeting the initial timeline due to circumstances beyond its control.*

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 Benton County, WAC 246-310-812(5) requires all CN approved stations in the planning area be operating at 4.5 in-center patients per station unless one of the circumstances demonstrated under WAC 246-310-812(5)(a) or (b) is present.

Fresenius

To comply with this sub criterion, Fresenius provided the following statements to show that the proposed project met this sub-criterion. [Source: Application, Page 8]

“Table 2 below presents the utilization reported by Benton County Dialysis Planning Area providers according to the applicable Northwest Renal Network (“NWRN”) modality report (December 31, 2018)”.

***Fresenius Table 2 Reproduced
Table 2. Benton County Dialysis Planning Area Provider Utilization – 4Q2018***

<i>Facility</i>	<i>Number of Stations</i>	<i>12/31/18 Number of Patients Per Quarterly In-Center Data</i>	<i>12/31/18 Patients/ Station</i>
<i>FKC Columbia Basin</i>	<i>13</i>	<i>76</i>	<i>5.85</i>
<i>DVA Kennewick</i>	<i>10</i>	<i>40</i>	<i>4.00</i>
<i>DVA Chinook</i>	<i>19</i>	<i>77</i>	<i>4.05</i>

Based on the data in table above, Fresenius stated:

“Please see comments below for each facilities’ accordance to the standards in WAC 246-310-812(5) and (6):

⁴ WAC 246-310-210(1)(b).

- *FKC Columbia Basin: as demonstrated in Table 2, it is above the 4.5 occupancy standard.*
- *DVA Kennewick and DVA Chinook: although both facilities in 4Q2018 operated below the 4.5 occupancy standard, they have been operational for at least three years. Therefore, according to WAC 246-310-812(5)(a), the Department may still approve new in-center stations in Benton County Dialysis Planning Area.” [Source: Application, Page 9]*

Public Comment

None

Rebuttal Comment

None

Department Evaluation

WAC 246-310-812(5) 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.*” For this project, the letter of intent is due on May 1, 2019. The most recent quarterly data available as of May 1, 2019, is December 31, 2018, fourth quarter data that was available on February 15, 2019. Summarized in the table below is the utilization for the three-dialysis facilities located within the planning area.

**Department’s Table 2
December 31, 2018, Utilization Data for Benton County**

Facility Name	# of Stations	# of Patients	Patients/Station
FKC Columbia Basin	13	76	5.85
DaVita Kennewick	10	39	3.90
DaVita Chinook	19	76	4.00

The department historical record show that DaVita Kennewick’s initial Medicare certification date was January 15, 2014, and DaVita Chinook’s initial Medicare certification was January 20, 2009. As shown by the initial Medicare certification dates both DaVita Kennewick and DaVita Chinook have been operating in Benton County for more than three years and DaVita has not requested a modification to the operational timeline for either facility. Therefore, under WAC 246-310-812(5)(a) new dialysis stations can be added in Benton County even though these two centers are operating below 4.5 patients per station.

Given the information reviewed, the department concludes Fresenius application **met the standard under WAC 245-310-812(5).**

- (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

To comply with this sub-criterion, Fresenius provided the following statements:

"Patient access is critical to improving the health and quality of life of our patients. But patient access is multi-faceted and not simply represented by the aggregate number of stations available. Patients require access to the specific treatment modality and convenient hours of operation that meet their individual clinical and personal needs.

Patients with limited financial means also face additional barriers to care due to the financial burden of out-of-pocket expenses. However, FMC strives to address this issue for our patients when needed by providing charity in our Washington facilities. A copy of our charity care policy is contained in Exhibit 6.

All individuals identified, as needing dialysis services will have access to FKC Columbia Basin. FKC Columbia Basin admission policies prohibit discrimination on the basis of race, income, ethnicity, sex or handicap. A copy of the admission policy is contained in Exhibit 7.

A copy of our charity care policy is contained in Exhibit 6". [Source: Application, Page 13-14]

"Please find attached as exhibits the following documents:

- Exhibit 6. Charity Care/Indigence Policy*
- Exhibit 7A. Patient Admission Policy*
- Exhibit 7B. Patient Rights and Responsibilities Policy*
- Exhibit 7C. Patient Rights and Responsibilities List*

⁵ WAC 246-453-010(4).

- *Exhibit 7D. Patient Acknowledgement of Receipt of Rights and Responsibilities*". [Source: Application page 14]

Public Comment

None

Rebuttal Comment

None

Department Evaluation

Fresenius provided copies of the policies used at all of the dialysis entities own or operated by Fresenius or its affiliates. These policies are currently use at FKC Columbia Basin facility located in Kennewick and are not expected to change with the addition of four stations.

Medicare and Medicaid Programs

FKC Columbia Basin Dialysis Center is currently Medicare and Medicaid certified below is the facility Medicare and Medicaid provider numbers.

Medicare Provider Number: 502518
 Medicaid Provider Number: 3990439

Fresenius provided FKC Columbia Basin Dialysis Center’s current and projected payer mix. The projected payer mix is based on 2018 actuals and does not change from the current payer mix. The information is restated below. [Source: August 12, 2019, Screening response, page 2]

<i>“Payer Class</i>	<i>Mix Based on Treatments</i>	<i>Mix Based on Revenue</i>
<i>Medicare</i>	70.2%	42.8%
<i>Commercial</i>	8.9%	44.7%
<i>Medicaid</i>	12.9%	6.7%
<i>Medicare Adv</i>	0.0%	0.0%
<i>Medicaid Risk</i>	4.0%	3.8%
<i>Misc. Ins</i>	2.9%	2.1%
<i>Self-Pay</i>	1.2%	-0.8%
<i>Old Revenue Accounts</i>	0.0%	0.7%
<i>Total</i>	100%	100%

Page 18 of application #19-74 states that the projected payer mix is based on FKC Columbia Basin's 2018 actuals. Therefore, the historic payer mix identified above is consistent with the projected payer mix presented as Table 10 in application #19-74”

Given that the dialysis center is currently operational, Fresenius did not provide any draft policies. The policies provided by Fresenius are those currently in use by the applicant Washington State facilities.

Based on the information above, the department concludes that Fresenius application **met 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 Fresenius Medical Care Holdings, Inc. 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 Holdings, Inc. 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 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.*

Fresenius

FKC Columbia Basin is an existing facility therefore, sub-sections (1)(a) and (b) apply to this project. Fresenius stated the four additional stations would be operational in December 2020. Using this timeline, calendar year one of the project is 2021 and calendar year three is 2023. [Source: Application, page 6-11]

To comply with this sub-criterion, Fresenius provided the following statements.

“Utilization Forecast Methodology

Please see below for a description of the methodology used to construct the in-center and home patient projections. It is assumed the number of treatments per patient is 144 treatments per year.

Table 7 below presents the projected utilization at FKC Columbia Basin. Given the four additional station are anticipated to become operational by December 2020, the first full year of operation will be CY2021.

Table 7. FKC Columbia Basin Utilization Forecast 2019 – 2023

	<i>May – Dec 2019</i>	<i>Jan – Nov 2020</i>	<i>Dec 2020</i>	<i>Full Year 1 (2021)</i>	<i>Full Year 2 (2022)</i>	<i>Full Year 3 (2023)</i>
<i>Total in-center stations*</i>	12	12	17	17	17	17
<i>Total in-center patients</i>	74	74	76	87	94	94
<i>Total in-center treatments</i>	7,104	9,768	912	12,528	13,536	13,536
<i>Total home patients</i>	21	24	24	26	29	31
<i>Total home treatments</i>	2,016	3,168	288	3,744	4,176	4,464

Station count excludes 1 isolation station. Any patients included in table above requiring medically necessary isolation will have access to Columbia Basin's one isolation room.

***The intervening periods' station count also excludes the 1 one-time station adjustment referenced in WAC246-310-809 that FKC Columbia Basin anticipates requesting in 2020.*

In-Center Patients

May to December 2019 and January to November 2020 utilization is based on the YTD2019 (January to April) patient counts given the existing facility is at full capacity. Incremental growth for in-center patient is assumed when the new stations become operational (December 2020) and is based on the incremental growth featured in step (b) of the need methodology. Further, 2023 utilization is held constant at 2022 levels given the patient per station will have reached 5.5.

Home Patients

The home projections incorporate a similar approach used in step (b) in the Department's need methodology for in-center patient demand, but with various modifications including (1) tailoring analysis to home patients, not in-center, (2) only using Columbia Basin historical patient counts, and (3) using the historical time period of 2016-YTD2019, not the previous five years. Therefore, the projected number of home patients at Columbia Basin is based on linear regression analysis using the previous 2016-YTD2019 average home patient counts at Columbia Basin that is then projected out throughout the relevant forecast periods". [Source: Application page 12]

In addition to the statements restated above, Fresenius stated, "Table 10 is FKC Columbia Basin Dialysis Center, Projected Payer Mix, by Revenue and by Patient.

Fresenius Table 10 Reproduced

Payor Class	Mix Based on Treatments	Mix based on Revenue
Medicare	70.2%	42.8%
Medicaid	12.9%	6.7%
Medicare Adv	0.0%	0.0%
Medicaid Risk	8.8%	4.1%
Commercial	8.9%	44.0%
Misc. Ins	2.9%	1.1%
Self-Pay	1.2%	0.8%
Old Revenue Accounts	0.0%	0.5%
TOTAL	100%	100%

[Source: Application, page 18]

In addition to the statement above, Fresenius states, "The project's projected payer mix is based on FKC Columbia Basin' 2018 actuals. Therefore, the historical payer mix is reported in Table 10 above". [Source: Application page 18]

To support its projected revenue and expenses for this project, Fresenius provided the rationale and assumptions used to project revenue and expenses. Restated below are the rationale and assumptions.

"Please see attached a new exhibit, Exhibit 8C, that presents a statement of revenues and expenses in a consistent format from 2016 to 2023. Please note the estimates provided in Exhibit 8C are linked to Revised Exhibits 8A-8B (also attached) based on the respective time period.

- 2016-2018 values are linked to Exhibit 8A
- 2019 values are based on YTD2019 (January to April) actuals from Exhibit 8A; adjusted by effective number of months.

- *Pre-project completion 2020 (January to November) is based on full year 2018 actuals from Exhibit 8B; adjusted by effective number of months.*
- Post-project completion 2020 (December) and 2021-2023 values are linked to Exhibit 8B.*

Revenues

In-center revenues are based on CY2018 FKC Columbia Basin data ("actuals"), given it is an existing facility. Payer mix statistics have also been obtained from FKC Columbia Basin 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 Columbia Basin actuals.

Expenses

- *Unless otherwise noted, expenses have been calculated based on CY2018 FKC Columbia Basin actuals.*
- *Medical supplies, ancillary, and 'other med' expenses have been calculated on a per treatment basis from FKC Columbia Basin 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 Columbia Basin facility.*
- *Depreciation is straight-line; assumes 10 years on leaseholds and 8 years on equipment.*
- *Rent Expense: the commencement date of the lease is March 2017. Base rent is projected based section 3.1 of the lease agreement.*
- *Other Property Exp includes common area maintenance ("CAM"), allocated taxes, and insurance costs. Estimated at 9.7% of base Rent Expense based on 2018 actuals*
- *Physician Compensation: see section 5.01 .1 of MDA for starting annual fee, including an annual 2% fee escalator. The effective date of the MDA is July 2014.*
[Source: Screening response received August 12, 2019, page 3, and Revised Exhibit 8B]

Fresenius also provided the following clarification for items in its revised pro forma financial statement. [Source: August 12, 2019, screening responses page 4-5]

- *Based on screening questions #8-9, Fresenius has further reviewed its charity care figures and has determined bad debt figures originally presented in the FKC Columbia Basin application included charity care in its historical financial statement (Exhibit 8A). Accordingly, Fresenius has revised charity care estimates on a going forward basis for both history and forecast periods (i.e. Exhibits 8A and 8B respectively). Charity care continues to be approximately 1 % of net revenues (0.88%), a figure based on the experience of Fresenius' facilities across Washington. It should be noted this revision has not affected historic net revenue estimates, expenses, or net income estimates.*
- *The reason why charity care under the December 2020 forecast period is lower than full years 2021-2023 is because it only represents one month of data. Charity care is calculated at one percent of net revenue.*

- 'G&A' includes: administrative allocations, which in turn is comprised of the contribution from FKC Columbia Basin 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.
- The reason why 2019 and 2020 values are lower than 2018 or 2021-2023 is because 2019 and 2020 are partial year forecast periods. As identified in Exhibit 8A, YTD 2019 comprised four months of data (January to April). Further, Exhibit 8B identified that 2020 only represented one month of data (December) when the project is anticipated to be complete.
- 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.
- Other property expenses include expenses such as common area maintenance, allocated taxes, property insurance, and miscellaneous property expenses (e.g. storage). The projected expenses are calculated at 9.7% of base rent expense based on 2018 actuals.

Based on the projected utilization and assumptions above, Fresenius projected FKC Columbia Basin's revenue, expenses, and net income for partial year 2020 and fiscal years 2021 through 2023.⁶ Partial year 2020 is one month of operation and years 2021 through 2023 are full calendar years. FMC's fiscal year is January 1 through December 31. [Source: August 19, 2019, screening responses page 3, Exhibit 8B and FMC consolidated statements]

Department's Table 3
FKC Columbia Basin Projected Revenue and Expenses
Partial Year 2020 and Calendar Years 2021-2023

	Partial Yr. 2020	FY 1- 2021	FY 2- 2022	FY 3- 2023
Net Revenue	\$480,939	\$6,521,538	\$7,098,665	\$7,214,091
Total Expenses	\$409,442	\$5,252,065	\$5,485,979	\$5,521,640
Net Profit / (Loss)	\$71,497	\$1,269,473	\$1,612,686	\$1,692,451

The 'Net Revenue' line item is gross in-center and training revenue, minus deductions for contractual allowances, bad debt, and charity care. The 'Total Expenses' line item includes all expenses related to the operation of the 18-station dialysis center.

Fresenius provided clarifying statements related to its pro forma revenue and expense statement. The statement is restated below. [Source: August 19, 2019, Screening responses page 2, Exhibit 8A-C]

"When reviewing application materials, it was identified that the financial data underlying the historical and forecasted financials did not account for small end-of-year accounting adjustments for a small subset of expenses. These adjustments effect medical supplies as well as having minor effects on 'other med' and ad min expenses. These changes DO NOT affect volumes, revenues, and most expenses items. In the interest of transparency, we provide as Revised Exhibits 8A-C revised historical data and financial projections that include these minor adjustments".

Public Comment

None

⁶ FMC's fiscal year is January through December.

Rebuttal Comment

None

Department Evaluation

Fresenius proposes to expand FKC Columbia Basin by adding four new stations. Fresenius based its projected utilization on the historical utilization of FKC Columbia Basin consistent with WAC 246-310-815(1)(a) and (b). Based on the review of Fresenius assumptions used to project utilization for the 18-station FKC Columbia Basin, the department concludes Fresenius assumptions and rationale are reasonable. In addition, Fresenius also provided the following specific documents that are associated with the costs for this project.

- Executed Lease Agreement [Application Exhibit 10A, and Screening response received August 12, 2019, Attachment 1]
- Proof of Land Ownership by Landlord [Application, Exhibit 10B]
- Medical Director Agreement [Application Exhibit 9]⁷

Since FKC Columbia Basin is currently operational, Fresenius provided an executed lease for the existing facility. The lease agreement is between P&L Land Company, LLC (Landlord), and QualiCenters Inland Northwest, LLC (Tenant). The document was executed on October 26, 2015 and it expires in October 2030. The costs of the lease can be substantiated in the revenue and expense statement. Fresenius also provided an executed Medical Director Agreement for the dialysis facility. The cost for the medical director position was identified in the each of the projection years in the pro forma revenue and expense financial statement.

Based on the above information provided in the application, the department concludes that Fresenius 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, the applicant 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

To comply with this sub-criterion, within the application Fresenius provided the following statements, *“Please see Exhibit 5 for single line drawing, including the relevant square footage tables. The square footage for the facility is 11,003 gross square feet and 10,586 net square feet”* [Source: Application page 7]

In addition to the statements above, Fresenius also provided additional information in response to screening questions. The information is below.

⁷ The Medical Director Agreement is further discussed under WAC 246-310-230 of this evaluation.

Fresenius Table Reproduced

"Space	# of Stations	Multiplier	Total
<i>(a) Incenter Space</i>	16	80	1,280
<i>(a) Training Space</i>	<i>Not specifically identified under WAC 246-310-800(11)</i>		
<i>(b) Isolation Space</i>	1	136	136
<i>(b) Permanent Bed Space</i>	1	100	100
Treatment Floor Space Total	-	-	1,516
<i>(c) Future Expansion Space (2 max)</i>	<i>No space available for additional stations</i>		0
Sum of (a), (b), & (c) Above	18	-	1,516
<i>(d) Other Treatment Space</i>	-	-	2,106
Total Treatment Space for Facility	-	-	3,702

Exhibit 5B did not allocate square footage to sub-item (c) ("Future Expansion Space) as there is no space in the main treatment area for further stations beyond our current request. Furthermore, sub-item (c) does not affect the total treatment space (3,702 sf), it only affects the split between the main treatment space (sum of a-c above) and other treatment space (d). Therefore, under either scenario the total treatment space (3,702 sf) is below the maximum allowable (5,425 sf)". [Source: August 12, 2019, screening response page 3]

Public Comment

None

Rebuttal Comment

None

Department Evaluation

Fresenius states that FKC Columbia Basin does not have space for future stations and this does not affect the facility's maximum square foot treatment floor area. Consistent with WAC 246-310-800(11), FKC Columbia Basin calculated maximum treatment floor area square footage for 17 in-center stations and one isolation station is 5,425. Fresenius will use 3,702 square feet.

Specific to the costs and charges for health services, Fresenius provided a non-binding contracting letter verifying the cost and considerations. [Source: Application, page 17 and Exhibit 11]

The total costs for this project is \$246,289. Fresenius is responsible for all costs involved with the construction of the proposed facility. Within the application, the applicant states, "Please find attached Revised Exhibit 13 for a letter from Mr. Mark Fawcett, Senior Vice President and Treasurer, attesting to the availability of funds and a commitment to this project by QualiCenters Inland Northwest, LLC". [Source: August 19, 2019, Screening response, page 5; and Exhibit 13]

A letter committing financial support of this effort was included as part of the application. A breakdown of the capital cost for this project is below. [Source; Application, page 19 and Exhibit 13]

Department's Table 4 Estimated Capital Costs

Item	Cost
Building Construction	\$197,438
Fixed Equipment	\$14,000
Moveable Equipment	\$16,920
Fees Architect and Engineering	\$15,272
Sales Tax	\$2,659
Total	\$246,289

Fresenius provided a letter of financial commitment from its corporate entity. The letter states that the corporate entity is responsible for all funds for the project. Furthermore, Fresenius also provided a contractor's letter that attests to the reasonableness of the costs of the project. [Source: Application, page 17 and Exhibit 11]

FKC Columbia Basin projected combine Medicare and Medicaid reimbursements is 53.6% of revenue. The remaining percentages of revenue from a combination of commercial insurance, HMO, other government miscellaneous insurance and unidentified other category is expected to be 46.4% of revenue. Given that majority of dialysis payments are from Medicare and Medicaid reimbursements, Fresenius percentages appears to be reasonable.

Regardless of Fresenius projections, under the new ESRD PPS payment system, the Centers for Medicare and Medicaid Services pays dialysis providers a bundled rate per treatment and that rate is not the same for each providers. Each provider, within a given geographic area, may receive the same base rate. However, due to the due number of adjustments both at the facility and at patient-specific level that affects the final reimbursement rate each provider will receive varies. The same variance also applies to what a dialysis facility receives from its commercial payers.

Even if two different dialysis providers billed the same commercial payer the same amount, the actual payment to each provider receive will depend on the negotiated discount rate obtained by the commercial payer for 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 Fresenius 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.

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

Fresenius

Fresenius stated it will use existing reserves to fund this project and provided a letter from Mark Fawcett, Senior Vice President of Finance of Fresenius Medical Center, attesting to the availability of funds and a commitment to this project. [Source: August 12, 2019, Screening response, page 5; and Exhibit 13]

Public Comment

None

Rebuttal Comment

None

Department Evaluation

Fresenius intends to finance this project with reserves and provided historical financial document to demonstrate that funds are available. The department concludes **this sub-criterion is met.**

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

Based on the source information reviewed, the department concludes that Fresenius Medical Care Holdings, Inc. **met** the need criteria in WAC 246-310-230 for this project.

- (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

Fresenius provided the following statement and table in order to comply with this sub-criterion. [Source: Application page 20]

“Historical and projected FTE staffing, by position and clinical setting, is provided below in Table 11

Table 11. FKC Columbia Basin, Proposed Staffing, by FTE and Position Reproduced

Productive FTEs, by Type	Current (2019)	Dec. 2020	2021	2022	2023
<i>In-Center FTE's</i>					
<i>Nurse Manager</i>	<i>1.0</i>	<i>1.0</i>	<i>1.0</i>	<i>1.0</i>	<i>1.0</i>
<i>LPN</i>	<i>1.0</i>	<i>1.0</i>	<i>1.0</i>	<i>1.0</i>	<i>1.0</i>
<i>Outpatient RN</i>	<i>3.0</i>	<i>3.9</i>	<i>4.4</i>	<i>4.7</i>	<i>4.7</i>
<i>Patient Care Technician</i>	<i>9.0</i>	<i>9.6</i>	<i>10.9</i>	<i>11.8</i>	<i>11.8</i>
<i>Equipment Technician</i>	<i>1.0</i>	<i>1.0</i>	<i>1.0</i>	<i>1.0</i>	<i>1.0</i>
<i>Social Worker</i>	<i>1.0</i>	<i>1.0</i>	<i>1.0</i>	<i>1.0</i>	<i>1.0</i>
<i>Dietitian</i>	<i>1.0</i>	<i>1.0</i>	<i>1.0</i>	<i>1.0</i>	<i>1.0</i>

Productive FTEs, by Type	Current (2019)	Dec. 2020	2021	2022	2023
Secretary	1.0	1.0	1.0	1.0	1.0
Subtotal	18.0	19.5	21.2	22.5	22.5
Home FTE's					
Home Manager	1	1.0	1.0	1.0	1.0
Home RN	2	2.0	2.0	2.0	2.0
Subtotal	3.0	3.0	3.0	3.0	3.0
Total	21.0	22.5	24.2	25.5	25.5

Fresenius also provided the following assumption used to develop the staffing table above. [Source: Application, Page 20]

Information and assumptions used to prepare Table 11 include:

- *The wage and salary figures are based on FKC Columbia Basin 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 35.8% of wages and salaries based on FKC Columbia Basin 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.*

Fresenius also provided the statements below.

“FKC Columbia Basin 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 Benton County as well as from neighboring counties in the region. To be effective in staff recruitment and retention, QualiCenters 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, Page 22]

“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: August 19, 2019, Screening response, page 2]

Public Comment

None

Rebuttal Comment

None

Department Evaluation

If this application is approved, Fresenius expects it would need 4.5 more FTEs with the additional stations, for a facility total of 25.5 FTEs by the end of the third year of operation or by year (2023). Fresenius intends to rely on its recruitment and retention strategies used in the past for this project. This approach is reasonable. The applicant is a well-established provider of dialysis services in Washington State and Benton County. Information provided in the application demonstrates that the applicant has the infrastructure in place to recruit necessary staff.

Fresenius identified Dr. Fareed Arif as the medical director of the proposed FKC Columbia Basin. Fresenius provided an executed medical director contract. The document outlines the roles and responsibilities for the position. Based on the information, the department concludes that Fresenius provided sufficient information to demonstrate compliance with this sub-criterion. 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

In the application, F provided a table listing of the vendors with whom FKC Columbia Basin currently has ancillary and support agreements. [Source; Application page 22-23]

Table 13: List of ancillary and support agreements for Columbia Basin (Reproduced)

Absolute Comfort Heating/Cooling	Charis Contractors	Hema Metrics	Medical Solutions	Stericycle
Absolute Medical Service	Chinook	Henry Schein	Messa Lab	Steve Herres
Air Gap	Chrystal Springs	Herres Back Flow & Construction	Metro Medical	Storage Land
Airsep	City of Kennewick	Horizon Construction	Moore Wallace	SunBelt
ALL CITY RESTORAGE	City of Kennewick-False Alarm	Horton and Associates	Mounts Lock and key	Superior Building Services
ALL DOORS	Coles	IDEARC	Myron L Company	SUPERIOR GLASS
ALL PHASE	Colman Oil	I-KEY (equipment order)	Orkin	Superior Uniforms
AM CLEANING	Columbia Basin Satellite	Ikon	Owens & Minor	Total Quality Medical
Apollo	Columbia Cleaners	Ingenix	Oxarc	Tri City Embroidery

AT&T	Compucaddy(equipment order)	In-Home Medical	Personnel Concepts	Tri City Lab
Batteries Plus	Country Gentleman	Innovative	Picatti	Tri City Radiology
BC Group (bio-med)	Crown	ISPA	PMI	Tri City Taxi
Benton Franklin Health Dist	D.M.G	JCB Lab	PUD	Vernon
Better Water	Dell	JJ Calibration	Quality Inn	Vista Park Mini Storage
BF Power Vac	Dept of Health	Kendall	Quill (PT Binders)	WA DEPT Health
Blind Cleaning Specialist	Dept of Labor and Indust.	Lab Safety	REA (3220)	WA State Patrol
Brashear Electric	Earthquake Management	Langbehn Randall	renal Nutrition Network	Wagoner Color Vision
Bruce Heating & Air Cond	Elite Construction	Language Link	Riggie Plumbing	Waste Management
Brucelli Advertising	Elite Renovations	Life Assist	RPC	Waterloo
Budget Printing	Eschelon Telecom Inc	Livix	Scale Tronix	Well Spoken Interpreting
C&H District	EZ-WAY	Lourdes Medical Center	Serim Research	West Coast Fire Systems
CALEM	Fast Signs	LSS	Seton	
Camtek	First Health Products	Lusk Pump	Shelby's Floral	
Cardiac science	Fresenius Medical Care	Mar Cor	Shred It	
Cascade Fire	Garner	Market Lab	Siemens	
CB Satellite	GE Osmotic	McKay Construction	Silver Line	
CDA	Grainger	McKesson	SMART SOURCE	
CDW-G	HACH	McKinney	Sports Booster	
CDW-Government (computers)	Harrington Industrial Plastics	Med Pro	STANLEY SECURITY SOLUTIONS	
Champion	Helmer	Media	State of WA Buisness Licesing	

Fresenius also provided the following statements regarding services provided on site and services provided through a parent corporation off site. [Source: Application, Page 23]

“All patient care and support services except senior management, financial, legal, planning, marketing, and architectural/construction and research and development are provided on-site at each clinic.”

As previously noted, Fresenius also provided an executed Medical Director Agreement and states, *“FKC Columbia Basin contracts with Fareed Arif, M.D. for medical director services. Dr. Arif’s professional license number is MD00043592. A medical director agreement is included in Exhibit 9”*. [Source: Application page 21, Exhibit 9]

Public Comment

None

Rebuttal Comment

None

Department Evaluation

As previously stated, the applicant has been operating in Washington State and Benton County for many years. The dialysis center has established ancillary and support agreements in place. Nothing in the information reviewed suggests that the additional four stations would require changes to the existing agreements.

The proposed medical director for FKC Columbia Basin is Fareed Arif, M.D. Fresenius provided an executed medical director agreement. The medical director is under contract and the reimbursement for this position varies from \$145,178 during the first full year in year 2021 to \$147,922 during the third full year of operation. Because the medical director is not an employee; that position is not included in the FTE table above. The executed medical director agreement (“Agreement”), is between QualiCenters Inland Northwest, LLC d/b/a Fresenius Medical Care Columbia Basin Dialysis Clinic and an affiliate of Fresenius Medical Care Holding, Inc. and Fareed Arif, M.D. (“Consultant”). [Source: Application page 21 and Exhibit 9]

The department notes that Fresenius Medical Care Holding, Inc. have a history of establishing dialysis facilities in Washington State. Fresenius is aware of the types of vendors that can be contracted with in order to have the appropriate ancillary and support services for FKC Columbia Basin if the four stations are added **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

To comply with the sub criterion, Fresenius provided the following statements.

“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 decertification’s 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”. [Source: Application, page 24-25]

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 these projects, 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, Fresenius Medical Care Holding, Inc. provides outpatient dialysis centers and services all across the United States and worldwide. Fresenius Medical Care Holding, Inc. reports dialysis services to CMS for approximately 2,634 facilities. Of the 2,634 facilities reporting to CMS, 206 do not have the necessary amount of data to compile a star rating. For the remaining 2,428 facilities with a star rating, the national average rating is 3.85. [Source: CMS data October 2019]

CMS Star Rating for Washington State Centers

FMC owns, operates, or manages 24 facilities in Washington. The average CMS star rating for the 24 facilities is 4.17 stars per facility. This information shows that for those FMC’s Washington facilities, their star ratings are within the CMS average.

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 24 of Fresenius Medical Care Holding, Inc. 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 identified Fareed Arif, M.D as the Medical Director for FKC Columbia Basin. Dr. Fareed Arif is credentialed in Washington State. Using data from the Medical Quality Assurance Commission, the department found that Dr. Fareed Arif is compliant with state licensure and has no enforcement actions on the license.

Fresenius provided a listing of credentialed staff, which includes four registered nurses, nine medical assistant hemodialysis, one social worker, and one dietitian. Using data from the DOH Office of Customer Service, the department found that of the credentialed staff, one social worker had an enforcement action in 2017 and the action is closed. This social worker credential is in full compliance and good standing.

In review of this sub-criterion, the department considered the total compliance history of the dialysis facilities owned or operated by Fresenius Medical Care Holding, Inc. or its affiliates. The department also considered the compliance history of the physician that would be associated with the facility. The department concludes that Fresenius has been operating in compliance with applicable state and federal licensing and certification requirements. The department also concludes there is reasonable assurance that the addition of a new dialysis center would not cause a negative effect on Fresenius Medical Care Holding, Inc. or its affiliate's compliance history. The department concludes that if this project is approvable, Fresenius project **met 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

Fresenius provided the following information related to this sub-criterion. [Source: August 19, 2019, Screening response page 5, Exhibit 15]

"Please find attached Exhibit 15 for a transfer agreement between Kadlec Medical Center and FKC Columbia Basin"

Public Comment

None

Rebuttal Comment

None

Department Evaluation

Fresenius has been a provider of dialysis services in Washington State for many years. Fresenius has a history of establishing relationships with existing healthcare networks in the planning areas where it operates a dialysis facility. The executed Patient Transfer Agreement provided in the application, is between Fresenius Kidney Care Columbia Basin and Kadlec Medical Center. Based on the information above, the department concludes that Fresenius project **met 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 Proposed Project

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, Fresenius Medical Care Holdings, Inc. **met** the cost containment criteria in WAC 246-310-240 for this project.

(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.

Step One

Department Evaluation

Fresenius 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

Fresenius identified the following two options considered before submitting this application. [Source: Application, page 26-28]

“The following three options were evaluated in the alternatives analysis:

- *Option One: Add four (4) stations to existing facility—The Project*
- *Option Two: Postponing the request—Do Nothing*
- *Option Three: Establish a new four (4) station center in Benton County at a different site.*

Please see Tables 14-17, respectively. They provide a summary of advantages and disadvantages of each of the three 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.

Table 14. Alternatives Analysis: Promoting Access to Healthcare Services

Option:	Advantages/Disadvantages:
<i>Option One Add four (4) stations to existing facility—The Project</i>	<ul style="list-style-type: none"> • <i>Adds additional dialysis stations to the Planning Area, as warranted by the department’s dialysis forecast model. (Advantage (“A”).</i> • <i>Residents of the Benton 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).</i>

Option:	Advantages/Disadvantages:
Option Two <i>Do nothing</i>	<ul style="list-style-type: none"> • <i>Would do nothing to improve access (Disadvantage (“D”).</i> • <i>Outmigration would increase (D).</i>
Option Three <i>Establish a new four (4) station center in Benton County at a different site</i>	<ul style="list-style-type: none"> • <i>Similar advantages to Option One. (A)</i>

Table 15. Alternatives Analysis: Promoting Quality of Care

Option:	Advantages/Disadvantages:
Option One <i>Add four (4) stations to existing facility—The Project</i>	<ul style="list-style-type: none"> • <i>Adds additional dialysis station capacity as warranted by the station forecast model (A).</i> • <i>This promotes access, reduces fragmentation, thus, and promotes quality (A).</i> • <i>Residents of Benton County Planning Area would have increased dialysis station capacity--this improves quality of care inasmuch as it improves continuity of care (A).</i>
Option Two <i>Do nothing</i>	<ul style="list-style-type: none"> • <i>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)</i>
Option Three <i>Establish a new four (4) station center in Benton County at a different site</i>	<ul style="list-style-type: none"> • <i>Adds additional dialysis station capacity as warranted by the station forecast model (A).</i> • <i>Relative to Option One, this option would fragment care and unnecessarily spread organizational resources that otherwise could be used for quality improvement and care coordination purposes. (D)</i>

Table 14. Alternatives Analysis: Promoting Cost and Operating Efficiency

Option:	Advantages/Disadvantages:
Option One <i>Add four (4) stations to existing facility—The Project</i>	<ul style="list-style-type: none"> • <i>Approval of the current project request will allow for the facility to optimize its capacity and achieve corresponding economies of scale. (A)</i> • <i>Would require limited re-location of supplies and equipment, minimizing impact on existing operations and capital expenditures associated with the project. (A)</i>
Option Two <i>Do nothing</i>	<ul style="list-style-type: none"> • <i>Capital and operating costs would be least under this option, since there would be none (A).</i> • <i>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).</i>
Option Three <i>Establish a new four (4) station center in Benton County at a different site</i>	<ul style="list-style-type: none"> • <i>A new site would require significantly more capital expenditures. (D)</i> • <i>Given there would be two sites, this Option would not capture as many economies of scale as a single site.</i>

Table 17. Alternatives Analysis: Legal Restrictions.

Option:	Advantages/Disadvantages:
<p>Option One Add four (4) stations to existing facility—The Project</p>	<p><i>This option requires certificate-of-need approval.</i></p>
<p>Option Two Do nothing</p>	<p><i>There are no legal implications with this option.</i></p>
<p>Option Three Establish a new four (4) station center in Benton County at a different site</p>	<p><i>This option requires certificate-of-need approval.</i></p>

Public Comment

None

Rebuttal Comment

None

Department Evaluation

FKC Columbia Basin is the only dialysis facility operating in Benton County. Fresenius provided discussions of the alternatives considered which include not submitting this application. After reviewing the information, the department concludes that Fresenius appropriately rejected the other alternative 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(2) under that sub-criterion, the department concluded **is not 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

Fresenius provided the following information related to this sub-criterion. [Source: Application page 28]

“Any proposed changes would meet QualiCenters 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

None

Department Evaluation

If this project is approved, it could have the potential to improve delivery of dialysis services to the residents of Benton County with the addition of four new dialysis stations in the planning area. The department concludes that the application submitted by Fresenius is the applicant best available alternative for the community **this sub-criterion is met.**



2019
Benton County
ESRD Need Projection Methodology

Planning Area		6 Year Utilization Data - Resident Incenter Patients					
Benton		2013	2014	2015	2016	2017	2018
Benton County		134	159	154	155	168	189
TOTALS		134	159	154	155	168	189
246-310-812(4)(a)	Rate of Change		18.66%	-3.14%	0.65%	8.39%	12.50%
	6% Growth or Greater?		TRUE	FALSE	FALSE	TRUE	TRUE
	Regression Method:	Linear					
246-310-812(4)(c)			Year 1 2019	Year 2 2020	Year 3 2021	Year 4 2022	Year 5 2023
Projected Resident Incenter Patients	from 246-310-812(4)(b)		187.20	194.60	202.00	209.40	216.80
Station Need for Patients	Divide Resident Incenter by 4.8		39.00	40.54	42.08	43.62	45.17
	Rounded to next whole number		39	41	43	44	46
246-310-812(4)(d)	subtract (4)(c) from approved stations						
Existing CN Approved Stations	Total		42	42	42	42	42
Results of (4)(c) above			39	41	43	44	46
Net Station Need			3	1	-1	-2	-4
Negative number indicates need for stations							
Planning Area Facilities							
Name of Center	# of Stations						
FMC Columbia Basin	13						
DaVita Kennewick	10						
DaVita Chinook	19						
Total	42						
Source: Northwest Renal Network data 2013 - 2018							
Most recent year-end data: 2018 posted 02/15/2019							



2019
Benton County
ESRD Need Projection Methodology

x	y	Linear						
2014	159	150						
2015	154	158						
2016	155	165						
2017	168	172						
2018	189	180						
2019		187.20						
2020		194.60						
2021		202.00						
2022		209.40						
2023		216.80						
SUMMARY OUTPUT								
<i>Regression Statistics</i>								
Multiple R	0.806446709							
R Square	0.650356295							
Adjusted R Square	0.533808393							
Standard Error	9.906226998							
Observations	5							
ANOVA								
	df	SS	MS	F	Significance F			
Regression	1	547.6	547.6	5.580163043	0.099198659			
Residual	3	294.4	98.13333333					
Total	4	842						
	Coefficients	Standard Error	t Stat	P-value	Lower 95%	Upper 95%	Lower 95.0%	Upper 95.0%
Intercept	-14753.4	6315.371605	-2.336109563	0.101580789	-34851.73103	5344.93103	-34851.7	5344.931
X Variable 1	7.4	3.132624033	2.362236873	0.099198659	-2.56940778	17.36940778	-2.56941	17.36941

