



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

Correction Letter

December 18, 2018

CERTIFIED MAIL # 7014 2120 0002 7589 9308

Casey Stowell  
Regional Vice President –Pacific Northwest  
Fresenius Medical Care  
20900 SW 115<sup>th</sup> Avenue, Suite 190  
Tualatin, OR 97062

RE: Certificate of Need Application #18-40 - Fresenius Kidney Care Gig Harbor

Dear Ms. Stowell:

This letter is to make you aware of an error in the Department's December 4, 2018 cover letter and evaluation for the Certificate of Need application submitted by Fresenius Medical Care Holding, Inc., proposing the addition of two dialysis stations to Fresenius Gig Harbor located in Pierce County planning area #3 under the special circumstance provisions of Washington Administrative Code 246-310-818. Correction of the error does not change the department's decision to approve the project.

This letter and enclosed evaluation supersedes the December 4, 2018 cover letter and evaluation. For the reasons stated in the enclosed decision, Fresenius Medical Care Holding, Inc., application is consistent with the applicable criteria of the Certificate of Need Program, provided Fresenius Medical Care Holding, Inc., agrees to the following in its entirety.

**Project Descriptions:**

This certificate approves the addition of two dialysis stations to the 12-station Fresenius Kidney Care Gig Harbor, for a facility total of 14 dialysis stations plus one isolation station. Fresenius Kidney Care Gig Harbor will continue to provide in-center hemodialysis, home hemodialysis and peritoneal dialysis training and support for dialysis patients, a dedicated isolation station, a permanent bed station, and shifts beginning after 5:00 p.m.

Certificate of Need #1686 was issued to Fresenius Medical Care Holding, Inc., approving the one-time addition of an isolation station to Fresenius Kidney Care Gig Harbor is consistent with Washington Administrative Code 246-310-809(3). The certificate was effective on January 1, 2018.

The table below provides a breakdown of the total number of stations at Fresenius Kidney Care Gig Harbor, which includes two additional stations approved under the special circumstance criterion outlined in Washington Administrative Code 246-310-818.

	<b>CMS Certified Stations</b>	<b>Stations Counted in Methodology</b>
General Use In-Center Stations	13	13
Permanent Bed Station	1	1
Private Isolation Station <sup>1</sup>	1	0
<b>Total Stations</b>	<b>15</b>	<b>14</b>

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

**Conditions:**

1. Approval of the project description as stated above. Fresenius Medical Care 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 capital reserves as described in the application.

**Approved Costs:**

The approved capital expenditure for this 2-station addition is \$8,763. This amount represents the costs for fixed and moveable equipment; construction and leasehold improvements; and architect and engineering fees. 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.

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<sup>1</sup> Fresenius has not yet completed the administrative station adjustment as allowed under WAC 246-310-809

Casey Stowell  
Regional Vice President –Pacific Northwest  
Fresenius Medical Center  
CN Application #18-37 Fresenius Kidney Care Gig Harbor  
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Send your written response to the Certificate of Need Program, at one of the following addresses.

Mailing Address:

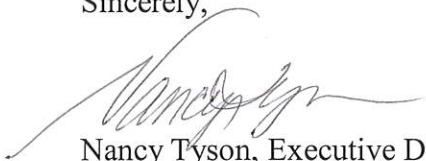
Department of Health  
Certificate of Need Program  
Mail Stop 47852  
Olympia, WA 98504-7852

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

**CORRECTED**

**2018 CYCLE 1 SPECIAL CIRCUMSTANCE EVALUATION DATED DECEMBER 4, 2018, FOR THE CERTIFICATE OF NEED APPLICATION SUBMITTED BY RENAL CARE GROUP NORTHWEST, INC., PROPOSING TO ADD TWO DIALYSIS STATIONS TO FRESenius KIDENY CARE GIG HARBOR DIALYSIS CENTER LOCATED IN PIERCE COUNTY ESRD PLANNING AREA #3.**

Renal Care Group Northwest, Inc., is one of three entities owned by Renal Care Group, Inc. (RCG). Renal Care Group Northwest, Inc. is responsible for the operation of facilities under three separate legal entities. These entities include Pacific Northwest Renal Services (PNRS), Renal Care Group Northwest and Inland Northwest Renal Care Group (IN-RCG). In March of 2006, Fresenius Medical Care Holdings, Inc. became the sole owner of RCG. Fresenius Medical Care Holdings, Inc. through its subsidiaries, owns and operates 23 dialysis centers in Washington State.

**Adams County**

FMC Leah Layne Dialysis Facility

**Benton County**

FMC Columbia Basin Dialysis Center

**Clark County**

PNRS Fort Vancouver Facility  
PNRS Clark County Dialysis Facility  
FMC Salmon Creek Facility

**Grant County**

FMC Moses Lake Dialysis Facility

**Grays Harbor County**

FMC Aberdeen Facility

**Lewis County**

FMC Chehalis Facility

**Mason County**

FMC Shelton Dialysis Facility

**Okanogan County**

FMC Omak Dialysis Facility

**Pierce County**

Fresenius Kidney Care Gig Harbor  
Fresenius Kidney Care Puyallup  
Fresenius Kidney Care East Tacoma  
Fresenius Kidney Care South Tacoma  
Fresenius Kidney Care Mount Rainier

**Spokane County**

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

**Stevens County**

FMC Colville Facility

**Thurston County**

FMC North Thurston County Dialysis Center  
FMC Lacey Facility

**Walla Walla County**

Qualicenters – Walla Walla

**PROJECT DESCRIPTION**

Fresenius Kidney Care Gig Harbor is a 12-station facility located at 4700 Point Fosdick Drive NW, Suite 101 in Gig Harbor [98335], within Pierce County ESRD planning area #3. This application proposes to add two additional stations to the 12-station facility resulting in a 14-station dialysis facility plus one isolation station. Fresenius Kidney Care Gig Harbor would remain at its current location in Gig Harbor and would continue to provide in-center hemodialysis, home hemodialysis and peritoneal dialysis training and support for dialysis patients, a dedicated isolation station, a permanent bed station, and shifts beginning after 5:00 p.m. [Source: Application, Page 10]

The capital expenditure associated with the additional two stations is \$8,763. Of that amount, approximately 67% is for fixed and moveable equipment; 26% is for building construction and the remaining 7% is associated with architect and engineering fees. All costs would be paid by Fresenius Medical Care Holdings, Inc. [Source: Application page 18]

Within this application, FMC determined this evaluation would be released in early October 2018. Using that timeline, Fresenius Medical Care Holdings, Inc. estimated the two station addition would be operational by the end of January 2019. [Source: Application 10] Under this timeline, calendar year one of the project is 2019 and calendar year three is 2021.

For ease of reference in this evaluation, the department will refer to the applicant Renal Care Group Northwest, Inc. ('RCGNW') and Fresenius Medical Care Holdings, Inc. as ('FMC'), and 12-station Fresenius Kidney Care Gig Harbor will be referred as ('FKC Gig Harbor').

### **APPLICABILITY OF CERTIFICATE OF NEED LAW**

FMC's applications proposes to add dialysis stations to existing dialysis centers. 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. It states:

*"Criteria contained in this section and in WAC 246-310-210, 246-310-220, 246-310-230, and 246-310-240 shall be used by the department in making the required determinations.*

*(a) In the use of criteria for making the required determinations, the department shall consider:*

- (i) The consistency of the proposed project with services or facility standards contained in this chapter;*
- (ii) In the event the standards contained in this chapter do not address in sufficient detail for a required determination the service or facilities for health services proposed, the department may consider standards not in conflict with those standards in accordance with subsection (2)(b) of this section; and*
- (iii) The relationship of the proposed project to the long-range plan (if any) of the person proposing the project."*

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

*(b) The department may consider any of the following in its use of criteria for making the required determinations:*

- (i) Nationally recognized standards from professional organizations;*
- (ii) Standards developed by professional organizations in Washington State;*
- (iii) Federal Medicare and Medicaid certification requirements;*
- (iv) State licensing requirements*
- (v) Applicable standards developed by other individuals, groups, or organizations with recognized expertise related to a proposed undertaking; and*

*(vi) The written findings and recommendations of individuals, groups, or organizations with recognized expertise related to a proposed undertaking, with whom the department consults during the review of an application.*

To obtain Certificate of Need approval, an applicant must demonstrate compliance with the applicable criteria found in WAC 246-310-210 (need); 246-310-220 (financial feasibility); 246-310-230 (structure and process of care); and 246-310-240 (cost containment).

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

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

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

An applicant is required to submit specific data elements to the Certificate of Need Program by a specific date. For the 2018 concurrent review cycle, the data must be received before February 16, 2018. Fresenius submitted its data elements on February 15, 2018.

### **TYPE OF REVIEW**

As directed under WAC 246-310-806 the department accepted this application under the Kidney Disease Treatment Centers-Special Circumstances Concurrent Review Cycle #1 for calendar year 2018. Even though applications submitted under WAC 246-310-806 are reviewed under a concurrent review cycle, the applications are not reviewed competitively. Below is the chronologic summary of the application’s review.

### **APPLICATION CHRONOLOGY**

Within the application FMC stated it will provide charity care at FKC Gig Harbor and it submitted a copy of its charity care policy and the eligibility criteria. During the review of this application, the department was unable to determine that the pro forma financial statement submitted for FKC Gig Harbor properly identify the amount of charity care that FMC intend to provide at this facility. To address this issue, FMC provided supplemental information and it states that charity care is already factored in its pro forma financial statement net revenue. However, the department was unable to identify the charity care amount because the revised pro forma financial statements did not provide the necessary charity care information for the department to appropriately assess the amount of charity care that FMC will provide at FKC Gig Harbor.

As a result, on August 23, 2018, the department declared a Pivotal Unresolved Issue (PUI). On August 24, 2018, in response to the PUI, FMC provided a revised pro forma financial documentation. The revised pro forma financial document identified the amounts of charity care that FMC intend to provide at FKC Gig Harbor. [Source: August 24, 2018, PUI documents]

Action	FMC
Letter of Intent Submitted	March 28, 2018
Application Submitted	May 1, 2018
Department's Pre-review Activities including <ul style="list-style-type: none"> <li>• DOH Screening Letter</li> <li>• Applicant's Responses Received</li> </ul>	May 15, 2018 June 14, 2018
Beginning of Review	June 25, 2018
Public Comment <ul style="list-style-type: none"> <li>• Public comments accepted through the end of public comment</li> <li>• No public hearing requested or conducted</li> </ul>	July 25, 2018
Rebuttal Comments Received <sup>1</sup>	August 1, 2018
Department Declares Pivotal Unresolved Issue (PUI)	August 24, 2018
End Public Comments on PUI Document	September 11, 2018
Rebuttal Comments Submitted for PUI Document	September 25, 2018
Department's Anticipated Decision Date	November 13, 2018
Department's Actual Decision Date	December 4, 2018

### **AFFECTED PERSONS**

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

“...an “interested person” who:

- (a) *Is located or resides in the applicant's health service area;*
- (b) *Testified at a public hearing or submitted written evidence; and*
- (c) *Requested in writing to be informed of the department's decision.”*

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

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

During the review of this project, Health Facilities Planning & Development requested interested persons status to the this application.

### **Health Facilities Planning & Development**

Health Facilities Planning & Development (HFPD) located in King County, is a consultation firm hired by applicants to prepare and submit Certificate of Need applications on their behalf. Health Facilities Planning & Development requested interested person status and to be informed of the department’s

<sup>1</sup> The department did not receive any public comment. As a result, FMC cannot provide rebuttal comments

decision. Health Facilities Planning & Development does meet the definition of an “interested person” under WAC 246-310-010(34). HFPD did not provide independent written or oral comment on this application. Therefore, it does not meet the definition of an “affected person” under WAC 246-310-010(2).

**SOURCE INFORMATION REVIEWED**

- FMC Certificate of Need application received May 1, 2018
- FMC screening response received June 14, 2018
- Pivotal Unresolved Issue (PUI) response received by 5:00 p.m. on August 24, 2018
- Years 2012 through 2017 historical kidney dialysis data obtained from the Northwest Renal Network
- Department of Health’s ESRD Need Projection Methodology for Pierce County planning area #3 posted to its website March 2018
- Licensing data provided by the Medical Quality Assurance Commission, Nursing Quality Assurance Commission, and Health Systems Quality Assurance Office of Health System Oversight
- FMC website at [www.freseniuskidneycare.com](http://www.freseniuskidneycare.com)
- Northwest Renal Network website at [www.nwrn.org](http://www.nwrn.org)
- Northwest Renal Network modality data
- Centers for Medicare and Medicaid website at [www.medicare.gov/dialysisfacilitycompare](http://www.medicare.gov/dialysisfacilitycompare)
- Certificate of Need historical files

**CONCLUSIONS**

For the reasons stated in this evaluation, the application submitted by Fresenius Medical Care Holdings, Inc. proposing to add two dialysis stations to Fresenius Kidney Care Gig Harbor located in Pierce County planning area #3 is consistent with applicable criteria of the Certificate of Need Program provided Fresenius Medical Care Holdings, Inc. accept the following in its entirety.

**Project Description:**

This certificate approves the addition of two dialysis stations to the 12-station Fresenius Kidney Care Gig Harbor, for a facility total of 14 dialysis stations plus one isolation station. Fresenius Kidney Care Gig Harbor will continue to provide in-center hemodialysis, home hemodialysis and peritoneal dialysis training and support for dialysis patients, a dedicated isolation station, a permanent bed station, and shifts beginning after 5:00 p.m. A breakdown of all stations at project completion is shown below:

	<b>CMS Certified Stations</b>	<b>Stations Counted in Methodology</b>
General Use In-Center Stations	13	13
Permanent Bed Station	1	1
Private Isolation Station <sup>2</sup>	1	0
<b>Total Stations</b>	<b>15</b>	<b>14</b>

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

**Conditions:**

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<sup>2</sup> Fresenius has not yet completed the administrative station adjustment as allowed under WAC 246-310-809



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 capital reserves as described in the application

Approved Costs:

The approved capital expenditure for this 2-station addition is \$8,763. This amount represents the costs for fixed and moveable equipment; construction and leasehold improvements; and architect and engineering fees. All costs will be paid by Fresenius Medical Care Holdings, Inc.

## **CRITERIA DETERMINATIONS**

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

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

- (1) *The population served or to be served has need for the project and other services and facilities of the type proposed are not or will not be sufficiently available or accessible to meet that need.*

### **WAC 246-310-818**

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

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

- (a) *For 4.8 planning areas, the facility has operated at or above an average of 5.0 patients per station for the most recent six consecutive month period preceding the letter of intent submission date for which data is available. Data used to determine patients per station must be obtained from the Northwest Renal Network; or*
- (c) *The facility can accommodate one or two additional stations within its existing building, which may include shelled space. If renovation is needed to accommodate the additional station(s), renovation must be within the existing building.*

### **FKC Gig Harbor.**

To demonstrate compliance with this sub-criterion, FMC provided the following data and document for the facility:

- Six month utilization data for FKC Gig Harbor; and
- Single line drawing showing the stations and support areas of the dialysis center both before and after the two stations are added to capacity. [Source: Application page 11, and June 14, 2018, screening response, Exhibit 5]

### **Public Comment**

None

### **Rebuttal Comment**

None

### **Department Evaluation**

For this project, the six months preceding the letter of intent submission period for the Special Circumstance submission cycle #1 for Pierce County is October 2017 through March 2018. The utilization data used by FMC is from the same time frame and it demonstrated that FKC Gig Harbor met this sub criterion. The data provided in the application shows that FKC Gig Harbor was operating at an average of 5.50 patients per station. The single line drawing provided in the application show the two new stations will be set up in existing spaces within the facility. Based on the information reviewed the department concludes the **sub-criterion is met**.

WAC 246-310-818(5) For 4.8 planning areas, a facility is ineligible for a special circumstance one- or two-station expansion if the owner or affiliate has approved certificate of need stations in the planning area that have operated below an average of 4.5 patients per station for the most recent six consecutive month period preceding the letter of intent submission date. Data used to calculate patients per station must be obtained from the Northwest Renal Network.

**FKC Gig Harbor.**

To demonstrate compliance with this sub-criterion, FMC provided the following data for the facility:

- Six month utilization data for FKC Gig Harbor. [Source: Application page 13]

Public Comment

None

Rebuttal Comment

None

**Department Evaluation**

The six months preceding the letter of submission period for the Special Circumstance submission # 1 for Peirce County is October 2017 through March 2018. The data to be used by FKC Gig Harbor is data for the same time frame September 2017 to February 2018. The data used by FMC provided in the application shows that as of that date, FKC Gig Harbor was operating at an average of 5.50 patient per station. **This sub-criterion is met.**

WAC 246-310-818(7) For 4.8 planning areas, a special circumstance one- or two-station expansion will not be approved if, with the requested new station(s), the applicant's kidney dialysis facility would fall below a calculated 4.5 patients per station. Data used to make this calculation is the average patients per station from subsection (1)(a) of this section.

**FKC Gig Harbor**

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

- “See Table 5 below for the calculation following application of this rule to FKC Gig Harbor demonstrating it meets the occupancy standard under WAC 246-310-818(7)-(8).

Table 5 (Reproduced)

	Sep-17	Oct - 17	Nov -17	Dec -17	Jan -18	Feb -18
Total in-center Stations (Current Station Count Plus Two According to WAC 246-310-818(7) – (8)	14	14	14	14	14	14
Total in-center patients	69	69	68	66	65	66
Patients per stations	4.93	4.93	4.86	4.71	4.64	4.71”

[Source: Application page 14]

Public Comment

None

Rebuttal Comment

None

**Department Evaluation**

The six months preceding the letter of intent submission period for the Special Circumstance submission cycle #1 for Pierce County is October 2017 through March 2018. The data used by FMC for this project is data for same the time frame. If this project is approved, FKC Gig Harbor would be operating 14 in center dialysis stations plus one isolation station. The data provided in the application shows that the 14-station center will be operating at an average of 4.71 patients per station. **This sub-criterion is met.**

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

**FKC Gig Harbor.**

To demonstrate compliance with this sub-criterion, FMC provided the following statement and the table reproduced below showing the projected timeline of operation for the two additional stations.

*“With the understanding that the review of a Certificate of Need application typically takes 6-9 months, provide an estimated timeline for project implementation, below:*

<i>Event</i>	<i>Anticipated Date</i>
<i>Design Complete</i>	<i>N/A, No design needed</i>
<i>Construction Commenced</i>	<i>9/7/18</i>
<i>Construction Completed</i>	<i>9/13/2018</i>
<i>Facility Prepared for Survey</i>	<i>10/7/18”</i>

[Source: Application page 10]

Public Comment

None

Rebuttal Comment

None

**Department Evaluation**

On August 24, 2018, FMC provided its response to the PUI and states, *“According to the Department’s PUI letter, the anticipated decision date is now November 13, 2018. Consequently, the previous forecast period of 4Q2018 can longer apply. Instead, the new stations are now anticipated to become operational on December 1, 2018. Revised Exhibit 8B features a forecast period of December 2018 to reflect the new decision date and the anticipated operational date”*. [Source: PUI response received August 24, 2018, page 2]

Given that WAC 246-310-818(10) requires stations to be operational within six months of approval, as identified by the applicant revised timeline the two stations will be operational in December 2018. Given the revised timeline identified by FMC, the department concludes the **sub-criterion is met.**

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

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

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

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

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

A facility's charity care policy should show a willingness of a provider to provide services to patients who have exhausted any third-party sources, including Medicare and Medicaid, and whose income is equal to or below 200% of the federal poverty standards, adjusted for family size or is otherwise not sufficient to enable them to pay for the care or to pay deductibles or coinsurance amounts required by a third-party payer.<sup>3</sup> With the passage of the Affordable Care Act (ACA), the amount of charity care is expected to decrease, but not disappear. The policy should also include the process one must use to access charity care at the facility.

#### **FMC.**

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

*"RCG and Fresenius have documented and proven history of providing charity care in all our Washington facilities. All individuals identified as needing dialysis services will continue having access..."* [Source: Application page 16]

#### **FKC Gig Harbor.**

*"A copy of the admission policy is contained in Exhibit 7. FKC Gig Harbor's admission policy includes language regarding non-discrimination, including prohibiting discrimination on the basis of race, income, ethnicity, sex or handicap."*

*A copy of our charity care policy is contained in Exhibit 6".* [Source: Application, Page 17]

In addition to the statements above, FMC provide a copy of its Dialysis Unit Emergency Backup Agreement dated March 28, 2012, between Fresenius Medical Care Holdings, Inc. d/b/a Fresenius

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<sup>3</sup> WAC 246-453-010(4).

Medical Care North America (“FMCNA”) on behalf of itself and its direct wholly-owned and /or controlled affiliates and /or subsidiaries (“entities”) which own or may in the future own outpatients dialysis facilities. [Source: Application Exhibit 14]

Medicare and Medicaid Programs

**FKC Gig Harbor.**

FKC Gig Harbor is currently Medicare and Medicaid certified. Within the application, FMC states, “*Table 1 [Revised] FKC Gig Harbor Dialysis Center, Projected Payer Mix, by Revenue and by Patient*”. [Source: August 23, 2018, PUI documents page 2]

*Table 1 (Reproduced)*

<i>Payer Class</i>	<i>Mix based on Treatments</i>	<i>Mix based on Revenue</i>
<i>Medicare</i>	<i>67.9%</i>	<i>46.9%</i>
<i>Medicaid</i>	<i>3.4%</i>	<i>2.3%</i>
<i>Commercial</i>	<i>1.8%</i>	<i>5.9%</i>
<i>Medicare ADV</i>	<i>15.7%</i>	<i>14.9%</i>
<i>Medicare RISK</i>	<i>6.7%</i>	<i>5.1%</i>
<i>MISC INS</i>	<i>3.8%</i>	<i>24.8%</i>
<i>Self-Pay</i>	<i>0.7%</i>	<i>0.5%</i>
<b><i>Total</i></b>	<b><i>100.0%</i></b>	<b><i>100.0%</i></b>

Public Comment

None

Rebuttal Comment

None

**Department Evaluation**

On August 24, 2018, FMC provided a revised pro forma financial statement in response to the PUI declared by the department. The revised pro forma financial statement show that charity care is available at the facility and all patients in the planning area will have access to dialysis services provided by FMC at its FKC Gig Harbor. Within the application, FMC states, “*A copy of the admission policy is contained in Exhibit 7. FKC Gig Harbor’s admission policy includes language regarding non-discrimination, including prohibiting discrimination on the basis of race, income, ethnicity, sex or handicap. A copy of our charity care policy is contained in Exhibit 6*”. [Source: Application page 17]

The department historical record shows that all FMC dialysis centers in Washington are Medicare and Medicaid certified. Documentation provided in the application demonstrates that FKC Gig Harbor would continue to be Medicare and Medicaid certified. FMC projected that Medicare revenues for FKC Gig Harbor will be 46.7% of total revenues and for Medicaid 2.3%. Given that FMC currently operates dialysis centers in Washington State and uses the same admission policy and non-discrimination policies it provided in this application at each facilities it operates in Washington the department concludes FMC’s project **meets this sub-criterion.**

(3) The applicant has substantiated any of the following special needs and circumstances the proposed project is to serve.

(a) The special needs and circumstances of entities such as medical and other health professions schools, multidisciplinary clinics and specialty centers providing a substantial portion of their services or resources, or both, to individuals not residing in the health service areas in which the entities are located or in adjacent health service areas.

**Department Evaluation**

This sub-criterion is not applicable to this application.

(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.

**Department Evaluation**

This sub-criterion is not applicable to this application.

(c) The special needs and circumstances of osteopathic hospitals and non-allopathic services.

**Department Evaluation**

This sub-criterion is not applicable to this application.

(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.

**Department Evaluation**

This sub-criterion is not applicable to this application.

(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.

**Department Evaluation**

This sub-criterion is not applicable to this application.

(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**

This sub-criterion is not applicable to this application.

## **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.

### *(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, FMC must demonstrate compliance with the following sub-sections of WAC 246-310-815(1). Using its experience and expertise the department evaluates if the applicant's pro forma income statements reasonably project the proposed project is meeting its immediate and long-range capital and operating costs by the end of the third complete year of operation.

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

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

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

### **FKC Gig Harbor**

Given that FKC Gig Harbor is currently operational, sub-sections (1)(a) and (b) above apply to this project. To comply with this sub criterion, FMC provided the assumptions it used to project the patients volume for FKC Gig Harbor. The assumptions are restated below.

- First Full Year— 2019, based on implementation by the end of January 2019 and survey by the end of December 2018.
- Patient Volumes— the number of in-center patient is expected to equal 69 patients in 2018, a modest increase from 66 patients the actual number for FKC Gig Harbor as of February 2018.
- The number of home patients is expected to equal 5 patients, a modest increase from 2 patients the actual number for FKC Gig Harbor as of February 2018.
- It is assumed the number of treatments per patient is 144/year. There is an adjustment in 4Q2018 to reflect only three months of operation during the forecast time period.

[Source: June 14, 2018, screening responses Exhibit 8B]



*“Upon further review and analysis, it was determined that the figure of bad debt included in our previously submitted financial model was incorrect, and in fact, included charity care. We have corrected and revised our charity care calculation, such that our pro forma forecast estimates of charity care are now based on:*

- (1) The percentage of treatments that are categorized as self-pay, based on actuals. However, FKC Gig Harbor did not have self-pay patients in 2017. Therefore, the closest Fresenius facility's (FKC Mt. Rainier) self-pay treatment percentage, 0.72%, was used in the revised pro forma financials. Please see Table 1 below for a revised payer mix;*
- (2) This [self-pay] percentage, multiplied by revenues, 1 as listed in the proforma, for both in-center and home;*
- (3) The sum of the two figures for in-center and home yields total charity care as listed in revised Exhibit 8B, attached<sup>4</sup>.*

*This charity care figure, along with the bad debt estimate, is subtracted from revenues to obtain net revenues, as listed in revised Exhibit 8B”. [Source: August 24, 2018, PUI documents page 2]*

In addition to the assumptions above, FMC also provided the assumptions it used to prepare its pro forma financial statement for FKC Gig Harbor. Those assumptions are restated below.

#### Patient Volume

*The number of in-center patients is expected to equal 69 patients in 2018, a modest increase from 66 patients, the actual number for FKC Gig Harbor as of February 2018. Modest growth is assumed for the subsequent years in the forecast period.*

*The number of home patients is expected to equal 5 patients, an increase from 2 patients, the actual number for FKC Gig Harbor as of February 2018. Further growth is assumed for the subsequent years in the forecast period.*

*It is assumed the number of treatments per patient is 144/year. There is an adjustment in December 2018 to reflect only one month of operation during the forecast time period.*

#### Revenues

*Revenues are based on CY2017 FKC Gig Harbor data (“actuals”), given it is an existing facility. Payer mix statistics have also been obtained from FKC Gig Harbor actuals for the most recent calendar year. Revenues are calculated by payer, by treatment.*

#### Charity care

*Calculated at the Self Pay treatment mix percentage. In the case of FKC Gig Harbor, there was no self pay in 2017. Therefore, the figure for FKC Mt. Rainier, the closest FMC facility, was used. This figure is 0.72% of treatments.*

#### Bad debt

*Calculated on a per treatment basis for in-center and home treatments from FKC Gig Harbor actuals.*

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<sup>4</sup> It should be noted this revision has not changed the total net revenue figure from previously, except for revisions to the timeline in 2018 which will be discussed further. Again, it was determined that the figure of bad debt was incorrect, and in fact, included charity care. This has been corrected.

### Expenses

*Unless otherwise noted, expenses have been calculated on a per treatment basis for variable expenses from FKC Gig Harbor actuals.*

*Personnel expenses have been released to drive off the FTE table included in this Exhibit. The table includes FTEs, by type and cost.*

*Depreciation is straight-line; assumes 10 years on leaseholds and 8 years on equipment. This figure has been corrected to include architectural fees associated with tenant TI costs.*

*Rent Expense is based on 'Base Rent' terms detailed on page 1 in the original lease between Franciscan Health System and Olympic Group, LLC, which was subsequently assigned to Fresenius in 2017. See [Application] Exhibit 10 for all related lease documents.*

*Other Property Exp includes common area maintenance ("CAM"), allocated taxes, and insurance costs. Estimated at 5% of base Rent Expense.*

*Physician compensation based on the Medical Director Agreement ("MDA"), in place beginning March 2017. The 12-month fee was \$90,000. Future 12-month periods inflated at 2% on anniversary dates. [Source: August 24, 2018, PUI revised financial statement-forecasts Exhibit 8B]*

### Public Comment

None

### Rebuttal Comment

None

### Department Evaluation

FKC Gig Harbor is currently operating with 12 stations. Based its projections, FMC projected the utilization for FKC Gig Harbor using the facility current utilization plus the two stations. This approach for an existing facility is reasonable. As a special circumstance application, WAC 246-310-815(1)(b) requires an applicant to base its revenue projections on the current payer mix and base its expense projections on current expenses. FMC provided both its revenue and expense projections and based them on its current operations. Since FKC Gig Harbor is currently operational, the facility has both an existing lease agreement and an existing medical director agreement.

The applicant provided a copy of an initial lease agreement, an assignment lease agreement, and a copy of an amendment to the assigned lease agreement between Franciscan Health Systems (Assignor) and Renal Care Group Northwest, Inc. (Assignee) and Olympic Group, LLC (Landlord). The assigned lease was executed on February 13, 2017 and later amended in June 2018. The lease gives FMC a renewal option. FMC also provided its executed Medical Director Agreement for FKC Gig Harbor. The Medical Director Agreement was executed in 2017 and it is due to expire in ten years or by year 2027. The costs identified in the medical director agreement can be substantiated in the revenue and expense statement.

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

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

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

**WAC 246-310-818(2)**

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

**FKC Gig Harbor.**

FMC identified the costs for this project, which includes building construction, moveable equipment and Washington State sales tax. The capital cost breakdown is shown in Table 1. FMC also provided a non-binding contractor letter related to the estimated building construction cost identified in the table below. [Source: Application page 18, and Exhibit 11]

Table 1

**Estimated Capital Costs  
FKC Gig Harbor Dialysis Center**

<b>Item</b>	<b>Total</b>
Building Construction	\$2,322
Fixed Equipment	\$5,860
Washington State Sales Tax	\$581
<b>Total Estimated Capital Costs</b>	<b>\$8,763</b>

Public Comment

None

Rebuttal Comment

None

**Department Evaluation**

The costs for adding the two stations to the 12-station FKC Mt. Rainier is \$8,763. The cost is comparable to those reviewed in past applications for similar size station addition. The department does not consider the capital expenditure to be excessive for this project. Documentation provided in the application shows that FMC expects that its projected Medicare and Medicaid payor mix based on revenue for FKC Gig Harbor will be 49.2%. The applicant also states that its historic payor mix from Medicare and Medicaid is the same as it projected payor mix. This amount is reasonable for a facility that has been in operation for many years. Furthermore, the amounts are consistent with percentages reviewed and approved in past FMC's projects.

The department notes that Medicare and Medicaid patients typically make up the largest percentage of patients served by a dialysis facility. CMS implemented an ESRD Prospective Payment System (PPS). Under the new ESRD PPS, Medicare pays dialysis facilities a bundled rate per treatment. The

rate is not the same for each facility. Each facility, within a given geographic area, may receive the same base rate. However, there are a number of adjustments both at the facility and at patient-specific level that affects the final reimbursement rate each facility will receive.

What a dialysis facility receives from its commercial payers will also vary. Even if two different dialysis providers billed the same commercial payer the same amount, the actual payment to each facility will depend on the negotiated discount rate obtained by the commercial payer from each individual provider. The department does not have an adopted standard on what constitutes an unreasonable impact on charges for health services. Based on department's understanding of how dialysis patients may qualify for Medicare payments, the department concludes that the information presented by FMC about its revenue indicates this project may not have an unreasonable impact on charges for Medicare and Medicaid, since that revenue is dependent upon cost based reimbursement. The remaining 50.8% of revenue is commercial and other revenues.

Based on the above information provided in the application, the department concludes that FMC's projected costs associated with the addition of two stations to the 12-station dialysis center would probably not have an unreasonable impact on the costs and charges for healthcare services in Pierce County planning area #3. **This sub-criterion is met.**

(3) *The project can be appropriately financed.*

WAC 246-310 does not contain specific source of financing criteria as identified in WAC 246-310-200(2)(a)(i). There are also no known recognized standards as identified in WAC 246-310-200(2)(a)(ii) and (b) that directs how a project of this type and size should be financed. Therefore, using its experience and expertise the department compared the proposed project's source of financing to those previously considered by the department.

**FKC Gig Harbor.**

FMC identified a capital expenditure of \$8,763 to add two stations to FKC Gig Harbor. FMC intends to fund the project using corporate reserves. FMC provided a letter from its vice president finance to demonstrate availability of funds and financial commitment to the project. [Source: Application, page 19-20, Exhibit 11]

FMC also provided a copy of its audited financial statements for years 2015, 2016, and 2017 to demonstrate sufficient reserves to finance the project. [Source: Application, Exhibit 13]

Public Comment

None

Rebuttal Comment

None

**Department Evaluation**

FMC intends to finance this project with reserves and it demonstrated the fund is available. Based on the documents reviewed in the application, 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 and agreement to the conditions identified in the conclusion section of this evaluation, the department concludes that Fresenius Medical Care Holdings, Inc., projects met the structure and process of care criteria in WAC 246-310-230

- (1) A sufficient supply of qualified staff for the project, including both health personnel and management personnel, are available or can be recruited.

WAC 246-310 does not contain specific WAC 246-310-230(1) criteria as identified in WAC 246-310-200(2)(a)(i). There are also no known recognized standards as identified in WAC 246-310-200(2)(a)(ii) and (b) that directs what specific staffing patterns or numbers of full time equivalents (FTEs) that should be employed for projects of this type or size. Therefore, using its experience and expertise the department determined whether the proposed staffing would allow for the required coverage.

**FKC Gig Harbor.**

If this project is approved, FMC expect that the additional two stations would be operational by December 2018. Under this timeline, year 2019 would be the facility’s first full calendar year of operation and 2021 would be year three. The reproduced Table 9 below provides a breakdown of FKC Gig Harbor year 2017 FTE’s, current year 2018, and projected years 2019 through 2021. [Source: Application, page 23 and August 24, 2018, PUI documents page 2]

*Table 10 (Reproduced)*

***FKC Gig Harbor, Current and Proposed Staffing, FTE and Position***

<b><i>FTE by Type</i></b>	<b><i>2017</i></b>	<b><i>2018 (Current)</i></b>	<b><i>2019</i></b>	<b><i>2020</i></b>	<b><i>2021</i></b>
<b><i>In-Center FTE’s</i></b>					
<i>Nurse Manager</i>	<i>1</i>	<i>1</i>	<i>1</i>	<i>1</i>	<i>1</i>
<i>Outpatient RN</i>	<i>4</i>	<i>4</i>	<i>4</i>	<i>5</i>	<i>5</i>
<i>LPN</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>
<i>Patient Care Tech</i>	<i>10</i>	<i>10</i>	<i>10</i>	<i>11</i>	<i>11</i>
<i>Equipment Tech</i>					
<i>Social Worker</i>	<i>0.75</i>	<i>0.75</i>	<i>0.75</i>	<i>0.75</i>	<i>0.75</i>
<i>Dietician</i>	<i>0.5</i>	<i>0.5</i>	<i>0.5</i>	<i>0.5</i>	<i>0.5</i>
<i>Facility Administrator</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>
<i>Secretary</i>	<i>0.85</i>	<i>0.85</i>	<i>0.85</i>	<i>0.85</i>	<i>0.85</i>
<b><i>Subtotal</i></b>	<b><i>17.1</i></b>	<b><i>17.1</i></b>	<b><i>17.1</i></b>	<b><i>19.1</i></b>	<b><i>19.1</i></b>
<b><i>Home FTE’s</i></b>					
<i>Home manager</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>
<i>Home RN</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>
<i>Home Other</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>0</i>
<b><i>Subtotal</i></b>	<b><i>0</i></b>	<b><i>0</i></b>	<b><i>0.5</i></b>	<b><i>0.5</i></b>	<b><i>1</i></b>
<b><i>Total</i></b>	<b><i>17.1</i></b>	<b><i>17.1</i></b>	<b><i>17.6</i></b>	<b><i>19.6</i></b>	<b><i>20.1</i></b>

FMC also provided the following statements related to the staffing table above.

“As illustrated above in Table 9, there are incremental FTE staffing increases for the project that corresponds with the similar modest utilization increases provided in Table 6. RCG based the staffing projections on its and its parent corporation’s experience in developing dialysis facilities in Washington State”. [Source: Application page 23]

Public Comment

None

Rebuttal Comment

None

**Department Evaluation**

FMC identified Dr. Won Lee Ho as the current medical director for FKC Gig Harbor. The facility nurse manager is Maria Conger and the clinical director is Erin Fossen. FMC provided a copy of the medical director agreement and a joinder to the agreement. The medical director agreement is between Renal Care Group Northwest, Inc. (“Company”) an affiliate of Fresenius Medical Care Holdings dba Fresenius Medical Care North America (“FMCNA”), and Pacific Nephrology Associates, PS (“Consultant”), and the following nephrologists Zheng Ge, MD, Yajuan He, MD, Ho Won Lee, MD, Di Zhao, MD, as (“Member Physicians”). The medical director agreement was signed in January 2011 and it has a 10 year term validity period. [Source: Application Exhibit 9]

In the addition to the agreements, FMC also provided the following statements related to FTE recruitment and retention.

*“FKC Gig Harbor is an operational dialysis facility, which is staffed with qualified clinical and support personnel. Table 9 provides the number of current and proposed FTEs, by type. By virtue of our geographic location, we anticipate recruiting additional staff from Pierce County as well as from neighboring counties in the region. To be effective in staff recruitment and retention, RCG offers competitive wage and benefit packages. For the above reasons, RCG believes that we will be successful in recruiting additional qualified, core staff to provide and promote quality of care at FKC Gig Harbor”.* [Source: Application page 25]

Information provided in the application demonstrates that FMC is a well-established provider of dialysis services in Washington State and in Pierce County planning area #3. For this project, FMC is proposing to add two stations to the existing 12 station facility. The increase in stations will require the addition of about three FTEs by the end of the third full year of operation or by year 2021. Based on the above information, the department concludes that FMC has the ability and expertise to recruit and retain a sufficient supply of qualified staff for this project. **This sub-criterion is met.**

- (2) The proposed service(s) will have an appropriate relationship, including organizational relationship, to ancillary and support services, and ancillary and support services will be sufficient to support any health services included in the proposed project.

WAC 246-310 does not contain specific WAC 246-310-230(2) as identified in WAC 246-310-200(2)(a)(i). There are also no known recognized standards as identified in WAC 246-310-200(2)(a)(ii) and (b) that directs what relationships, ancillary and support services should be for a project of this type and size. Therefore, using its experience and expertise the department assessed the materials contained in the application.

**FKC Gig Harbor.**

FMC provides dialysis services throughout Washington State, including its FKC Gig Harbor Dialysis Center in Pierce County planning area #3. If this project is approved, FKC Gig Harbor Dialysis Center’s stations will increase from 12 to 14. To comply with this sub criterion FMC states,

*“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.*

*There are no anticipated changes to the existing ancillary or support agreements as a result of this project.”* [Source: Application, page 27]

For a listing of the healthcare facilities that FKC Gig Harbor has working relationships with, FMC states, *“Please see Exhibit 14”*. [Source: Application page 27]

Public Comment

None

Rebuttal Comment

None

**Department Evaluation**

FKC Gig Harbor is an existing kidney dialysis facility all ancillary and support services have been established for the 12-station center. FMC states that no new agreement or revisions to existing agreement are necessary for this project. Based on the document provided in the application, the department concludes that FMC project **met this sub-criterion**.

- (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.

**FKC Gig Harbor.**

FMC provided the following statement in response to this sub-criterion. [Source: Application page 28]

*“The applicant has no history with respect to the actions noted in WAC 246-310-230(5)(a)”*.

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. The department 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 provided the following overview regarding its star rating for dialysis centers.

*“The star ratings are part of Medicare’s efforts to make data on dialysis centers easier to understand and use. The star ratings show whether your dialysis center provides quality dialysis care - that is, care known to get the best results for most dialysis patients. The rating ranges from 1 to 5 stars. A facility with a 5-star rating has quality of care that is considered ‘much above average’ compared to other dialysis facilities. A 1- or 2- star rating does not mean that you will receive poor care from a facility. It only indicates that measured outcomes were below average compared to those for other facilities. Star ratings on Dialysis Facility Compare are updated annually to align with the annual updates of the standardized measures.”* [Source: CMS website]

#### CMS Star Rating for Washington State Centers

FMC owns, operates, or manages 23 facilities in Washington. Of the 23 centers, four<sup>5</sup> do not have the necessary amount of data to compile a star rating. The department reviewed the star rating for the remaining 19 centers.<sup>6</sup> The average CMS star rating for the nineteen facilities is 4.47 stars per facility. This information shows that for those FMC’s Washington facilities, their star ratings are within the CMS average.

#### Washington State Survey Data

Finally, the department reviewed the state survey data performed by the Department of Health Office of Health System Oversight for the compliance history of the dialysis facilities owns or operates by FMC in Washington State. For FKC Gig Harbor, the initial Centers for Medicare and Medicaid Certification or Recertification date is February 13, 2017. The Department of Health Office of Health Systems Oversight conducted a survey on behalf of the Centers for Medicare and Medicaid and the survey did not result in significant non-compliance issues. [Source: DOH OHSO survey data]

FMC identified Dr. Won Lee Ho as the medical director for FKC Gig Harbor and provided a copy of the medical director agreement. The department review of the compliance history for the medical director, using data from the Medical Quality Assurance Commission, shows that Dr. Won Lee Ho has no enforcement actions. [Source: Application page 24]

In its review of this sub-criterion, the department considered the total compliance history of the dialysis facilities owned and operated by FMC. The department also considered the compliance history of the medical director associated with this facility. The department concludes that FKC Gig Harbor has been operating in compliance with applicable state and federal licensing and certification requirements. The department also conclude there is reasonable assurance that the addition of stations to FKC Gig Harbor will not have negative effects on the facility compliance history. The department concludes that FMC meet **this sub-criterion**.

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<sup>5</sup> The following four facilities did not have star ratings: Fresenius Kidney Care Gig Harbor, Fresenius Kidney Care East Tacoma; Fresenius Kidney Care South Tacoma, and Fresenius Kidney Care Mt. Rainier.

<sup>6</sup> CMS Star Rating Data updated as of October 9, 2018.



- (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.

**FKC Gig Harbor.**

FMC provided the following statements in response to this sub-criterion.

*"The proposed project promotes continuity of care as it seeks to expand FKC Mt. Gig Harbor's existing dialysis care services. Further, we have provided documentation that FKC Gig Harbor has met all standards contained in WAC 246-310-818, demonstrating 'Special Circumstance' evident by the high demand for the facility's services and warranting approvable for expansion of 2 additional stations".* [Source: Application page 27]

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 establishing relationships with existing healthcare networks in Pierce County planning area #3 for its FKC Gig Harbor's facility. Additionally, FMC's project would promote continuity in the provision of healthcare services in the planning area by adding needed stations to FKC Gig Harbor. FMC provided documentation in the application to demonstrate that the project would promote continuity in the provision of health care services in the community and not result in unwarranted fragmentation.

In addition, within the application FMC also provided its exiting transfer policy for FKC Gig Harbor. The transfer policy known as "Dialysis Unit Emergency Back Up Agreement dated March 2012, is between Fresenius Medical Care Holdings, Inc., d/b/a Fresenius Medical Care North America ("FMCNA") on behalf of itself, and indirect wholly-own, or may in the future own, outpatient dialysis facilities. Based on the information above, the department concludes that FMC's 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.

**FKC Gig Harbor.**

FMC provided the following statements in response to this sub-criterion.

*"The applicant has no history with respect to the actions noted in WAC 246-310-230(5)(a)".* [Source: Application, page 27]

Public Comment

None

Rebuttal Comment

None

**Department Evaluation**

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

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

Based on the source information reviewed and agreement to the conditions identified in the conclusion section of this evaluation, the department concludes that Fresenius Medical Care Holdings, Inc., met the cost containment criteria in WAC 246-310-240.

- (1) Superior alternatives, in terms of cost, efficiency, or effectiveness, are not available or practicable.  
To determine if a proposed project is the best alternative, the department takes a multi-step approach. Step one determines if the application has met the other criteria of WAC 246-310-210 thru 230. If it has failed to meet one or more of these criteria, then the project is determined not to be the best alternative, and would fail this sub-criterion.

If the project has met the applicable criteria in WAC 246-310-210 through 230 criteria, in step two, the department assesses the other options considered by the applicant. If the department determines the proposed project is better or equal to other options considered by the applicant and the department has not identified any other better options this criterion is determined to be met unless there are multiple applications.

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

**Step One**

**FKC Gig Harbor.**

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

**Step Two**

**FKC Gig Harbor.**

For this sub-criterion, FMC states, "*The following three options were evaluated in the alternatives analysis:*

- *Option One: Add two (2) stations to the existing facility—The Project*
- *Option Two: Postponing the request—Do Nothing*
- *Option Three: Add one (1) stations to the existing facility.*" [Source: Application page 28]

Public Comment

None

Rebuttal Comment

None

**Department Evaluation**

FMC provided a comprehensive discussion of the options it considered and the alternatives it rejected before submitting this application. Specifically, FMC states that by adding additional dialysis stations to the Planning Area, residents of the planning area will be better able to access needed dialysis services and are not forced to out-migrate to other facilities outside the planning area.

FMC submitted this application during the special circumstances review cycle. According to the eligibility criteria, the department will approve one or two additional special circumstance stations for an existing kidney dialysis facility, if it meets certain criteria regardless of whether the methodology show need. The application submitted by Fresenius for its FKC Gig Harbor dialysis facility shows that the facility was operating at or above 4.8 during the most recent six consecutive months prior to the application submission. This information was collaborated by the data in the application.

Also, information provided in the application demonstrates that superior alternatives in terms of cost, efficiency, or effectiveness, is not available or practicable for the patients in Pierce County planning area #3. Special circumstance applications are by default designed to quickly bring stations online in facilities that are highly utilized. Therefore, Fresenius proposal to add two special circumstance dialysis stations to FKC Gig Harbor, will result in patients having more flexibility scheduling dialysis services in the planning area. The capital expenditures costs associated with this application is related to fixed and moveable equipment and minor remodeling of station spaces and the costs will be paid by FMC.

Given that the only other option to the project is to do nothing, and taking into account that the demonstration of need is not necessary, the department concludes that the application submitted by FMC to add two dialysis station to FKC Gig Harbor, is the best available alternatives for the community. **This sub-criterion is met.**

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

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

(b) The project will not have an unreasonable impact on the costs and charges to the public of providing health services by other persons.

Since FMC's capital cost expenditures for the projects are solely related to equipment and the sales tax associated with the purchase, the department concludes this sub-criterion does not apply to this project. **This sub-criterion is 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.

**FKC Gig Harbor.**

FMC provided the statements below related this sub-criterion for all three applications.

*“The proposed changes will meet all 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.”* [Source: Application page 32]

**Public Comment**

None

**Rebuttal Comment**

None

**Department Evaluation**

FMC’s project have the potential to improve delivery of dialysis services to the residents of Pierce County planning area #3 with the addition of two dialysis stations to FKC Gig Harbor. **This sub-criterion is met.**