September 26, 2019

CERTIFIED MAIL # 7016 3010 0001 0575 0235

Casey Stowell, Regional Vice President Pacific Northwest
Fresenius Medical Care
20900 SW 115th Avenue, Suite 190
Tualatin, Oregon 97062

RE: CN Application #19-70 – FKC Thurston Dialysis Center

Dear Ms. Stowell:

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

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

**Project Description:**
This certificate approves the addition of one dialysis station to the seven-station FKC Thurston, for a facility total of eight dialysis stations.¹ Services provided at FKC Thurston include hemodialysis patients who dialyze in the chronic setting, home hemodialysis and peritoneal dialysis training and support, hemodialysis patients requiring isolation, hemodialysis patients requiring dialysis in a permanent bed station, and hemodialysis patients requiring treatment shifts that begin after 5:00 PM

The table on the following page provides a breakdown of the total number of stations at FKC Thurston, which includes one additional station approved under the special circumstance criterion outlined in Washington Administrative Code 246-310-818.

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¹ Certificate of Need #1683 was issued to FMC approving the one-time addition of an isolation station to FKC Thurston consistent with Washington Administrative Code 246-310-809(3). The certificate was effective on January 1, 2018. This station has not yet been added.
As required under Washington Administrative Code 246-310-818(10), the additional station must be operational within six months of approval, otherwise this Certificate of Need is revoked.

**Conditions:**

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

**Approved Costs:**
The approved capital expenditure for this one-station addition is $2,047. This amount represents the costs for moveable equipment. All costs will be paid by Fresenius Medical Care.

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

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

Send your written response to the Certificate of Need Program, at one of the following addresses.

**Mailing Address:**
Department of Health  
Certificate of Need Program  
Mail Stop 47852  
Olympia, WA 98504-7852

**Physical Address:**
Department of Health  
Certificate of Need Program  
111 Israel Road SE  
Tumwater, WA 98501

If you have any questions, please contact the Certificate of Need Program at (360) 236-2955.

Sincerely,

Nancy Tyson, Executive Director  
Health Facilities and Certificate of Need

Enclosure
APPLICANT DESCRIPTION

Fresenius Medical Care

Renal Care Group Northwest (RCGNW) is one of three entities owned by Renal Care Group, Inc. (RCG). 
RCGN is responsible for the operation of facilities under three separate legal entities. These entities
include Pacific Northwest Renal Services (PNRS), Renal Care Group Northwest (RCGNW), and Inland
Northwest Renal Care Group (IN-RCG). In March of 2006, Fresenius Medical Care Holdings (FMC
Holdings) became the sole owner of RCG. In addition to the three entities listed above, FMC also
operates two other entities, including QualiCenters, Inc. and National Medical Care, Inc. As all of these
subsidiaries are owned by one parent corporation-Fresenius Medical Care. This evaluation shall refer to
the applicant and all subsidiaries as Fresenius Medical Care or FMC.

FMC operates outpatient dialysis centers in 48 states, the District of Columbia, and Puerto Rico through
these subsidiaries. In Washington State, FMC owns, operates, or manages 25 kidney dialysis facilities.
These facilities are listed below. Some facilities have started operating under the name “Fresenius
Kidney Care (FKC).” [source: Application, Exhibit 2, CMS Dialysis Facility Compare website]

<table>
<thead>
<tr>
<th>Adams County</th>
<th>Okanogan County</th>
</tr>
</thead>
<tbody>
<tr>
<td>FMC Leah Layne Dialysis Center</td>
<td>FMC Omak Dialysis Center</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Benton County</th>
<th>Pierce County</th>
</tr>
</thead>
<tbody>
<tr>
<td>FMC Columbia Basin</td>
<td>FKC Mt. Rainier</td>
</tr>
<tr>
<td></td>
<td>FKC South Tacoma</td>
</tr>
<tr>
<td></td>
<td>FKC Tacoma East</td>
</tr>
<tr>
<td></td>
<td>FKC Gig Harbor</td>
</tr>
<tr>
<td></td>
<td>FKC Puyallup</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Clark County</th>
<th>Spokane County</th>
</tr>
</thead>
<tbody>
<tr>
<td>PNRS Fort Vancouver</td>
<td>FMC Spokane Kidney Center</td>
</tr>
<tr>
<td>PNRS Clark County Dialysis Clinic</td>
<td>FMC Northpointe Dialysis Unit</td>
</tr>
<tr>
<td>PNRS Salmon Creek</td>
<td>Panorama Dialysis</td>
</tr>
<tr>
<td></td>
<td>FMC North Pines Dialysis Unit</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Cowlitz County</th>
<th>Stevens County</th>
</tr>
</thead>
<tbody>
<tr>
<td>FKC Longview (CN #1811 issued August 29, 2019)</td>
<td>FMC Colville</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Grant County</th>
<th>Thurston County</th>
</tr>
</thead>
<tbody>
<tr>
<td>FMC Moses Lake Dialysis Unit</td>
<td>FKC Thurston</td>
</tr>
<tr>
<td></td>
<td>FKC Lacey</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Grays Harbor County</th>
<th>Walla Walla County</th>
</tr>
</thead>
<tbody>
<tr>
<td>FMC Aberdeen</td>
<td>Qualicenters – Walla Walla LLC</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>King County</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>FKC Cascade Peak (CN #1804 issued August 22, 2019)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Lewis County</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>FMC Chehalis</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Mason County</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>FMC Shelton</td>
<td></td>
</tr>
</tbody>
</table>
PROJECT DESCRIPTION
This project focuses on FMC Thurston County Dialysis Center, also known as Fresenius Kidney Care Thurston (FKC Thurston) located at 8770 Tallon Lane Northeast in Lacey [98516] within Thurston County. Currently, FKC Thurston is approved as a 7-station facility as shown in Table 1 below.¹

<table>
<thead>
<tr>
<th>Station Type</th>
<th>CMS Certified Stations</th>
<th>Station Counted for Station Use and Methodology</th>
</tr>
</thead>
<tbody>
<tr>
<td>General Use In-Center Stations</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>Permanent Bed Station</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Isolation Station</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td><strong>Total Stations</strong></td>
<td><strong>7</strong></td>
<td><strong>6</strong></td>
</tr>
</tbody>
</table>

This application proposes to add one additional station at FKC Thurston, resulting in 7 in-center stations and one isolation station. FKC Thurston would remain at its current location in Lacey and would continue to provide the following services.

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

The capital expenditure associated with the addition of one station is $2,047 and all costs are associated with the equipment. All costs would be paid from FMC Holdings’ corporate reserves. [source: Application, p14 and Exhibit 11]

In this application, and based on Washington Administrative Code (WAC) 246-310-806 Special Circumstances Cycle 1’s timeline, FMC determined this evaluation would be released in August 2019. Using that timeline, FMC estimated the additional station would be operational in September 2019. [source: Application, p6] Under this timeline, full year one is 2020 and full year three is 2022.

Department Information on Timelines for Completion of the Projects
FMC identified a timeline for completion of this project based on an August 2019 evaluation release date. Due to delays in releasing this evaluation, the projected timeline may not be achievable or accurate. If this project is approved, the department will adjust the operational timeline to account for the additional days of delay of the release of this evaluation.

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

¹ Effective January 1, 2018, FKC Thurston was issued CN #1683 allowing the addition of one station consistent with WAC 246-310-809(3). To date, FKC Thurston has not activated and certified this station.
EVALUATION CRITERIA
WAC 246-310-200(1)(a)-(d) identifies the four determinations that the department must make for each application. WAC 246-310-200(2) provides additional direction on how the department is to make its determination. It states:

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

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

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

(b) The department may consider any of the following in its use of criteria for making the required determinations:
   (i) Nationally recognized standards from professional organizations;
   (ii) Standards developed by professional organizations in Washington State;
   (iii) Federal Medicare and Medicaid certification requirements;
   (iv) State licensing requirements
   (v) Applicable standards developed by other individuals, groups, or organizations with recognized expertise related to a proposed undertaking; and
   (vi) The written findings and recommendations of individuals, groups, or organizations with recognized expertise related to a proposed undertaking, with whom the department consults during the review of an application.

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

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

WAC 246-310-809 One-time exempt isolation station reconciliation
WAC 246-310-812 Kidney disease treatment facilities—Methodology
WAC 246-310-821 Kidney disease treatment facilities—Standards for planning areas without an existing facility
WAC 246-310-830 Kidney disease treatment facilities—Relocation of facilities
WAC 246-310-833 One-time state border kidney dialysis facility station relocation
WAC 246-310-803
WAC 246-310-803 requires an applicant to submit specific data elements to the Certificate of Need Program. For the 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.

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 2019. 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

<table>
<thead>
<tr>
<th>Action</th>
<th>Fresenius</th>
</tr>
</thead>
<tbody>
<tr>
<td>Letter of Intent Submitted</td>
<td>March 28, 2019</td>
</tr>
<tr>
<td>Application Submitted</td>
<td>April 30, 2019</td>
</tr>
<tr>
<td>Department’s Pre-review Activities including</td>
<td></td>
</tr>
<tr>
<td>• DOH 1st Screening Letter</td>
<td>May 16, 2019</td>
</tr>
<tr>
<td>• Applicant’s 1st Screening Responses Received</td>
<td>June 13, 2019</td>
</tr>
<tr>
<td>Beginning of Review</td>
<td>June 24, 2019</td>
</tr>
<tr>
<td>End of Public Comment</td>
<td>July 24, 2019</td>
</tr>
<tr>
<td>• Public comments accepted through the end of public comment</td>
<td></td>
</tr>
<tr>
<td>• No public hearing requested or conducted</td>
<td></td>
</tr>
<tr>
<td>Rebuttal Comments Received</td>
<td>July 31, 2019</td>
</tr>
<tr>
<td>Department’s Anticipated Decision Date</td>
<td>August 15, 2019</td>
</tr>
<tr>
<td>Department's Anticipated Decision Date with a 60-day extension</td>
<td>October 15, 2019</td>
</tr>
<tr>
<td>Department’s Actual Decision Date</td>
<td>September 26, 2019</td>
</tr>
</tbody>
</table>

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;

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2 Public comments were accepted through June 24, 2019, however no public comments were submitted for this project. As a result, FMC did not provide rebuttal comments.
3 Thirty-day extension letters were sent to FMC Casey Stowell on August 13, 2019, and September 13, 2019.
(c) Third-party payers reimbursing health care facilities in the health service area;
(d) Any agency establishing rates for health care facilities and health maintenance
organizations in the health service area where the proposed project is to be located;
(e) Health care facilities and health maintenance organizations which, in the twelve months
prior to receipt of the application, have submitted a letter of intent to provide similar
services in the same planning area;
(f) Any person residing within the geographic area to be served by the applicant; and
(g) Any person regularly using health care facilities within the geographic area to be served
by the applicant.

For this project, one entity requested interested person status: DaVita, Inc.:

DaVita, Inc.
DaVita, Inc. (DaVita) is a national provider of dialysis services operating in 45 states and the District of
Columbia. When this application was submitted, DaVita was approved to own and operate a total of 42
dialysis centers in 19 separate counties within Washington State. Since then DaVita has obtained
approval to operate additional dialysis centers throughout Washington State. As of the writing of this
evaluation, DaVita operates two dialysis centers in Thurston County. DaVita did not provide any
comment on this application, therefore it does not qualify for affected person status.

SOURCE INFORMATION REVIEWED
• Fresenius Medical Care’s Certificate of Need application received April 30, 2019
• Fresenius Medical Care’s 1st screening response received June 13, 2019
• Years 2016 through 2018 historical kidney dialysis data obtained from the Northwest Renal Network
• Licensing data provided by the Medical Quality Assurance Commission, Nursing Quality Assurance
Commission, and Health Systems Quality Assurance Office of Customer Service
• Compliance history obtained from the Washington State Department of Health Office of Health
Systems Oversight
• FMC website at www.fmcna.com
• Northwest Renal Network website at www.nwrn.org
• Centers for Medicare and Medicaid website at www.medicare.gov/dialysisfacilitycompare
• Certificate of Need historical files

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

Project Description:
This certificate approves the addition of one dialysis station to the seven-station FKC Thurston, for a
facility total of eight dialysis stations. Services provided at FKC Thurston include hemodialysis patients

4 Olympia Dialysis Center and Tumwater Dialysis Center.
5 Certificate of Need #1683 was issued to FMC approving the one-time addition of an isolation station to FKC
Thurston consistent with Washington Administrative Code 246-310-809(3). The certificate was effective on
who dialyze in the chronic setting, home hemodialysis and peritoneal dialysis training and support, hemodialysis patients requiring isolation, hemodialysis patients requiring dialysis in a permanent bed station, and hemodialysis patients requiring treatment shifts that begin after 5:00 PM.

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

<table>
<thead>
<tr>
<th>CMS Certified Stations</th>
<th>Stations Counted in Methodology</th>
</tr>
</thead>
<tbody>
<tr>
<td>General Use In-Center Stations</td>
<td>6</td>
</tr>
<tr>
<td>Permanent Bed Station</td>
<td>1</td>
</tr>
<tr>
<td>Private Isolation Station</td>
<td>1</td>
</tr>
<tr>
<td><strong>Total Stations</strong></td>
<td>8</td>
</tr>
</tbody>
</table>

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

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

**Approved Capital Expenditure:**
The approved capital expenditure for this one-station addition is $2,047. This amount represents the costs for moveable equipment. All costs will be paid by Fresenius Medical Care.
CRITERIA DETERMINATIONS

A. Need (WAC 246-310-210)

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

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

WAC 246-310-818

WAC 246-310-818(1) - (13) outline the review requirements for dialysis projects submitted under the special circumstance review criteria. For this project, 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.

Fresenius Medical Care

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

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

[source: Application, pp9-10, and 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 Thurston County is October 2018 through March 2019. The data to be used by FMC for this project is the same time frame. The data provided in the application shows that FKC Thurston was operating at an average of approximately 5.92 patients per station, not counting the exempt isolation station.
The single line drawings shows the one additional station will be set up in existing space within the facility. Based on the information reviewed the department concludes the sub-criterion is met.

\textit{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.

\textbf{Fresenius Medical Care}

To demonstrate compliance with this sub-criterion, FKC Thurston provided six month utilization data as submitted to Northwest Renal Network and later validated by the department. This data focuses on FKC Thurston located in Thurston County. [source: Application, p10; September 24, 2019, email from Northwest Renal Network]

\textbf{Public Comment}

None

\textbf{Rebuttal Comment}

None

\textbf{Department Evaluation}

For this project, the six months preceding the letter of intent submission period for the Special Circumstance submission cycle #1 for Thurston County is October 2018 through March 2019. The data to be used by FMC for this project is the same time frame. Thurston County has five facilities, two of which – FKC Lacey and FKC Thurston – are operated by FMC. The data shows that FKC Lacey operated at approximately 6.14 patients per station, not counting the exempt isolation station, and FKC Thurston operated at 5.92 patients per station. \textit{This sub-criterion is met.}

\textit{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.

\textbf{Fresenius Medical Care}

To demonstrate compliance with this sub-criterion, FKC Thurston provided six month utilization data as submitted to Northwest Renal Network and later validated by the department. This data focuses on FKC Thurston located in Thurston County. [source: Application, pp10-11; September 24, 2019, email from Northwest Renal Network]

\textbf{Public Comment}

None

\textbf{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 Thurston County is October 2018 through March 2019. The data to be used by FMC for this project is the same time frame. If this project is approved, FKC Thurston would be operating 7 counted in center dialysis stations, not counting the exempt isolation station. The data provided in the application shows that the 8-station center would be operating at an average of 5.14 patients per station. This sub-criterion is met.

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

Fresenius Medical Care
To demonstrate compliance with this sub-criterion, FMC provided the following table showing the projected timeline for operation of the additional station at FKC Thurston. [source: Application, p6]

<table>
<thead>
<tr>
<th>FKC Thurston</th>
<th>Anticipated Dates of Commencement &amp; Completion of Project</th>
</tr>
</thead>
<tbody>
<tr>
<td>Design Complete</td>
<td>NA</td>
</tr>
<tr>
<td>Construction Commenced</td>
<td>NA</td>
</tr>
<tr>
<td>Construction Completed</td>
<td>NA</td>
</tr>
<tr>
<td>Facility Prepared for Survey</td>
<td>September 1, 2019</td>
</tr>
</tbody>
</table>

Public Comment
None

Rebuttal Comment
None

Department Evaluation
The timeline identified in FMC’s Table 1 above projects the new dialysis station would be operational at FKC Thurston within approximately one month of approval. FMC identified a timeline for completion of this project based on an August 2019 evaluation release date. Due to delays in releasing this evaluation, FMC’s timeline could not be achievable, so the department recalculated an operational date for this project. Using the actual September 2019 decision date, plus one month would be mid-October or early November 2019. Given that WAC 246-310-818(10) requires additional stations to be operational within six months of approval, this sub-criterion is met.

(2) All residents of the service area, including low-income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly are likely to have adequate access to the proposed health service or services.
To evaluate this sub-criterion, the department evaluates an applicant’s admission policies, willingness to serve Medicare and Medicaid patients, and to serve patients that cannot afford to pay for services.

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

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

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

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

**Fresenius Medical Care**

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

“All individuals identified as needing dialysis services will continue having access to FKC Thurston. FKC Thurston’s admission policies prohibits discrimination on the basis of race, income, ethnicity, sex or handicap. [source: Application, p12]

FMC provided copies of the following policies used at all FMC dialysis centers, including the existing FKC Thurston. [source: Application, Exhibits 6 and 7]

- Admission Policy
- Charity care or financial assistance policy

**Medicare and Medicaid Programs**

FKC Thurston is currently Medicare and Medicaid certified and provided the facility’s Medicare and Medicaid provider numbers. FMC also included a table showing the current and projected percentages of revenues by payer and revenues by patient for FKC Thurston. The information is summarized below and on the following page. [source: Application, pp7 and 16]

<table>
<thead>
<tr>
<th>Medicare Provider Number:</th>
<th>50-2575</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medicaid Provider Number:</td>
<td>2039958</td>
</tr>
</tbody>
</table>

---

6 WAC 246-453-010(4).
**Applicant Table**

<table>
<thead>
<tr>
<th>Source</th>
<th>Percentage of Treatments by Payer</th>
<th>Percentage of Revenue by Payer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medicare</td>
<td>72.4%</td>
<td>34.7%</td>
</tr>
<tr>
<td>Commercial</td>
<td>10.1%</td>
<td>51.8%</td>
</tr>
<tr>
<td>Medicaid</td>
<td>1.7%</td>
<td>0.6%</td>
</tr>
<tr>
<td>Medicare Adv</td>
<td>9.8%</td>
<td>8.8%</td>
</tr>
<tr>
<td>Medicare Risk</td>
<td>2.1%</td>
<td>0.9%</td>
</tr>
<tr>
<td>Misc Insurance</td>
<td>3.9%</td>
<td>2.9%</td>
</tr>
<tr>
<td>Self Pay</td>
<td>0.1%</td>
<td>0.1%</td>
</tr>
<tr>
<td>Old Revenue Acc</td>
<td>0.0%</td>
<td>0.3%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>100.00%</strong></td>
<td><strong>100.00%</strong></td>
</tr>
</tbody>
</table>

**Public Comment**
None

**Rebuttal Comment**
None

**Department Evaluation**

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

All FMC dialysis centers are Medicare and Medicaid certified. Documentation provided in the application demonstrates that FKC Thurston would continue both Medicare and Medicaid certifications. FMC projected the Medicare and Medicaid revenues for FKC Thurston to be 45% of total revenues. Pro forma financial data provided in the application shows Medicare and Medicaid revenue.

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

Given that FMC currently operates dialysis centers in Washington State and uses the same policies and procedures at each center, the policies provided in the application are executed policies used by FMC in its Washington State facilities. 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.

(b) The special needs and circumstances of biomedical and behavioral research projects designed to meet a national need and for which local conditions offer special advantages.

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

(4) The project will not have an adverse effect on health professional schools and training programs. The assessment of the conformance of a project with this criterion shall include consideration of:

(a) The effect of the means proposed for the delivery of health services on the clinical needs of health professional training programs in the area in which the services are to be provided.

(b) If proposed health services are to be available in a limited number of facilities, the extent to which the health professions schools serving the area will have access to the services for training purposes.

(5) The project is needed to meet the special needs and circumstances of enrolled members or reasonably anticipated new members of a health maintenance organization or proposed health maintenance organization and the services proposed are not available from nonhealth maintenance organization providers or other health maintenance organizations in a reasonable and cost-effective manner consistent with the basic method of operation of the health maintenance organization or proposed health maintenance organization.

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

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

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

(1) The immediate and long-range capital and operating costs of the project can be met.

WAC 246-310-815 outlines the financial feasibility review requirements for dialysis projects. For this project, 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.

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

**Fresenius Medical Care**

As previously stated, FMC proposes the one additional station would be operational September 2019 based on an August 2019 evaluation release date. [source: June 13, 2019, screening responses, p1] Under this timeline, calendar year one of this project is 2019 and full year one is 2020; calendar year three is 2022.

Once the additional station is added, FKC Thurston would be operating with 7 total in center dialysis stations including one isolation station. FMC provided the assumptions used to project in-center and home treatments and patients for calendar year 2019, referenced as the ‘expansion year’ and full calendar years 2020 through 2022. The assumptions are restated below. [source: Application, p11]

- **First Full Year:** 2020, based on a first patient date in September 2019 for the expansion.
- **Total Stations:** CON Approved stations. One CON-exempt isolation station is also included in driving relevant category calculations (bio-med FTE, overall existing facility depreciation).
- **Total Capacity:** 6 shift capacity of CON-approved stations is assumed to be 100% utilization.
- **Patient Census Projections:** January to August 2019 utilization is based on 4Q2018 patient count with the current in-center station count at six (6) stations. Modest incremental growth for in-center and home patients is assumed when the new station becomes operational (September 2019) and in subsequent years.

Using the assumptions stated above, FMC’s projected number of in-center dialyses and patients for the 7-station facility in years 2019 through 2022 is shown in Table 2. [source: Application, p 11]

<table>
<thead>
<tr>
<th>Department’s Table 2</th>
<th>FKC Thurston</th>
<th>Projected Patients and Dialyses for Years 2019 – 2022</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>CY 2019 Partial Year</td>
<td>CY 2020 Full Year</td>
</tr>
<tr>
<td>Number of Stations</td>
<td>7</td>
<td>7</td>
</tr>
<tr>
<td>Total In center Patients</td>
<td>37</td>
<td>38</td>
</tr>
<tr>
<td>Total In center Treatments</td>
<td>1,776</td>
<td>5,472</td>
</tr>
</tbody>
</table>
FMC provided the following assumptions used for its projected financial statements. [source: Application, p11, Exhibit 8B; June 13, 2019, screening response, Exhibit 8B]

Patient Volumes
- January to August 2019 utilization is based on 4Q2018 patient count with the current in-center station count at six (6) stations. Modest incremental growth for in-center and home patients is assumed when the new station becomes operational (September 2019) and in subsequent years.
- It is assumed the number of treatments per patient is 144/year. There is an adjustment 2019 to reflect only 4 months of operation during the forecast time period.

Revenues
- In-center revenues are based on CY2018 FKC Thurston data ("actuals"), given it is an existing facility. Payer mix statistics have also been obtained from FKC Thurston 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. Gross revenue: the total charges at the facility’s full established rates for services rendered and goods sold (including patient related and non patient related).

Charity Care
- Calculated at one percent of revenue based on the experience of Fresenius' facilities in Washington State.

Bad Debt
- Calculated on a per treatment basis from FKC Thurston actuals.

Expenses
- Unless otherwise noted, expenses have been calculated based on CY2018 FKC Thurston actuals.
- Medical supplies, ancillary, and 'other med' expenses have been calculated on a per treatment basis from FKC Thurston actuals.
- Personnel expenses are based on identified patient to staff ratios and incorporates a 10% non-productive factor. Wage figures have been compiled from actuals at the FKC Thurston facility.
- The existing depreciation figures included in Exhibit 8B are based on FKC Thurston’s 2018 actual financial data and held constant through the forecast period. The approximate $250,000 annual existing depreciation is from a $1.5M project in 2014, capitalized expenses tied to the recent completion of a $300K renovation, and a total of 245 other assets that are currently on the books depreciating (with original book values of approximately $500K). Project-related depreciation is based on the equipment with capital costs estimated at $2,047. The equipment costs will be depreciated, based on a straight-line depreciation, over 8 years. All depreciation figures included in Exhibit 8B are time-adjusted to reflect the number of months in the forecast period.

7 ‘Other Med’ includes: leased medical equipment, repairs & maintenance to medical equipment, water treatment supplies, patient transportation, and unbillable lab and ancillary services.
• Rent Expense: 2018 actual base rent is increased throughout the forecast period at the 2017-2018 Consumer Price Index growth rate (3.15%). Note: the use of the CPI as a lease escalator is in accordance with Section 3.1 of the lease.
• Other Property Exp includes common area maintenance ("CAM"), allocated taxes, and insurance costs. Estimated at 21% of base Rent Expense based on 2018 actuals
• Physician Compensation: according to Section 2 of the first amendment to the MDA, if a new fee has not been agreed upon, then Fresenius shall continue to pay fee then in effect ($53,000). While there are provisions in the MDA for potential amendments to reflect station expansion, none have been executed at this time. Therefore, the annual fee currently in effect ($53,000) is held constant. Expenses have been calculated on a per treatment basis for variable expenses from three closest clinic actuals.
• ‘G&A’ includes: administrative allocations, which are comprised of the expected contribution from FKC Thurston toward Fresenius’ administrative support functions, including billing, computer infrastructure, regional administration, finance center & financial coordinators, sales & account management, human resources, and strategic business operations. It is calculated based on FKC Thurston 2018 actuals, which is held constant over the forecast period.

Specific to the lease expense category, FMC provided the following clarification. [source: June 13, 2019, screening responses, pp3-4]

“The commencement date of the lease is estimated to be August 2013. Although Section 3.1 of the lease stipulates that the base rent should increase in accordance with consumer price index growth, actual incurred expense data does not reflect this. For instance, in CY2018, the total base rent expenses summed to $209,803 in total, or $17,484 per month. The lease projections provided in Exhibit 8B take a conservative approach3 by increasing the 2018 actual lease expense ($17,484 per month) by the 2017-2018 Consumer Price Index growth rate (3.15%) on an annual basis at the beginning of each calendar year (i.e. January). Please see the table below for a breakdown of the projected monthly base rent throughout the forecast period.”

Applicant’s Screening Table 1
FKC Thurston Lease – Monthly Base Rent

<table>
<thead>
<tr>
<th>BLS CPI-U Average Annual Growth (CY2017 to CY2018)</th>
<th>2018 Actual</th>
<th>2019</th>
<th>2020</th>
<th>2021</th>
<th>2022</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.15%</td>
<td>$17,484</td>
<td>$18,083</td>
<td>$18,604</td>
<td>$19,191</td>
<td>$19,796</td>
</tr>
</tbody>
</table>

“Based on Table 1 above, Table 2 below provides the projected base rent included in the pro forma forecast period featured in Exhibit 8B, adjusted for number of months in the forecast period.”

Applicant’s Screening Table 2
FKC Thurston Pro Forma Lease Expenses

<table>
<thead>
<tr>
<th></th>
<th>2019</th>
<th>2020</th>
<th>2021</th>
<th>2022</th>
</tr>
</thead>
<tbody>
<tr>
<td># of Months</td>
<td>4</td>
<td>12</td>
<td>12</td>
<td>12</td>
</tr>
<tr>
<td>Base Rent</td>
<td>$72,141</td>
<td>$223,250</td>
<td>$230,293</td>
<td>$237,558</td>
</tr>
</tbody>
</table>
Based on the assumptions above, FMC projected the revenue, expenses, and net income for years 2019 through 2022. A summary of the projections are shown in Table 3. [source: June 13, 2019, screening response, Exhibit 8C]

<table>
<thead>
<tr>
<th></th>
<th>CY 2019</th>
<th>CY 2020</th>
<th>CY 2021</th>
<th>CY 2022</th>
</tr>
</thead>
<tbody>
<tr>
<td>Net Revenue</td>
<td>$4,283,331</td>
<td>$4,528,317</td>
<td>$4,595,904</td>
<td>$4,595,904</td>
</tr>
<tr>
<td>Total Expenses</td>
<td>$3,765,290</td>
<td>$3,990,662</td>
<td>$4,016,273</td>
<td>$4,025,043</td>
</tr>
<tr>
<td>Net Profit / (Loss)</td>
<td>$518,041</td>
<td>$537,655</td>
<td>$579,631</td>
<td>$570,861</td>
</tr>
</tbody>
</table>

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

The ‘Total Expenses’ line item includes all expenses related to the projected operation of the 7-station facility in years 2019 through 2022. The expenses also include allocated costs and medical director fees as described above.

Public Comment
None

Rebuttal Comment
None

Department Evaluation
FKC Thurston is currently operating with six dialysis stations. FMC based its projected utilization of FKC Thurston on its current utilization, plus one additional station. This approach for an existing facility is reasonable.

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

Since FKC Thurston is currently operational, the facility has both an existing lease agreement and an existing medical director agreement. The lease agreement was executed in September 2012 and is valid through August 2023. The costs identified in the lease agreement can be substantiated in the revenue and expense statement.

FMC provided a copy of the initial Medical Director Agreement between FMC and RVS, LLC, a professional services corporation comprised of Julia Anuras, MD; Chris Burtner, MD; Michael Mondress, MD; Vo Nyugen, MD; and Seth Thaler, MD. The agreement is currently effective and includes automatic annual renewals. The costs identified in the medical director agreement can be substantiated in the revenue and expense statement.

Based on the above information provided in the application, the department concludes that 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 246-310-815(2)**

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

**Fresenius Medical Care**

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

<table>
<thead>
<tr>
<th>Department’s Table 4 Estimated Capital Costs</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>FKC Thurston</strong></td>
</tr>
<tr>
<td>Item</td>
</tr>
<tr>
<td>Moveable Equipment (one dialysis chair)</td>
</tr>
<tr>
<td><strong>Total Estimated Capital Costs</strong></td>
</tr>
</tbody>
</table>

Specific to costs and charges for health services, FMC provided the following statements. [source: Application, p15]

“This project has no impact on either charges or payment, as reimbursement for kidney dialysis services is based on a prospective composite per diem rate. In the case of government payers, reimbursement is based on CMS (Center for Medicaid and Medicare) fee schedules which have nothing to do with capital expenditures by providers such as Fresenius. In the case of private sector payers, Fresenius negotiates national, state, and regional contracts with payers. These negotiated agreements include consideration/negotiation over a number of variables, including number of covered lives being negotiated; the provider’s accessibility, including hours of operation; quality of care; the provider’s patient education and outreach; its performance measures such as morbidity and/or mortality rates; and increasingly, consideration of more broad performance/quality measures, such as the CMS Quality Incentive Program (“QIP”) Total Performance Score (“TPS”).

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

**Public Comment**

None
Rebuttal Comment
None

Department Evaluation
The costs for adding one station to FKC Thurston is $2,047. The costs are comparable to those reviewed in past applications for similar size station addition without construction. The department does not consider the capital expenditure to be excessive for this project.

Documentation provided in the application shows that FKC Thurston currently has Medicare and Medicaid reimbursements that equal 45% of the revenue at the dialysis center. This amount is reasonable and consistent with percentages reviewed and approved in past FMC 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 55% of revenue is combined 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 one station to FKC Thurston would probably not have an unreasonable impact on the costs and charges for healthcare services in Thurston County. This sub-criterion is met.

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

Fresenius Medical Care
FMC identified a capital expenditure of $2,047 to add one station to FKC Thurston. FMC intends to fund the project using corporate reserves. FMC provided a letter from its senior vice president and treasurer to demonstrate an operational and financial commitment to the project. [source: Application, Exhibit 11]
FMC also provided a copy of its audited financial statements for years 2017 and 2018 to demonstrate sufficient reserves to finance the project. [source: Application, Exhibit 12]

Public Comment
None

Rebuttal Comment
None

**Department Evaluation**

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

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

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

Based on the source information reviewed and agreement to the conditions identified in the conclusion section of this evaluation, the department concludes that the FMC project **has met** the structure and process of care criteria in WAC 246-310-230.

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

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

**Fresenius Medical Care**

If this project is approved, FMC expects the additional station would be operational by the end of August 2019. Year 2020 would be the facility’s first full calendar year of operation and 2022 would be year three. Table 5 on the following page provides a breakdown of projected FTEs for projected years 2019 through 2022. No net FTE increase is projected for the one station addition. [source: Application, p19 and June 13, 2019, screening responses, Exhibit 8B]
### Department’s Table 5
**FKC Thurston**
**Projected FTEs**

<table>
<thead>
<tr>
<th>Staff Type</th>
<th>Partial Year 2019</th>
<th>Year 2019 Increase</th>
<th>Full Year 2020 Increase</th>
<th>Full Year 2022 Increase</th>
<th>Total FTES Year 2022</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical Director</td>
<td></td>
<td>Contracted Position</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Facility Admin</td>
<td>0.50</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.50</td>
</tr>
<tr>
<td>Charge Nurse</td>
<td>3.50</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>3.50</td>
</tr>
<tr>
<td>Outpatient RN</td>
<td>6.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>6.00</td>
</tr>
<tr>
<td>Patient Care Tech</td>
<td>0.50</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.50</td>
</tr>
<tr>
<td>Equipment Tech</td>
<td>0.50</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.50</td>
</tr>
<tr>
<td>MSW</td>
<td>0.50</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.50</td>
</tr>
<tr>
<td>Dietitian</td>
<td>0.50</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.50</td>
</tr>
<tr>
<td>Secretary</td>
<td>1.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>1.00</td>
</tr>
<tr>
<td>Home Manger</td>
<td>3.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>3.00</td>
</tr>
<tr>
<td>Home RN</td>
<td>0.50</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.50</td>
</tr>
<tr>
<td>Home Other</td>
<td>0.50</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.50</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>17.00</strong></td>
<td><strong>0.00</strong></td>
<td><strong>0.00</strong></td>
<td><strong>0.00</strong></td>
<td><strong>17.00</strong></td>
</tr>
</tbody>
</table>

FMC’s medical director is under contract, but is not an employee and is not included in the table above. FMC also stated that personnel expenses are based on identified patient to staff ratios. [source: June 13, 2019, screening response, Exhibit 8B]

Fresenius Kidney Care provided a copy of the initial Medical Director Agreement among Renal Care Group Northwest, Inc. (Company) dba Fresenius Medical Care North America (FMCNA), and RVS, PLLC (Consultant), and Seth Thaler, M.D. (Member Physicians of Washington professional services corporation.) The agreement is currently effective and includes automatic annual renewals. The costs identified in the medical director agreement can be substantiated in the revenue and expense statement. [source: Application, p19 and Exhibit 9 and June 13, 2019, screening response, p4]

FMC provided the following statements related to recruitment and retention of staff. [source: Application, p20]

“FKC Thurston is an operational dialysis facility, which is staffed with qualified clinical and support personnel. Table 12 provides the number of current and proposed FTEs, by type. Although we do not anticipate needing additional staff due to the project, by virtue of our geographic location, any additional staff would be expected to principally come from Thurston 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. 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.”

**Public Comment**
None
Rebuttal Comment
None

**Department Evaluation**
Information provided in the application demonstrates that FMC is a well-established provider of dialysis services in Washington State and in Thurston County. Its FKC Thurston has been operational since August 2014.

For this project, FMC is proposing to add one station to the existing center. The one station increase will require no addition of FTES by the end of the third full year of operation.

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.

**Fresenius Medical Care**
FMC provides dialysis services throughout Washington State, including its FKC Thurston in Thurston County. If this project is approved, FKC Thurston’s in-center stations will increase by one station. FMC states that all patient care and support services except senior management, financial, legal, planning, marketing, architectural/construction and research and development are provided on-site at each clinic.

FMC also provided a listing of the entities it currently has working relationships with for its FKC Thurston. [source: Application, p21]

FMC provided the following statement related to the existing working relationships for FKC Thurston. [source: Application, p22]

“FKC Thurston is an existing provider and trusted member of the community. Backed by its history in the planning area, Fresenius has already established relationships that support coordinated care processes with local hospitals, medical groups, and other health service providers. For example, please see our transfer agreement with Providence St. Peter Hospital, attached as Exhibit 13”

Public Comment
None

Rebuttal Comment
None
**Department Evaluation**
FKC Thurston has been operating in Thurston County since the year 2014. All ancillary and support services have been established for the dialysis center since that time. FMC states that no new agreements or revisions to existing agreements are necessary for this project.

The department also concludes that all other required ancillary and support agreements and relationships are already in place. **This sub-criterion is met.**

(3) *There is reasonable assurance that the project will be in conformance with applicable state licensing requirements and, if the applicant is or plans to be certified under the Medicaid or Medicare program, with the applicable conditions of participation related to those programs.*

WAC 246-310 does not contain specific WAC 246-310-230(3) criteria as identified in WAC 246-310-200(2)(a)(i). There are no known recognized standards as identified in WAC 246-310-200(2)(a)(ii) and (b) that a facility must meet when it is to be Medicare certified and Medicaid eligible. Therefore, using its experience and expertise the department assessed the applicant’s history in meeting these standards at other facilities owned or operated by the applicant.

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

**Fresenius Medical Care**
FMC provided the following statements in response to this sub-criterion. [source: Application p23]

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

**Public Comment**
None

**Rebuttal Comment**
None

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

**CMS Star Rating for Out-of-State Centers**
In the application, FMC states that it provides outpatient dialysis centers and services all across the United States and worldwide. FMC reports dialysis services to CMS for approximately 2,579 facilities. Of the 2,728 facilities reporting to CMS by FMC, 549 do not have the necessary amount of data to compile a star rating. For the remaining 2,357 facilities with a star rating, the national average rating is 3.87. [source: CMS data July 2019]
CMS Star Rating for Washington State Centers
FMC owns, operates, or manages 23 facilities in Washington. The average CMS star rating for the 23 facilities is 3.65 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 survey data performed by the Department of Health’s Office of Health Systems Oversight as a contractor for CMS.

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

In this application, FMC provided a copy of the initial Medical Director Agreement among Renal Care Group Northwest, Inc. (Company) dba FMC North America (FMCNA), and RVS, PLLC. FMC identified Dr. Thaler as the medical director, Jerald Rodman as facility administrator, Erin Fossen, RN, as the director of operations and Pamela Augg, RN, as the charge nurse for the clinic. Using data from the Medical Quality Assurance Commission and the Office of Customer Service, the department found that all three professionals are compliant with state licensure and have no enforcement actions on their licenses.

The department also reviewed the compliance history of all known staff working at FKC Thurston which includes five registered nurses, six dialysis technicians, a dietician, and two social workers. All known staff are compliant with state licensure and have no enforcement actions on the license.

In review of this sub-criterion, the department considered the total compliance history of the dialysis facilities owned and operated by FMC. The department concludes that FMC 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 one new station to FKC Thurston would not cause a negative effect on FMC’s compliance history. The department concludes that FKC Thurston’s project meets this sub-criterion.

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

Fresenius Medical Care
FMC provided statements and supporting documentation to demonstrate compliance with this sub-criterion. [source: Application, p22]

“The proposed project promotes continuity of care as it seeks to expand FKC Thurston’s existing dialysis care services.”
Department Evaluation
FMC has been a provider of dialysis services in Washington State for many years. FKC Thurston also has a history of establishing relationships with existing healthcare networks in Thurston County. Additionally, Fresenius’s project would promote continuity in the provision of healthcare services in the Thurston County planning area by increasing the number of stations at FKC Thurston.

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

Based on the information above, the department concludes that FMC’s project meets this sub-criterion.

(5) There is reasonable assurance that the services to be provided through the proposed project will be provided in a manner that ensures safe and adequate care to the public to be served and in accord with applicable federal and state laws, rules, and regulations.

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

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

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

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

If there are multiple applications, the department’s assessment is to apply any service or facility superiority criteria contained throughout WAC 246-310 related to the specific project type in Step three. Under WAC 246-310-818(11) this step does not to apply Special Circumstance applications.
**Step One**
For this project, FMC met the applicable review criteria under WAC 246-310-210, 220, and 230. Therefore, the department moves to step two for this project.

**Step Two**
For this sub-criterion, FMC considered and discussed two options before submitting this application. Below is FMC’s discussion related to both options. [source: Application, pp24-25]

**Do nothing**
The advantages and disadvantages of this option were presented in three tables identifying the advantages and disadvantages of this option and the project proposed in the application. FMC’s discussion of the do nothing option is summarized below:

*Promoting Access to Healthcare Services*
- Would do nothing to improve access (Disadvantage (“D”))
- Outmigration would increase (D)

*Promoting Quality of Care*
- 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)

*Promoting Cost and Operating Efficiency*
- Capital and operating costs would be least under this option, since there would be none (Advantage (“A”)).
- However, would inefficiently use existing space as there is space for one additional station that is warranted by WAC 246-310-818. (D)
- 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).

*Legal Restrictions*
- There are no legal restrictions with this option

**Add two stations to FKC Thurston, rather than one station**
“Add two (2) stations to the existing facility, was initially considered but not further analyzed because FKC Thurston does not meet the standards under WAC 246-310-818 to be approved for two additional stations.”

**Public Comment**
None

**Rebuttal Comment**
None
Department Evaluation
FMC provided a comprehensive discussion of the “do nothing” alternative before submitting this application. Specifically, FMC operates only one other center in Thurston County and it is also a highly utilized facility. FMC appropriately rejected the ‘do nothing’ alternative.

FMC’s rationale for rejecting the option of adding two stations to FKC Thurston is reasonable because it is consistent with the standard outlined in WAC 246-310-828(7).

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

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

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

Department Evaluation
Since FMC’s capital expenditure is solely related to dialysis equipment, this sub-criterion does not apply to this project.

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

Fresenius Medical Care
FMC provided the following information for this sub-criterion. [source: Application, p25]

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

Public Comment
None

Rebuttal Comment
None

Department Evaluation
FMC’s project could have the potential to improve delivery of dialysis services to the residents of Thurston County with the addition of another station in the planning area. Consistent with the special circumstance rules, FKC Thurston would be operating the additional station within six months of approval. This sub-criterion is met.