



STATE OF WASHINGTON
DEPARTMENT OF HEALTH
Olympia, Washington 98504

June 12, 2020

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

RE: CN Application #20-14

Sent via email

Dear Ms. Stowell:

We have completed review of the Certificate of Need application submitted by Fresenius Medical Care proposing to establish a new 27-station dialysis center in Camas within the Clark County Planning Area. Enclosed is a written evaluation of the application.

For the reasons stated in this evaluation, the department has concluded that the project is not consistent with the Certificate of Need review criteria identified below, and a Certificate of Need is denied.

Washington Administrative Code 246-310-210	Need
Washington Administrative Code 246-310-220	Financial Feasibility
Washington Administrative Code 246-310-230	Structure and Process of Care
Washington Administrative Code 246-310-240	Cost Containment

This decision may be appealed. The two appeal options are listed below.

Appeal Option 1:

You or any person with standing may request a public hearing to reconsider this decision. The request must state the specific reasons for reconsideration in accordance with Washington Administrative Code 246-310-560. A reconsideration request must be received within 28 calendar days from the date of the decision at one of the following addresses:

<u>Mailing Address:</u>	<u>Physical Address</u>
Department of Health	Department of Health
Certificate of Need Program	Certificate of Need Program
Mail Stop 47852	111 Israel Road SE
Olympia, WA 98504-7852	Tumwater, WA 98501

Appeal Option 2:

You or any person with standing may request an adjudicative proceeding to contest this decision within 28 calendar days from the date of this letter. The notice of appeal must be filed according to the provisions of Revised Code of Washington 34.05 and Washington Administrative Code 246-310-610. A request for an adjudicative proceeding must be received within the 28 days at one of the following addresses:

Mailing Address:

Department of Health
Adjudicative Service Unit
Mail Stop 47879
Olympia, WA 98504-7879

Physical Address

Department of Health
Adjudicative Service Unit
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,

A handwritten signature in black ink, appearing to read "Eric Hernandez", with a stylized flourish at the end.

Eric Hernandez, Program Manager
Certificate of Need

Enclosure

**YEAR 2020 CYCLE 2 NON-SPECIAL CIRCUMSTANCE EVALUATION DATED JUNE 12, 2020,
FOR THE CERTIFICATE OF NEED APPLICATION SUBMITTED BY FRESENIUS MEDICAL
CARE PROPOSING TO ESTABLISH A NEW 27-STATION DIALYSIS CENTER IN CLARK
COUNTY**

APPLICANT DESCRIPTION

Fresenius Medical Care

Renal Care Group Northwest (RCGNW) is one of three entities owned by Renal Care Group, Inc. (RCG). RCGN is responsible for the operation of facilities under three separate legal entities. These entities include Pacific Northwest Renal Services (PNRS), Renal Care Group Northwest (RCGNW), and Inland Northwest Renal Care Group (IN-RCG). In March of 2006, Fresenius Medical Care Holdings (FMC) became the sole owner of RCG. In addition to the three entities listed above, FMC also operates two other entities, including QualiCenters, Inc. and National Medical Care, Inc. As all of these subsidiaries are owned by one parent corporation-Fresenius Medical Care. This evaluation shall refer to the applicant and all subsidiaries as 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 several kidney dialysis facilities. [source: Application Exhibit 2, CMS Dialysis Facility Compare website]

PROJECT DESCRIPTION

FMC proposes to establish a new 27-station dialysis center in Camas, within Clark County. The site has not yet been assigned an address but FMC provided the following description of the premises:

“Although located in the City of Camas, WA, the proposed site does not have a specific address at this time. A description of the premises and property is provided below:

An approximately 1.5-acre parcel of land known as all of Lot 47 (and possibly a portion of Lot 46 to be subdivided), Estates at the Archery (NW Camas Meadows Drive), recorded in Plat Book 311, page 924, City of Camas, Clark County, Washington.” [source: Application pdf6]

The new center would be known as FKC Fisher’s Landing. FMC provided the following description of services to be provided at the new dialysis center:

“FKC Fisher’s Landing will serve patients with end-stage renal disease. FKC Fisher’s Landing will offer in-center hemodialysis, home hemodialysis and peritoneal dialysis training and support for dialysis patients, a dedicated isolation area, and a dedicated bed station. FKC Fisher’s Landing will also offer an evening shift, beginning after 5 pm, for dialysis patients.” [source: Application pdf7]

If approved, FMC expects the 27-station dialysis center would be operational by December 2021. [source: Application, pdf6] The application frequently refers to 26 stations – though there would be 27 total stations, one would be an uncounted exempt isolation station. The capital expenditure for this project is \$6,945,847. Of that amount, FMC’s portion of capital expenditure is \$2,607,819—or 37.5% of the costs. The landlord is responsible for the remaining \$4,338,028, which is 62.5% of the costs. [source: Application pdf16]

APPLICABILITY OF CERTIFICATE OF NEED LAW

Fresenius Medical Care’s proposal to establish a new facility in Clark County is subject to Certificate of Need review as the construction, development, or other establishment of a new health care facility under the provisions of Revised Code of Washington (RCW) 70.38.105(4)(a) and Washington Administrative Code (WAC) 246-310-020(1)(a).

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.

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. S

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).

For this project, FMC must also demonstrate compliance with applicable kidney disease treatment center criteria outlined in WAC 246-310-800 through 833. The following review criteria do not apply to applications submitted under WAC 246-310-806 Nonspecial Circumstance. These criteria will not be discussed in this evaluation.

WAC 246-310-809	One-time exempt isolation station reconciliation
WAC 246-310-818	Special circumstances one- or two-station expansion—Eligibility criteria and application process
WAC 246-310-821	Kidney disease treatment facilities—Standards for planning areas without an existing facility
WAC 246-310-824	Kidney disease treatment centers—Exceptions
WAC 246-310-830	Kidney disease treatment facilities—Relocation of facilities
WAC 246-310-833	One-time state border kidney dialysis facility station relocation

WAC 246-310-803

This application was received during the year 2019 concurrent review. WAC 246-310-803 requires an applicant to submit specific data elements to the Certificate of Need Program. For the 2019 concurrent review cycle, the data must be received before February 16, 2019. FMC submitted the data elements timely. This data is used to calculate superiority in the event that more than one application meets the applicable review criteria. Consistent with WAC 246-310-827, these data elements are the only means by which two or more applications may be compared to one another.

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

TYPE OF REVIEW

As directed under WAC 246-310-806, the department accepted this application under the Kidney Disease Treatment Centers-Nonspecial Circumstances Concurrent Review Cycle #2 for calendar year 2019. It appeared the application was going to be reviewed alongside a project submitted by DaVita, Inc. When DaVita failed to respond to screening, their application was returned and FMC's project was converted to a regular review, as it was the only project submitted for the Clark County planning area. Consistent with sub-section WAC 246-310-806(8), the department converted the review to a regular review timeline. The project was subsequently amended, which followed the regular review schedule. Below is the chronological summary of the review timelines.

APPLICATION CHRONOLOGY

Action	FMC Clark County
Letter of Intent Submitted	October 31, 2019
Initial Application Submitted	December 2, 2019
Department's pre-review activities <ul style="list-style-type: none"> • DOH 1st Screening Letter • Applicant's Responses Received 	December 31, 2019 January 30, 2020
Beginning of Review	March 10, 2020
End of Public Comment <ul style="list-style-type: none"> • Public comments accepted through the end of public comment • No public hearing requested or conducted 	April 14, 2020
Rebuttal Comments Submitted	May 6, 2020 ¹
Department's Initial Anticipated Decision Date	June 12, 2020
Department's Actual Decision Date	June 12, 2020

Public Comments

Puget Sound Kidney Centers provided the following comments:

“FMC submitted its new nonspecial circumstance application for Clark County, while the Program’s decision was pending on PSKC’s application from the previous cycle in that same planning area. The Program issued its timely evaluation of PSKC’s application on December 2, 2019, within six months of PSKC’s application, and according to the decision deadline in the Beginning of Review Notice issued by Analyst Beth Harlow on August 21, 2019 and revised on August 28, 2019, and published in The Columbian on August 29, 2019. The Program thus “will not accept” FMC’s application, and it should be summarily denied.”

Rebuttal

Puget Sound Kidney Centers (“PSKC”) incorrectly labels Fresenius’ application as ‘Premature’. However, PSKC arrives at this erroneous conclusion by failing to acknowledge the appropriate timelines expressed in WAC 246-310-806. This is surprising given PSKC included the correct timeline in a quoted section of WAC 246-310-806(7) included in its public comment:

The department will not accept new nonspecial circumstance applications for a planning area if there are any nonspecial circumstance applications for which the certificate of need program has not made a decision in that planning area filed under a previous concurrent review cycle. This restriction does not apply if the department has not made a decision on the pending applications within the review timelines of nine months for a concurrent review and six months for a regular review. This restriction also does not apply to special circumstance applications. (PSKC’s emphasis) (Fresenius emphasis)

PSKC mistakenly believes the anticipated decision deadline included in the CN Program’s Beginning of Review Notice is the appropriate timeline to determine whether a decision is timely under WAC 246-310-806. However, this is incorrect. WAC 246-310-806(2) is very clear and precise in defining the timeline:

The department should complete the regular review process within six months, which begins the first day after the letters of intent are due for that particular review cycle.

¹ Distribution of public comment was delayed – as a result, the deadline for rebuttal was extended for the commensurate amount of time.

Further, this is clearly applicable to the ‘application acceptance’ standard identified in WAC 246-310-806(7), as the rule reiterates that the timeline is “six months for a regular review” application (highlighted in orange above). Thus, the effective timeline is consistent with the dates presented in Table 1 below. Therefore, the department was able to accept new nonspecial circumstance application(s) in 2019 Cycle Two for the Clark County ESRD planning area given the actual decision date on PSKC’s nonspecial application under regular review was December 2, 2019, well past the six month deadline per WAC 246-310-806(7) (November 2, 2019).

Department’s Evaluation

Fresenius appropriately rebutted PSKC’s comments – while the decision was timely, the decision did not take place within six months, leaving the planning area available for additional applications. The implications on numeric need will be discussed further along in this evaluation.

AFFECTED PERSONS

“Affected persons” are defined under WAC 246-310-010(2). In order to qualify as an affected person, someone must first qualify as an “interested person,” defined under WAC 246-310-010(34).

During the review of this project, Puget Sound Kidney Centers sought and received affected person status. DaVita, as an original participant in the concurrent review and current provider in the planning area, could have qualified for interested or affected person status, but did not provide comments.

SOURCE INFORMATION REVIEWED

- Fresenius Medical Care’s Certificate of Need application
- Fresenius Medical Care’s screening responses
- Public comments accepted through April 14, 2020
- Rebuttal comments accepted through May 6, 2020
- Years 2013 through 2018 historical kidney dialysis data obtained from the Northwest Renal Network
- Department of Health’s ESRD Need Projection Methodology for Clark County posted to its website in March 2019
- Puget Sound Kidney Centers approval to serve Clark County according to the above-referenced methodology dated December 2, 2019
- Licensing data provided by the Medical Quality Assurance Commission, Nursing Quality Assurance Commission, and Health Systems Quality Assurance Office of Customer Service
- Compliance history obtained from the Washington State Department of Health Office of Health Systems and Oversight
- Fresenius Medical Care website at www.fmcna.com
- Centers for Medicare and Medicaid Services website at www.medicare.gov/dialysisfacilitycompare
- 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 establish a 27 station dialysis facility in Camas, within Clark County is not consistent with applicable criteria of the Certificate of Need Program. A Certificate of Need is denied.

CRITERIA DETERMINATIONS

A. Need (WAC 246-310-210)

Based on the source information reviewed, the department concludes that Fresenius Medical Care has not met the need criteria in WAC 246-310-210, which includes the applicable sub-criterion identified in WAC 246-310-812(4) and (5).

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

WAC 246-310-812 requires the department to evaluate kidney disease treatment centers applications based on the population's need for the service and determine whether other services and facilities of the type proposed are not, or will not, be sufficiently available or accessible to meet that need as required in WAC 246-310-210. The kidney disease treatment center specific numeric methodology is applied and detailed under WAC 246-310-812(4). WAC 246-310-210(1) criteria and also identified in WAC 246-310-812(5) and (6).

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

WAC 246-310-812 contains the methodology for projecting numeric need for dialysis stations within a planning area. This methodology projects the need for kidney dialysis treatment stations through a regression analysis of the historical number of dialysis patients residing in the planning area using verified utilization information obtained from the Northwest Renal Network (NWRN).²

The first step in the methodology calls for the determination of the type of regression analysis to be used to project resident in-center station need. [WAC 246-310-812(4)(a)] This is derived by calculating the annual growth rate in the planning area using the year-end number of resident in-center patients for each of the previous six consecutive years, concluding with the base year.³

In planning areas experiencing high rates of growth in the dialysis population (6% or greater growth in each of the last five annual change periods), the method uses exponential regression to project future need. In planning areas experiencing less than 6% growth in any of the last five annual change periods, linear regression is used to project need.

Once the type of regression is determined as described above, the next step in the methodology is to determine the projected number of resident in-center stations needed in the planning area based on the planning area's previous five consecutive years NWRN data, again concluding with the base year. [WAC 246-310-812(4)(b) and (c)]

[WAC 246-310-812(5)] identifies that for all planning areas except Adams, Columbia, Douglas, Ferry, Garfield, Jefferson, Kittitas, Klickitat, Lincoln, Okanogan, Pacific, Pend Oreille, San Juan, Skamania, Stevens, and Wahkiakum counties, the number of projected patients is divided by 4.8 to determine the number of stations needed in the planning area. For the specific counties listed above, the number of

² NWRN was established in 1978 and is a private, not-for-profit corporation independent of any dialysis company, dialysis unit, or transplant center. It is funded by Centers for Medicare and Medicaid Services, Department of Health and Human Services. Northwest Renal Network collects and analyzes data on patients enrolled in the Medicare ESRD programs, serves as an information resource, and monitors the quality of care given to dialysis and transplant patients in the Pacific Northwest. [Source: Northwest Renal Network website]

³ WAC 246-310-280 defines base year as the most recent calendar year for which December 31 data is available as of the first day of the application submission period from the *Northwest Renal Network's Modality Report* or successor report." For this project, the base year is 2017.

projected patients is divided by 3.2 to determine needed stations. Additionally, the number of stations projected as needed in the target year is rounded up to the nearest whole number.

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

CLARK COUNTY NUMERIC METHODOLOGY

The department annually calculates the numeric methodology for each of the 57 ESRD planning areas in Washington State and posts each of the results to its website. The department's year 2019 numeric methodology was posted in March 2019. Based on the calculation of the annual growth rate in the planning area, the department used the linear regression to determine numeric need in all planning areas. For Clark County, the number of projected patients was divided by 4.5 to determine the number of stations needed.

Fresenius Medical Care

FMC proposes to establish a 27-station dialysis center to be located in Camas, within Clark County. FMC relied on the Clark County numeric methodology posted to the department's website in March 2019.

Public Comment

Puget Sound Kidney Centers provided the following comments:

“Application of the methodology for additional dialysis station need (WAC 246-310-812(4)(a) through (c)), as outlined in the FMC application, demonstrates a gross need for 112 stations in 2023 (see application, p. 10). But FMC’s calculation that Clark County has 84 stations of supply (application, p. 10 Table 5) is in error: it fails to include the 24 stations approved for PSKC Clark County, even after FMC was specifically asked about those stations in screening.

Under WAC 246-310-812(4)(d), the “total number of certificate of need approved stations” must be counted and subtracted from gross need to determine net need. Unlike gross need, which must be based on NWRN in-center patient data available as of the Letter of Intent submission date (WAC 246-310-812(2)), the calculation of net need must be determined based on CN approved stations at the time of the Program’s decision. When an earlier filed application is granted, even after the application record has closed following public comment and rebuttal, the Program will include the newly-approved stations in its calculation of net need. For example, in the August 2019 denial of Northwest Kidney Centers’ (NKC) King 11 application, the Program wrote:

The department calculates the numeric methodology for each of the 57 ESRD planning areas in Washington and posts each of the results to its website. The department’s year 2018 numeric methodology was posted in March 2018. . . . [O]nce the 26 existing stations are subtracted from the projected need, the result is a net need of 22 stations. This is the methodology that was effective when NKC submitted this application.

On June 1, 2018, DaVita, Inc. (DaVita) submitted a non-special circumstance application under the year 2018 cycle #1 timeline proposing to establish a 22-station dialysis center in Auburn, within King County planning area #11. [Footnote: Certificate of Need application #18-59.] On July 10, 2019, [more than two months after the rebuttal to public comment], the department released its evaluation to DaVita

conditionally approving the project. On July 11, 2019, CN #1788 was issued to DaVita approving the establishment of a 22-station dialysis center with one exempt isolation station. With the issuance of CN #1788, there is no longer numeric need in the planning area for 22 stations.

So, too, here: with the issuance of CN#1828, there was no longer numeric need in the planning area for FMC's proposed 26 stations.

The current dialysis rules have been in effect since January 1, 2018. During that time, several dialysis CN applications have been denied because another applicant was awarded the same stations during a previous CN review cycle. Each time, the Program has consistently processed the applications in the order received and revised net need accordingly when reviewing subsequent applications.

FMC failed to update its net need calculation following the approval of PSKC's 24-station CN. With the proper inclusion of those approved stations, there was and is projected net need for only four stations in 2023. FMC's 26 station request must be denied."

Rebuttal Comment

None – FMC's rebuttal comments did not address this issue.

Department Evaluation of the Numeric Methodology for Clark County

FMC's applications requests the number of stations calculated to be needed in the Clark County planning area. However, on December 2, 2019, Puget Sound Kidney Center was approved to establish a 25-station dialysis facility, in response to that need. As of the writing of this evaluation, there is not sufficient numeric need for the additional dialysis stations proposed in Clark County⁴. The methodology available on the departments website and PSKC's Certificate of Need #1828 issued December 2, 2019 are attached as Appendices A and B, respectively. The department made FMC aware of this limitation in screening. As a result, the department concludes FMC **does not meet the numeric methodology standard**.

In addition to the numeric need, the department must determine whether other services and facilities of the type proposed are not or will not be sufficiently available or accessible to meet the dialysis station need.⁵ The department uses the standards in WAC 246-310-812(5) and WAC 246-310-812(6).

WAC 246-310-812(5)

Before the department approves new in-center kidney dialysis stations in a 4.8 planning area, all certificate of need counted stations at each facility in the planning area must be operating at 4.5 in-center patients per station. However, when a planning area has one or more facilities with stations not meeting the in-center patients per stations standard, the department will consider the 4.5 in-center patients per station standard met for those facilities when:

- (a) All stations for a facility have been in operation for at least three years; or*
- (b) Certificate of need approved stations for a facility have not become operational within the timeline as represented in the approved application.*

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

⁴ Though Puget Sound Kidney Centers' approval has been contested by FMC, the department has not yet received any ruling.

⁵ WAC 246-310-210(1)(b).

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

Fresenius Medical Care

FMC identified five dialysis centers currently operating in Clark County. Three are FMC facilities and two are DaVita facilities. FMC provided a table showing the utilization at each of the centers. FMC's table is recreated below. [source: Application, pdf8]

Applicant's Table

Facility	Number of Stations	06/30/19 Number of Patients Per Quarterly In-Center Data	06/30/19 Patients/ Station
DaVita Vancouver	12	76	6.33
FKC/PNRS Fort Vancouver	24	136	5.67
FKC/PNRS Salmon Creek	16	96	6.00
DaVita Battle Ground	10	46	4.60
FKC/PNRS Battle Ground	22	102	4.64

*Station count excludes 1 isolation station

Public Comment

Puget Sound Kidney Centers provided the following comments:

“Even if FMC were proposing to add only four stations in Clark County, consistent with net need in the planning area, its application could not be approved now. In addition to numeric need, rules require that the CN Program determine whether other services and facilities of the type proposed are not or will not be sufficiently available or accessible to meet the dialysis station need. The department uses the standards in WAC 246-310-812(5) to make this determination:

*Before the department approves new in-center kidney dialysis stations in a 4.8 planning area, **all certificate of need counted stations at each facility in the planning area must be operating at 4.5 in-center patients per station.** However, when a planning area has one or more facilities with stations not meeting the incenter patients per stations standard, the department will consider the 4.5 in-center patients per station standard met for those facilities when:*

- (a) All stations for a facility have been in operation for at least three years; or*
- (b) Certificate of need approved stations for a facility have not become operational within the timeline as represented in the approved application. For example, an applicant states the stations will be operational within eight months following the date of the certificate of need approval. The eight months would start from the date of an uncontested certificate of need approval. If the certificate of need approval is contested, the eight months would start from the date of the final department or judicial order. However, the department, at its sole discretion, may approve a one-time modification of the timeline for purposes of this subsection upon submission of documentation that the applicant was prevented from meeting the initial timeline due to circumstances beyond its control.*

(Emphasis added.) CN #1828 was issued to PSKC in December 2019, with an anticipated operational date of March 2023. Not all CN “counted stations” in the planning area are operating at or above the 4.5 station utilization standard: PSKC’s approved stations under CN #1828 presently have no

utilization. The subsection (a) exception does not apply because PSKC's 24 approved stations are not yet operational. Nor does the subsection (b) exception apply, because PSKC's project is still in development within its proposed timeline.

Below, PSKC has replicated Table 2 from FMC's application (p. 8) with the addition of PSKC's Vancouver facility. The utilization of the all CN approved stations located in Clark County confirms that PSKC's recently approved center is not yet operational and has no utilization. Therefore, and consistent with the August 2019, King 11 decision, the CN Program must conclude that FMC does not conform with WAC 246-310-812 (5), and no additional stations may be awarded within the planning area at this time.

Public Comment Table

Facility	Number of Stations	06/30/2019 Number of Patients Per Quarterly In-Center Data	06/30/2019 Patients Per Station
DaVita Vancouver	12	76	6.33
FKC/PNRS Fort Vancouver	24	136	5.67
FKC/PNRS Salmon Creek	16	96	6.00
DaVita Battle Ground	10	46	4.60
FKC/PNRS Battle Ground	22	102	4.64
PSKC Clark County	24	0	0.00

Source: FMC December 2019 CN Application, p. 8

Rebuttal Comment

None – FMC's rebuttal comments did not address this issue.

Department Evaluation

Puget Sound Kidney Centers accurately points out that their recently approved facility prevents approval of additional stations under WAC 246-310-812(5). The utilization of the five existing dialysis centers located in Clark County is shown below.

**Department's Table 1
June 30, 2019, Utilization Data for Clark County Plus PSKC Recent Approval**

Facility Name	# of Stations	# of Patients	Patients/Station
DaVita Battle Ground	10	46	4.60
DaVita Vancouver	12	76	6.33
(FMC) PNRS Battle Ground	22	102	4.64
(FMC) PNRS Fort Vancouver	24	136	5.67
(FMC) PNRS Salmon Creek	16	96	6.00
PSKC Clark County	24	0	0

In conclusion, neither WAC 246-310-812(5)(a) or (b) applies to this project. The department concludes that this project **does not meet the standard under WAC 246-310-812.**

- (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 a provider'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.⁶ 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

In response to this sub-criterion, FMC provided the following statements:

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

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

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

A copy of our charity care policy is contained in Exhibit 6." [source: Application, pdf12-13]

FMC provided the following policies for this project. [source: Application, Exhibits 6 and 7]

- Admission Policy
- Charity Care Policy

⁶ WAC 246-453-010(4).

Public Comment

None

Rebuttal Comment

None

Department Evaluation

FMC provided copies of the necessary policies used at all FMC dialysis centers, including the proposed FKC Fisher's Landing facility to be located in Camas.

Medicare and Medicaid Programs

FMC currently participates in the Medicare and Medicaid programs for its operational dialysis centers.

As directed in WAC 246-310-815, FMC based its payer mix on FMC's three closest facilities. These facilities include FKC Fort Vancouver in Vancouver, FKC Clark County Dialysis in Battle Ground, and FKC Salmon Creek Dialysis Facility in Vancouver. For the proposed Camas facility, FMC provided a table showing the proposed percentages of revenues by payer and revenues by patient. The information is summarized below. [source: Application, pdf19]

**Department's Table 2
FKC-Fisher's Landing Projected Payer Mix**

Payor Class	Mix Based on Treatments	Mix based on Revenue
Medicare	48.3%	35.8%
Commercial	8.5%	23.1%
Medicaid	4.8%	2.5%
Medicare Adv	31.5%	31.6%
Medicaid Risk	3.2%	2.8%
Misc. Ins	2.8%	2.8%
Self Pay	0.9%	0.1%
Old Revenue Accounts	0.0%	1.3%
TOTAL	100%	100%

*Based on FKC Ft. Vancouver, FKC Salmon Creek, and FKC Battle Ground's 2018 actuals.

Based on the information above, the department concludes that **FMC's application 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, the department concludes that Fresenius Medical Care has not 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, each applicant must demonstrate compliance with the following sub-sections of WAC 246-310-815(1).

WAC 246-310-815(1)

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

Fresenius Medical Care

For FMC's Clark County project, sub-sections (a) and (c) of WAC 246-310-815(1) apply. FMC provided the following information related to this sub-criterion. [source: Application, pdf12]

"In-Center Patients"

In-center patients are projected based on the net station need projections from step (d) of the Department's need methodology. Net station need is multiplied by 4.8 and rounded up to calculate the

projected potential number of in-center patient. This figure is then multiplied by a factor to reflect a reasonable ramp rate in Fisher's Landing share of in-center patients. Please note that the operational timeline required extending net need projections out to 2024 where there is net station need for 32 stations. However, FKC Fisher's Landing is assumed to only capture part of the incremental patient demand growth in 2024 because 2024 is projecting net need for 32 stations yet FKC Fisher's Landing will only have 26 stations.

Home Patients

The three closest clinics² to the proposed FKC Fisher's Landing project are PNRS Ft. Vancouver, PNRS Salmon Creek, and PNRS Battle Ground. Of these three facilities, only PNRS Ft. Vancouver reported home patients in the 2Q2019 NWRN modality report. Of PNRS Ft. Vancouver's 178 total reported patients, 136 were in-center and 42 were home patients.

Therefore, PNRS Ft. Vancouver's home patients were 30.9% of its in-center patient count. The 30.9% home percentage was applied to FKC Fisher's Landing's projected in-center patient projections discussed above to forecast home patients."

Applicant's Table

	Dec 2021	Full Year 1 (2022)	Full Year 2 (2023)	Full Year 3 (2024)
Total in-center stations	26	26	26	26
Total in-center patients	29	93	122	131
Total in-center treatments	348	13,392	17,568	18,864
Total home patients	9	29	38	40
Total home treatments	108	4,176	5,472	5,760

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

The payer mix assumptions below are based on the closest three comparable facilities for year 2018. The three facilities are FKC Battle Ground, FKC Fort Vancouver, and FKC Salmon Creek [source: Application pdf19]

Applicants Table

Payor Class	Mix Based on Treatments	Mix based on Revenue
Medicare	48.3%	35.8%
Commercial	8.5%	23.1%
Medicaid	4.8%	2.5%
Medicare Adv	31.5%	31.6%
Medicaid Risk	3.2%	2.8%
Misc. Ins	2.8%	2.8%
Self Pay	0.9%	0.1%
Old Revenue Accounts	0.0%	1.3%
TOTAL	100%	100%

*Based on FKC Ft. Vancouver, FKC Salmon Creek, and FKC Battle Ground's 2018 actuals.

FMC provided other financial assumptions used to prepare the Pro Forma Revenue and Expense Statement. [source: screening response pdf39]

Patient Volumes

- *It is assumed the number of treatments per patient is 144/year. There is an adjustment in 2021 to reflect only partial year of operations during the forecast time period.*

Revenues

- *In-center revenues are based on three comparable clinics' (Ft. Vancouver, Salmon Creek, and Battle Ground) CY2018 experience ("actuals"). Payer mix statistics have also been obtained from actuals for the most recent calendar year. Revenues are calculated by payer and treatment. Bad debt and charity care are subtracted from revenues to yield net revenue figures.*

Charity Care

- *Calculated at 0.88% of revenue based on the experience of Fresenius' facilities in Washington State.*

Bad Debt

- *Calculated on a per treatment basis from actuals*

Expenses

- *Unless otherwise noted, expenses have been calculated on a per treatment basis based on actuals*
- *Personnel expenses are based on identified patient to staff ratios and incorporates a 10% nonproductive factor. Wage figures have been compiled from actuals at the three comparable clinics*
- *Depreciation is straight-line; assumes 10 years on leaseholds and 8 years on equipment.*
- *Rent Expense: based on Commencement date of May 2021. See Section 3.1 in Lease Agreement for base rent schedule. Note: some revisions were made in screening to match the lease terms by months. Lease year 1 spans May 2021 - April 2022, Lease year 2 May 2022 to April 2023, etc. Therefore, Rent Expense in calendar year 2022 equals 4 months at Lease Year 1 rates (i.e. Jan to Apr 2022) plus 8 months from Lease Year 2 rates (May to Dec 2022)*
- *Other Property Exp includes common area maintenance ("CAM"), allocated taxes, and insurance costs. Estimated at 7% of base Rent Expense based on 2018 experience of three comparable clinics*
- *Physician Compensation: see MDA section 3.01.1*
- *Other Expense (Startup): seven months of lease payments (and other property expenses) prior to operations.*
- *Other Expense (Net Interest): calculated on a per treatment basis based on actuals. The net interest figure can be positive or negative any given year depending on whether interest revenues or interest expenses are higher. For example, if interest revenue is greater than interest expense, net interest will be expressed as a negative expense. Because WAC 246- 310-815(1)(c)(iii) requires other expenses for new facilities to be based on the applicant's three comparable facilities, Fresenius based FKC Fisher's Landing's net interest on the average net interest per treatment value of its three closest facilities. This average interest per treatment figure happened to be a negative expense in 2018 based on actual data from the three comparable facilities. Therefore, FKC Fisher's Landing's "other expense" related to net interest is also expected to be negative expense because it is using the negative interest expense actual multiplied by FKC Fisher's Landing's treatment projections.*

Based on the assumptions above, FMC projected the revenue, expenses, and net income for years 2021 through 2024. Year 2021 includes just one month of operation and years 2022 through 2024 are full years. The projections are shown in the table below. [source: Screening Response pdf38]

Department's Table 3
FKC Fisher's Landing
Projected Revenue and Expenses for Fiscal Years 2021 - 2024

	FY 2020	FY 2021	FY 2022	FY 2023
Net Revenue	\$184,475	\$7,107,159	\$9,320,864	\$9,961,673
Total Expenses	\$393,289	\$4,822,915	\$6,061,931	\$6,430,855
Net Profit / (Loss)	(\$208,814)	\$2,284,244	\$3,258,933	\$3,530,818

The 'Net Revenue' line item is gross in-center and training revenue, minus deductions for contractual allowances, bad debt, and charity care. The 'Total Expenses' line item includes all expenses related to the operation of the 27-station dialysis center.

Public Comment

Puget Sound Kidney Centers provided the following comments:

“Consistent with the CN Program’s past practice, if an application fails to meet Need (WAC 246-310-210), it also fails Financial Feasibility.”

Rebuttal Comment

None – FMC’s rebuttal did not address this issue

Department Evaluation

FMC proposes a new 27 station dialysis center in Camas, within Clark County. FMC based its projected utilization of the facility consistent with WAC 246-310-815(1)(a) and (c). The department concluded that this project did not meet WAC 246-310-812 or WAC 246-310-812(5) evaluated under WAC 246-310-210 (need). The failure to demonstrate need for additional stations due to the recent approval of another provider calls into question the assumptions used by FMC in their application. For this reason and based on a review of the assumptions used for projecting utilization of the 27 station dialysis center, the department concludes the utilization projections are not reasonable.

FMC provided a detailed description of the assumptions used for projecting revenue, expenses, and net income of proposed dialysis center located in Camas.

All agreements provided to support the financial feasibility of the project have executed. Further, the costs identified in all of the agreements referenced above can be substantiated in the pro forma revenue and expense statement.

However, based on the failure under WAC 246-310-210, there isn’t sufficient need to support the approval of this project and this project cannot meet some of the review criteria under WAC 246-310-220. Absent reliable volume assumptions, the department cannot conclude that the subsequent financial projections are attainable. Based on this information, the department concludes that the immediate and long-range operating costs of the new Camas facility cannot be substantiated. **This sub-criterion is not 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, each applicant must demonstrate compliance with the following sub-sections of WAC 246-310-815(2).

WAC 246-310-815(2)

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

Fresenius Medical Care

FMC provided the following information under this sub-criterion. [source: Application, pdf18]

“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 Fisher's Landing facility 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 Fisher's Landing facility will have no effect on rates Fresenius would receive in the Clark County Dialysis Planning Area.

FMC also provided a copy of its proposed line drawings for the new dialysis center in Clark County with the square footage calculations. [source: Application Exhibit 5]

Public Comment

None

Rebuttal Comment

None

Department Evaluation

The total costs for this project is \$6,945,847. FMC's portion of the costs is \$2,607,819 and the landlord is committed to funding 62.5% of the costs at \$4,338,028. The capital costs includes all costs associated with the establishment of the dialysis center, including \$915,429 from the landlord to purchase the site. The costs are comparable to those reviewed in past applications for similar type projects and similar sized facilities. The department does not consider the capital expenditure to be excessive for this project.

The projected Medicare and Medicaid percentage of patients is 87.2% and commercial/other is 8.5%. Medicare and Medicaid reimbursement represents 72.7% of revenue. Given that majority of dialysis, payments are by Medicare and Medicaid reimbursement, the percentages are reasonable.

Regardless of the number of patients projected, under the new ESRD PPS payment system, Medicare pays dialysis facilities a bundled rate per treatment and that rate is not the same for each facility. Each facility, within a given geographic area, may receive the same base rate. However, there are a number of adjustments both at the facility and at patient-specific level that affects the final reimbursement rate each facility will receive. What a dialysis facility receives from its commercial payers will also vary.

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

To be compliant with WAC 246-310-800(11), FKC Fisher's Landing maximum floor space for a 27 station facility is 7,788 square feet. FMC projects the actual treatment floor space will be 4,795 square feet. FMC's project does not exceed the maximum treatment floor area square footage allowable.

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

Fresenius Medical Care

FMC provided the following table related to the capital expenditure for this project and information about financing. FMC also provided audited financial statements. [source: Application, pdf17-18 and Exhibit 14]

**Department's Table 4
Capital Expenditure Breakdown**

Item	Fresenius Medical Care	Landlord	Total
Land Purchase	\$0	\$915,429	\$915,429
Land Improvements	\$0	\$2,325,911	\$2,325,911
Building Construction	\$1,954,506	\$0	\$1,954,506
Fixed Equipment (not in construction contract)	\$266,760	\$0	\$266,760
Moveable Equipment	\$175,512	\$0	\$175,512
Architect & Engineering Fees	\$166,814	\$181,000	\$347,814
Consulting Fees	\$0	\$32,500	\$32,500
Supervision & Inspection of Site	\$0	\$55,000	\$55,000
Costs Associated with Securing Financing	\$0	\$183,119	\$183,119
Other-Permit Fees, Real Estate	\$0	\$645,069	\$645,069
Washington State Sales Tax	\$44,227	\$0	\$44,227
Total	\$2,607,819	\$4,338,028	\$6,945,847

FMC stated it will use existing reserves to fund this project and provided a letter from Mark Fawcett, Senior Vice President of Finance, attesting to the availability of funds and a commitment to this project. [source: Application, Exhibit 13]

Public Comment

None

Rebuttal Comment

None

Department Evaluation

FMC intends to finance its portion of the project with reserves and demonstrated the funds are available. The landlord, Camas Renal Construction, LLC, is financially committed to the project through the executed lease. 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 this FMC project **meets this sub-criterion**.

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

Based on the source information reviewed, the department concludes that Fresenius Medical Care has not met the structure and process of care criteria in WAC 246-310-230 for this project.

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

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

Fresenius Medical Care

FMC provided the following staffing table showing projected staff for the new dialysis center. [source: screening response pdf40]

Department's Table 5
Projected FTEs

Staff Type	Partial Year 2021	Full Year 2022	Full Year 2023	Full Year 2024
Facility Administrator	1.00	1.00	1.00	1.00
Outpatient RN	1.50	4.70	6.10	6.60
Patient Care Tech	3.60	11.60	15.30	16.40
Equipment Tech	0.20	0.70	1.00	1.00
Social Worker	0.20	0.70	1.00	1.00
Dietitian	0.20	0.70	1.00	1.00
Secretary	0.20	0.70	1.00	1.00
Home RN	0.50	1.50	1.90	2.00
Total	7.40	21.60	28.30	30.00

FMC provided the following clarification regarding the staffing table above. [source: Application, pdf20]

“Information and assumptions used to prepare Table 12 include:

- The wage and salary figures are based on FKC Ft. Vancouver, FKC Salmon Creek, and FKC Battle Ground 2018 data. They are held constant over the forecast period.*
- It is assumed a FTE (“full time equivalent”) employee works 2,080 hours per year.*
- Non-productive hours are estimated at 10% of productive hours, based on FMC experience.*
- Benefits are calculated at 37.1% of wages and salaries based on the three facilities’ 2018 data.*
- The staff to patient ratio matrix below was used to construct minimum FTE counts for the projection years based on future patient counts presented in Table 7.”*

Applicant's Table

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

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

Focusing on recruitment and retention of necessary staff, FMC provided the following information. [source: Application, pdf21-22]

“By virtue of the proposed geographic location, we anticipate recruiting staff from Clark County as well as from neighboring counties. In order 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

With the establishment of a 27-station dialysis center in Camas, FMC expects to need approximately 30 FTEs by the end of year three (2024). FMC intends to rely on its recruitment and retention strategies used in the past for this project. This approach is reasonable. FMC is a well-established provider of dialysis services in Washington State and in Clark County. Information provided in the application demonstrates that FMC has the infrastructure in place to recruit necessary staff.

Based on the above information, the department concludes that FMC provided sufficient information to demonstrate compliance with this sub-criterion. **This sub-criterion is met.**

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

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

Fresenius Medical Care

FMC provided the table below showing the anticipated ancillary and support agreements for its new facility in Clark County.

Applicant's Table

NAME	DESCRIPTION
AIR GAS-NOR PAC	oxygen
CALEM MEDICAL INC.	equipment
CDW DIRECT (COMPUTERS)	Computers
CHAMPION MANUFACTURING (CHAIRS)	Furniture
CHG Medical Staffing	Travel Staff
CINTAS	Lab Services
City Wide Maintenance	Janitor services
CLIA LABORATORY USER FEE	Janitor services
Culligan	Water
DELL (ERS)	Computers
DELL MARKETING LP	Computers
DEPT. OF HEALTH	Regulation
FEDEX	Mailing
FIRE SYSTEMS WEST	Fire Prevention
GRAINGER	Supplies
JCB	lab supplies
LANGUAGE LINE	Translation
Iemay	Trash
MAR COR PURIFICATIONS	Equipment
MASCO PETROLEUM	Diesel
MESA LABORATORIES	Lab Services
Staples	Office Supplies
STERICYCLE (BIO-HAZARD)	Bio Hazard
Storemans(Thriftway)	Grocery/ Supplies
SUPERIOR BUILDING SERVICE INC	Building/ Construction Services
TCMS (HVAC SERVICES)	HVAC Services
TELEHEALTH (TV'S)	TV supply
ULINE	medical supplies
WA Dept of Health	Regulation

FMC also provided the following statements regarding services provided on site and services provided through a parent corporation off site. [source: Application, pdf23]

“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 an executed Medical Director Agreement between Renal Care Group Northwest, Inc. (a subsidiary of FMC) and Cascade Multi-Specialty Associates, PLLC. In addition to the agreement, FMC provided the following statements regarding medical director services for the new Clark County center. [source: Screening Response pdf2 and Revised Exhibit 9]

“Dr. Majd Isreb (MD00048412) will be the medical director.”

Public Comment

None

Rebuttal Comment

None

Department Evaluation

As previously stated, FMC has been operating in Clark County for many years. FMC has established ancillary and support agreements in place for its three Clark County facilities, and would use the same strategies to establish ancillary and support agreements for its Camas facility.

Additionally, FMC provided a draft Patient Transfer Agreement with PeaceHealth Southwest Medical Center. The department would attach a condition requiring that FMC provide a copy of the executed agreement prior to operation if this project was approved.

FMC also provided a copy of an executed Medical Director Agreement for the dialysis center. The agreement outlines all roles and responsibilities for each entity, includes all costs associated with the agreement, and has an initial term of ten years. This agreement is acceptable.

Based on the information above, FMC demonstrated that it would have the necessary ancillary and support services at the proposed Camas facility. The department concludes that **this sub-criterion is met.**

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

WAC 246-310 does not contain specific WAC 246-310-230(3) criteria as identified in WAC 246-310-200(2)(a)(i). There are no known recognized standards as identified in WAC 246-310-200(2)(a)(ii) and (b) that a facility must meet when it is 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 identified in their application that they have no history of actions noted in WAC 246-310-230(5).
[source: Application, pdf25]

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 2,634 facilities. Of the 2,634 facilities reporting to CMS by FMC, 237 do not have the necessary amount of data to compile a star rating. For the remaining facilities with a star rating, the national average rating is 3.85.
[source: CMS data]

CMS Star Rating for Washington State Centers

For Washington State, FMC owns, operates, or manages 25 operational facilities. The Washington State average rating is 4.17. [source: CMS data].

CMS Survey Data

While 25 FMC facilities are operational in Washington State, in the most recent three years, not all facilities have been surveyed. All surveys that did take place resulted in no significant non-compliance issues. [source: DOH OHSO survey data]

In this application, FMC Majd Isreb as the proposed Medical Director for the new facility. Dr. Isreb is credentialed in Washington State. Using data from the Washington State Department of Health Office of Customer Service, the department found that Dr. Isreb is compliant with state licensure and has no enforcement actions on their license. Given that FMC proposes a new facility, other staff have not been identified.

In 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 physician that would be associated with the facility. 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 a new dialysis center would not cause a negative effect on FMC's compliance history. The department concludes that FMC'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 the following information related to this sub-criterion. [source: Application, pdf24]

"The establishment of a new facility in the Clark Dialysis Planning Area in Camas, owned and operated by RCG, will not only ensure timely access to dialysis services, but it will also realize efficiency, coordination and continuity of care through shared System-level staff, administration and other functions.

Further, there is net need in the planning area that requires an increase in capacity to be able to accommodate planning area demand and prevent unnecessary and burdensome out-migration. Therefore, the development of the FKC Fisher's Landing will not lead to fragmentation of care, but rather prevent it by reducing out-migration and ensure care is accessible in the community."

FMC also provide a copy of a draft Transfer Agreement that would be used for this facility. [source: Application, Exhibit 15]

Public Comment

Above comments applicable to need are also applicable to this sub-criterion – they will not be restated.

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 Clark County. Specific to the draft patient Transfer Agreement provided in the application, while the agreement does not identify a hospital, the agreement is acceptable because Transfer Agreements do not include any costs associated with the transfer for the dialysis provider.

FMC provided documentation in the application to demonstrate that the project would promote continuity in the provision of health care services in the community by adding stations in a planning area, assuming additional dialysis stations are needed. If approvable, the project would not result in unwarranted fragmentation. However, there is not sufficient numeric need to support the approval of this project. The department cannot conclude this project would not result in an unwarranted fragmentation of services based on the lack of numeric need. Based on the information above, the department concludes that FMC's project **does not meet this sub-criterion**.

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

Department Evaluation for Fresenius Medical Care

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

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

Based on the source information reviewed, FMC does not meet the cost containment criteria in WAC 246-310-240 for this project.

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

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

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. The department completes step three under WAC 246-310-827.

Step One

For this project, FMC did not meet the applicable review criteria under WAC 246-310-210, WAC 246-310-220, and 246-310-230. A review of step two or three is unnecessary for this project.

Department Evaluation

Based on the failures to meet applicable review criteria under WAC 246-310-210, and the related failures under WAC 246-310-220 and WAC 246-310-230, **this sub-criterion is not 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

This sub-criterion was evaluated in conjunction with WAC 246-310-220(2) above and is considered met.

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

Fresenius Medical Care

FMC provided the following information related to this sub-criterion. [source: Application p33]

“The new facility 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.”

Public Comment

None

Rebuttal

None

Department Evaluation

If this project was approved, it could have the potential to improve delivery of dialysis services to the residents of Clark County with the addition of 27 dialysis stations in the planning area. However, this project was denied under WAC 246-310-210, WAC 246-310-220, and WAC 246-310-230. **As a result, this sub-criterion is not met.**

Appendix A

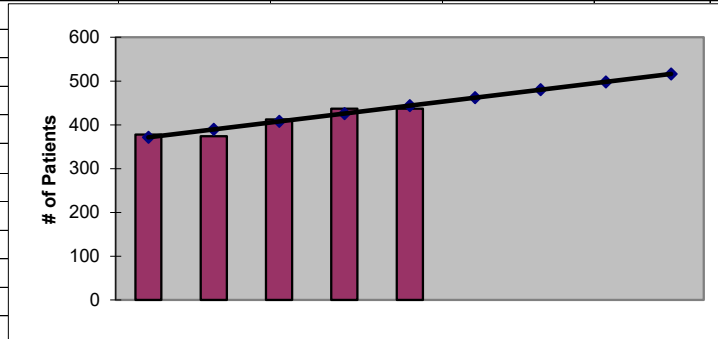


2019
Clark County
ESRD Need Projection Methodology

	Planning Area	6 Year Utilization Data - Resident Incenter Patients					
	Clark	2013	2014	2015	2016	2017	2018
	Clark County	359	378	374	412	437	437
	TOTALS	359	378	374	412	437	437
246-310-812(4)(a)	Rate of Change		5.29%	-1.06%	10.16%	6.07%	0.00%
	6% Growth or Greater?		FALSE	FALSE	TRUE	TRUE	FALSE
	Regression Method:	Linear					
246-310-812(4)(c)			Year 1	Year 2	Year 3	Year 4	Year 5
			2019	2020	2021	2022	2023
Projected Resident Incenter Patients	from 246-310-812(4)(b)		461.90	480.00	498.10	516.20	534.30
Station Need for Patients	Divide Resident Incenter by 4.8		96.23	100.00	103.77	107.54	111.31
	Rounded to next whole number		97	100	104	108	112
246-310-812(4)(d)	subtract (4)(c) from approved stations						
Existing CN Approved Stations	Total		84	84	84	84	84
Results of (4)(c) above			97	100	104	108	112
Net Station Need			-13	-16	-20	-24	-28 *
Negative number indicates need for stations							
*Applications currently pending in the planning area - contact the CN program with questions							
Planning Area Facilities							
Name of Center	# of Stations						
DaVita Vancouver	12						
PNRS Ft. Vancouver	24						
PNRS Salmon Creek	16						
DaVita Battle Ground	10						
PNRS Battle Ground	22						
Total	84						
Source: Northwest Renal Network data 2013-2018							
Most recent year-end data: 2018 posted 02/15/2019							

**2019
Clark County
ESRD Need Projection Methodology**

x	y	Linear							
2014	378	371							
2015	374	389							
2016	412	408							
2017	437	426							
2018	437	444							
2019		461.90							
2020		480.00							
2021		498.10							
2022		516.20							
2023		534.30							
SUMMARY OUTPUT									
Regression Statistics									
Multiple R	0.934281439								
R Square	0.872881808								
Adjusted R Square	0.830509077								
Standard Error	12.6108419								
Observations	5								
ANOVA									
	<i>df</i>	<i>SS</i>	<i>MS</i>	<i>F</i>	<i>Significance F</i>				
Regression	1	3276.1	3276.1	20.60008384	0.020023399				
Residual	3	477.1	159.0333333						
Total	4	3753.2							
	<i>Coefficients</i>	<i>Standard Error</i>	<i>t Stat</i>	<i>P-value</i>	<i>Lower 95%</i>	<i>Upper 95%</i>	<i>Lower 95.0%</i>	<i>Upper 95.0%</i>	
Intercept	-36082	8039.605073	-4.488031399	0.020637577	-61667.61146	-10496.3885	-61667.6	-10496.4	
X Variable 1	18.1	3.98789836	4.538731523	0.020023399	5.408727597	30.7912724	5.408728	30.79127	



Appendix B



STATE OF WASHINGTON

DEPARTMENT OF HEALTH

PO Box 47852•Olympia, Washington 98504-7852

December 11, 2019

CERTIFIED MAIL # 7018 2290 0001 8591 8780

Amanda Crain, COO
PSKC
1019 Pacific Ave
Everett, WA 98201

RE: Certificate of Need Application #19-75

Dear Ms. Crain:

Enclosed is Certificate of Need #1828 issued to Puget Sound Kidney Centers to establish a new ESRD facility that will serve the residents of Clark County.

The certificate is not an approval for any other local, federal, or state statutes, rules, or regulations. Such a project may also need Department of Health approval for a construction plan and facility licensing or certification, as well as other federal or local jurisdiction permits.

The Certificate of Need is valid for two years. The project must begin during this time. If there is substantial and continuing progress, we may extend the certificate for one six month period. For an extension, you must submit an extension request at least 120 days before the expiration. You cannot begin a project after the expiration date.

This decision may be appealed. The appeal options are listed below.

Appeal Option 1:

Any person with standing may request a public hearing to reconsider this decision. The request must state the specific reasons for reconsideration in accordance with Washington Administrative Code 246-310-560. A reconsideration request must be received within 28 calendar days from the date of the decision 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

Appeal Option 2:

Any person with standing may request an adjudicative proceeding to contest this decision within 28 calendar days from the date of this letter. The notice of appeal must be filed according to the provisions of Revised Code of Washington 34.05 and Washington Administrative Code 246-310-610. A request for an adjudicative proceeding must be received within the 28 days at one of the following addresses:

Mailing Address:

Department of Health
Adjudicative Service Unit
Mail Stop 47879
Olympia, WA 98504-7879

Physical Address

Department of Health
Adjudicative Service Unit
111 Israel Road SE
Tumwater, WA 98501

We monitor projects until completed or the expiration date, whichever occurs last. We do this with quarterly progress reports. At least 30 days before the report's due date, you will receive a form to complete and return.

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

Sincerely,



Nathan Weed, Director
Community Health Systems

Enclosure



This Certificate is granted under the authority of RCW 70.38. Issuance of this Certificate does not constitute approval under any other local, federal or state statute, implementing rules and regulations. Examples where additional approval may be necessary include, but are not limited to, construction plan approval through the Construction Review Unit of the Department of Health, facility licensing/certification through the Department of Social and Health Services or Department of Health, and other federal or local jurisdiction permits.

Certificate of Need #1828 is issued to:

Applicant's Legal Name: Puget Sound Kidney Centers
Applicant's Address: 1019 Pacific Avenue, Everett, WA 98201
Facility Type End State Renal Disease Facility
Project Type End State Renal Disease Facility
Facility Name: PSKC Vancouver
Facility Address: 10301 NE 117th Avenue, Vancouver, WA 98662

**ISSUANCE OF THIS CERTIFICATE OF NEED IS BASED ON THE DEPARTMENT'S
RECORD AND EVALUATION DATED DECEMBER 2, 2019 (CN APP # 19-75)**

Project Description

This certificate approves the construction of a 25-station Dialysis facility called PSKC Vancouver. Services provided at the center include one (1) isolation station in addition to the 23 general use in-center stations and one permanent bed station. PSKC Vancouver will include in-center hemodialysis, home hemodialysis and home peritoneal dialysis training, isolation capabilities and a permanent bed station. There will also be a patient shift starting after 5pm.

Service Area
Clark County

Conditions

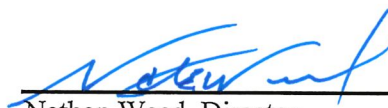
1. Approval of the project description as stated above. PSKC further agrees that any change to the project as described in the project description is a new project that requires a new Certificate of Need.
2. PSKC shall finance this project using a bank loan and reserves, as described in the application.
3. PSKC shall adhere to their commitment to provide written consent in the instance that Dr. Ramon Añel requests such relief a relief letter allowing outside employment from Puget Sound Kidney Centers as outlined in Section 12 of the submitted medical director agreement.
4. PSKC shall provide the executed final version of a patient transfer agreement, consistent with the draft in the application, with an area partner prior to opening.

Approved Capital Expenditure

The approved capital expenditure for this project is \$8,904,224

This Certificate authorizes commencement of the project from December 11, 2019 to December 11, 2021 unless extended, withdrawn, suspended, or revoked in accordance with applicable sections of the Certificate of Need law and regulations.

Date Certificate Issued: December 11, 2019



Nathan Weed, Director
Community Health Systems

This Certificate is not transferable