STATE OF WASHINGTON

DEPARTMENT OF HEALTH

Olympia, Washington 98504

August 16, 2019

CERTIFIED MAIL # 7016 6010 0001 0575 0099

Casey Stowell, RVP Pacific Northwest
Fresenius Medical Care
20900 Southwest 115th Avenue, #190
Tualatin, Oregon 97062

RE: Certificate of Need Application #18-48A – FKC Fisher's Landing

Dear Ms. Stowell:

We have completed review of the Certificate of Need application submitted by Fresenius Medical Care proposing to establish a 26-station dialysis center in Clark County. 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:

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

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:	Physical Address
Department of Health	Department of Health
Adjudicative Service Unit	Adjudicative Service Unit
Mail Stop 47879	111 Israel Road SE
Olympia, WA 98504-7879	Tumwater, WA 98501

If you have any questions, or would like to arrange for a meeting to discuss our decision, please contact the Certificate of Need Program at (360) 236-2955.

Sincerely,

Nancy Tyson, Executive Director
Health Facilities and Certificate of Need

Enclosure

YEAR 2018 CYCLE 1 NON-SPECIAL CIRCUMSTANCE EVALUATION DATED AUGUST 16, 2019, FOR THE CERTIFICATE OF NEED APPLICATION SUBMITTED BY FRESENIUS MEDICAL CARE PROPOSING TO ESTABLISH A NEW 26-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 23 kidney dialysis facilities. These facilities are listed below. [source: Amendment Application, pp6-9, CMS Dialysis Facility Compare website]

Adams County
FMC Leah Layne Dialysis Center

Benton County
FMC Columbia Basin

Clark County
PNRS Fort Vancouver
PNRS Clark County Dialysis Clinic
PNRS Salmon Creek

Grant County
FMC Moses Lake Dialysis Unit

Grays Harbor County
FMC Aberdeen

Lewis County
FMC Chehalis

Mason County
FMC Shelton

Okanogan County
FMC Omak Dialysis Center

Pierce County
Fresenius Kidney Care Mt. Rainier
Fresenius Kidney Care South Tacoma
Fresenius Kidney Care Tacoma East
Fresenius Kidney Care Gig Harbor
Fresenius Kidney Care Puyallup

Spokane County
FMC Spokane Kidney Center
FMC Northpointe Dialysis Unit
Panorama Dialysis
FMC North Pines Dialysis Unit

Stevens County
FMC Colville

Thurston County
FMC North Thurston County Dialysis Center
FMC Lacey

Walla Walla County
Qualicenters – Walla Walla LLC

APPLICANT DESCRIPTION

Fresenius Medical Care

FMC proposes to establish a new 26-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."*

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 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. FKC Fisher's Landing's services will also include one (1) isolation station and a one (1) room expandable home program." [source: Application, p10]

If approved, FMC expects the 26-station dialysis center would be operational by July 2020. [source: Application, p11] When FMC submitted its initial application in May 2018, it assumed a Certificate of Need decision date within 6-9 months. When this amendment application was converted to a regular review, FMC again assumed a 6-9 month decision date. Given that this evaluation is delayed by approximately 150 days, if this project is approved, the department will take the evaluation delay into consideration during the progress report monitoring. However, for this review, the department will use FMC's timeline within the application.

The total 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: Amendment Application, p21 and September 28, 2018, screening response, p2]

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. 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).

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

WAC 246-310-803 requires an applicant to submit specific data elements to the Certificate of Need Program. For the 2018 concurrent review cycle, the data must be received before February 16, 2018. Each applicant submitted the data elements on February 15, 2018. This data is used to calculate superiority in the event that more than one application meets the applicable review criteria. Consistent with WAC 246-310-827, these data elements are the only means by which two or more applications may be compared to one another.

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

CONCURRENT REVIEW, AMENDMENT APPLICATION, REGULAR REVIEW

Concurrent Review

As directed under WAC 246-310-806, the department accepted this application under the Kidney Disease Treatment Centers-Nonspecial Circumstances Concurrent Review Cycle #1 for calendar year 2018. When this project was initially submitted on June 1, 2018, under the concurrent review timeline for year 2018 cycle 1, a competing project was submitted by Puget Sound Kidney Centers (PSKC).

Amendment Application

Before the department screened both applications, it was noted that the Clark County numeric methodology posted to the department's website identified an incorrect number of operational dialysis stations for the county. The department corrected the numeric methodology which resulted in a calculated increase of stations needed in the county.

Given that dialysis providers rely on the department's posted numeric methodology before submission of applications, both applicants were provided an opportunity to submit an amendment application that takes into account the corrected methodology. FMC submitted its amendment application on July 30, 2018. PSKC did not submit an amendment application.

The department screened both applications on August 31, 2018. In the PSKC screening letter, the department noted that PSKC had submitted five separate applications during the year 2018 cycle 1 review. Of the five, four of PSKC's applications relied the same three facilities as comparables under WAC 246-310-827.

Subsection (3)(c) of the rule limits the number of the same comparables to two applications in the same review cycle. [1] In response to the department's screening question, PSKC elected to withdraw two of its cycle 1 applications, including the competing application for Clark County.

Regular Review

When PSKC's application for Clark County was withdrawn, only FMC's application remained. As a result, the FMC application was converted to a regular review as allowed under WAC 246-310-806(8). Under a regular review, an applicant may request a second screening of its application. FMC opted for a second screening of this project.

Below is the chronological summary of the review timeline, which includes submission and screening of the PSKC project. Given that PSKC withdrew its application, this evaluation does not include a review of the PSKC project. This evaluation will reference the PSKC application to provide clarity background information.

---

[1] *WAC 246-310-827(3) states:*

When available, Washington facilities must be used as comparables, as follows:

(a) For existing kidney dialysis facilities proposing to expand, use data for the existing facility plus the next two closest Washington facilities as comparables owned by or affiliated with the applicant as measured by a straight line. Straight lines will be calculated using "Google Maps" or equivalent mapping software (mileage calculated out to two decimal points, no rounding).

(b) For new kidney dialysis facilities, use data for the next three closest facilities as comparables owned by or affiliated with the applicant as measured by a straight line from the proposed new kidney dialysis facility location. Straight lines will be calculated using "Google Maps" or equivalent mapping software (mileage calculated out to two decimal points, no rounding).

(c) The number of applications per concurrent review cycle that rely on the same three comparables is limited to two.

APPLICATION CHRONOLOGY

Action	FMC Clark County	PSKC Clark County
Letter of Intent Submitted	April 30, 2018	May 1, 2018
Initial Application Submitted	June 1, 2018	June 1, 2018
Amendment Application Submitted	July 30, 2018	No Amendment Submitted
Department's pre-review activities • DOH 1st Screening Letter • Applicant's Responses Received	August 31, 2018 September 28, 2018	August 31, 2018 **Application Withdrawn September 28, 2018**
• DOH 2nd Screening Letter • Applicant's Responses Received	October 19, 2018 November 30, 2018	
Beginning of Review	December 7, 2018	
End of Public Comment • Public comments accepted through the end of public comment • No public hearing requested or conducted	January 11, 2019	
Rebuttal Comments Submitted	January 28, 2019	
Department's Initial Anticipated Decision Date	March 14, 2019	
Department's Anticipated Decision Date with 180-day extension[2]	September 10, 2019	
Department's Actual Decision Date	August 16, 2019	

AFFECTED PERSONS

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

"…an "interested person" who:

(a) Is located or resides in the applicant's health service area;

(b) Testified at a public hearing or submitted written evidence; and

(c) Requested in writing to be informed of the department's decision."

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

(a) The applicant;

(b) Health care facilities and health maintenance organizations providing services similar to the services under review and located in the health service area;

(c) Third-party payers reimbursing health care facilities in the health service area;

(d) Any agency establishing rates for health care facilities and health maintenance organizations in the health service area where the proposed project is to be located;

(e) Health care facilities and health maintenance organizations which, in the twelve months prior to receipt of the application, have submitted a letter of intent to provide similar services in the same planning area;

(f) Any person residing within the geographic area to be served by the applicant; and

(g) Any person regularly using health care facilities within the geographic area to be served by the applicant.

[2] The department extended application deadlines at thirty day increments dated March 14, 2019; April 12, 2019; May 13, 2019; June 12, 2019; July 12, 2019, and August 12, 2019.

Three entities sought affected person status. Below is a description of each entity and status for this review.

Northwest Kidney Centers

Northwest Kidney Centers (NKC) is a private, not-for-profit corporation, incorporated in the state of Washington. Established in 1962, NKC operates a community based dialysis program to meet the needs of dialysis patients and their physicians. NKC does not currently serve Clark County, did not submit an application for Clark County, or provide public comments related to this application. As a result, NKC does not qualify as an interested person and cannot qualify as an affected person.

Puget Sound Kidney Centers

Puget Sound Kidney Centers (PSKC) is a private, not-for-profit corporation, incorporated in the state of Washington. PSKC does not own or operate dialysis centers outside of Washington State. When this application was submitted in June 2018, PSKC operated six outpatient centers throughout Snohomish, Skagit, and Island Counties. Since then PSKC has obtained approval to operate additional dialysis centers throughout Washington State.

PSKC submitted a competing application for Clark County during this review cycle. Even though the application was withdrawn, PSKC qualifies for interested person status. PSKC provided both public and rebuttal comments on this FMC application. Since PSKC does not currently operate a facility in Clark County, PSKC does not qualify for affected person status for this project.

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 Clark County.[3] DaVita provided public comments, but not rebuttal comments, on this FMC application. DaVita qualifies for affected person status.

SOURCE INFORMATION REVIEWED

As previously stated, FMC submitted its initial application under the concurrent review timeline for year 2018 cycle 1. Subsequently, FMC submitted its amendment application on July 30, 2018. When an amendment application is submitted for a Certificate of Need review, it takes the place of the initial application. As a result, the initial application is not reviewed.

- Fresenius Medical Care's Certificate of Need application received July 30, 2018
- Fresenius Medical Care's screening responses received September 28, 2018. and November 30, 2018
- Public comments accepted through January 11, 2019
- Rebuttal comments accepted through January 28, 2019
- Years 2012 through 2017 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 on March 2018 and the revised methodology posted to the website on July 2018
- Licensing data provided by the Medical Quality Assurance Commission, Nursing Quality Assurance Commission, and Health Systems Quality Assurance Office of Customer Service

[3] Vancouver Dialysis Center and Battle Ground Dialysis Center.

SOURCE INFORMATION REVIEWED (continued)

- 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 26 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).[4]

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.[5]

In planning areas experiencing high rates of growth in the dialysis population (6% or greater growth in

[4] 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]

[5] 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.

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 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 METHODOLGY: INITIAL AND REVISED

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 2018 numeric methodology was posted in March 2018. 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.

Within its competing application, PSKC noted that FMC's Battle Ground facility should be operating 22 stations rather than 24. To support this assertion, PSKC provided an excerpt of a 'Dispute Resolution Agreement' specific to Clark County.

On March 12, 2013, the Department of Health, DaVita, Inc., and FMC entered into a 'Dispute Resolution Agreement' (Agreement) specific to Clark County. The Agreement required specific facility utilization at each of the new dialysis centers to be constructed in Clark County by the two providers. Focusing on the FMC facility known as PNRS Clark County Dialysis Center, Condition #6 of the agreement is restated below.

"If at the end of forty-two (42) months from the PNRS Trigger Date, the PNRS Battle Ground Facility is operating at less than 4.8 in-center patients per station as measured by the Northwest Renal Network Quarterly Modality Report, or successor report, issued for the first full quarter following the end of the forty-two (42) month period, then the Department shall issue an amended Certificate of Need to PNRS to reduce PNRS's authorized Battle Ground station award by up to two (2) stations in order for the PNRS Battle Ground Facility to achieve 4.8 in-center patients per station or closer thereto."

After reviewing the Agreement in its entirety and the Northwest Renal Network data for end of year December 2017, the department issued CN #1484R to FMC that reduced the number of dialysis stations from 24 to 22 at its PNRS Clark County Dialysis Center. Subsequent to the reissuance of CN #1484R,

the department calculated and posted its Revised Clark County methodology. On June 29, 2018, the department allowed both FMC and PSKC an opportunity to amend their applications. FMC's amended application was submitted on July 30, 2018.

Below is a summary of the department's initial and revised numeric methodology.

Department's Table 1
Clark County Numeric Methodology Summary

	4.5 in-center patients per station		
	2022 Projected # of stations	**Minus Current # of stations**	**2022 Net Need or (Surplus)**
DOH Methodology Posted to Website March 2018	110	86	24
Revised DOH Methodology Posted to Website July 2018	110	84	26

As shown in the table above, the March 2018 methodology counted 86 existing stations in the county; the revised methodology counted 84 existing stations. The July 2018 revised methodology that calculates a need for 26 new stations is the methodology that will be used throughout this evaluation. The department's methodology is included in this evaluation as Appendix A.

Fresenius Medical Care
FMC proposes to establish a 26-station dialysis center to be located in Camas, within Clark County. FMC relied on the revised Clark County numeric methodology posted to the department's website in July 2018.

Public Comment
None

Rebuttal Comment
None

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. The department concludes FMC **meets 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.[6] 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

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

(b) Certificate of need approved stations for a facility have not become operational within the timeline as represented in the approved application.
...Both resident and nonresident patients using the kidney dialysis facility are included in this calculation. Data used to make this calculation must be from the most recent quarterly modality report from the Northwest Renal Network as of the letter of intent submission date.

For 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
There are 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, p14]

Applicant's Table
Clark County Dialysis Planning Area Provider Utilization – 4Q2017

Facility	***# of Stations***	***December 31, 2017 # of Patients Per Quarterly In-Center Data***	***December 31, 2017 Patients/Station***
DaVita, Vancouver	*12*	*68*	*5.67*
FKC Fort Vancouver	*24*	*139*	*5.79*
FKC Salmon Creek	*16*	*91*	*5.69*
DaVita Battle Ground	*10*	*32*	*3.20*
FKC Battle Ground	*22*	*97*	*4.41*

FKC Battle Ground was technically operating 24 stations in 4Q2017, but as of July 2, 2018, it is now only authorized to operate 22 stations (see CN#1484R). Thus, for the purposes of evaluating Planning Area provider occupancy, Table 2 uses the recently authorized 22 station count. Source: Northwest Renal Network Modality Reports, 12/31/17

Public Comment
During the review of this project, both PSKC and DaVita, Inc. provided comments under WAC 246-310-812(5). The comments are restated below.

Puget Sound Kidney Centers [source: PSKC public comment, p1-3]
"The Program's rule for new dialysis stations in Clark County requires a projected need of 4.8 patients per station (WAC 246-310-812(3)). Furthermore, to prevent overbuilding, there must not be underutilization of existing stations in the county:

(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. (WAC 246-310-812(5).

The data to be used for existing station utilization is "must be from the most recent quarterly modality report from the Northwest Renal Network as of the letter of intent submission date." (WAC 246-310-812(5).)

FMC submitted its letter of intent on May 1, 2018. As FMC acknowledges on page 14 and Table 2 of its amended application, as of the operative date there were two facilities operating below the 4.5 standard, including its own facility in Battle Ground. In fact, the opportunity for an amendment became

available only because the Battle Ground facility had not achieved the utilization requirement outlined in a 2013 settlement agreement, and subsequently had its station count reduced by two stations on July 2, 2018.

There is a limited exception to the 4.5 utilization standard, designed to prevent one provider's poor performance from blocking other providers from meeting the service needs of residents:

> *[W]hen 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…*

(WAC 246-310-812(5)) FMC argues that the (5)(a) exception applies, and thus that its underutilization is acceptable, because the PNRS Battle Ground facility had been in operation for more than three years.

The (5)(a) exception is not intended to allow a provider, operating below standards at its existing facilities, to be able to apply for additional stations. Rather, the rulemaking history indicates that the three-year limitation protecting existing providers was intended to improve access to services for dialysis patients despite the existence of an underperforming facility, while still providing a protection period for providers to achieve the utilization estimates that were outlined in the approved applications.

Early in the dialysis rulemaking process, stakeholders raised a concern that access could and would be affected when a poorly performing facility in a planning area precluded additional stations from being approved. The Program's meeting minutes from the October 17, 2013, stakeholder workshop note that:

> *'Under [the prior CN rules], we can't approve that additional capacity because of an existing operator's under-utilization. This is saying at some point in time, whatever the dynamics are in the planning area, we simply say we can't prevent access to what would appear to be predicted additional station need because of under-utilization. This is trying to solve an access problem.'*

Accordingly, the rules were revised to allow the Program to approve needed stations, despite isolated under-performing facilities, provided that certain requirements were met. (The initial proposal of a four year protective period was later shortened to three years in the final rule.) The intent of the change was to allow the department to approve such expanded capacity at facilities at or above the 4.5 performance standard, not to bestow benefits on providers whose facilities were already performing below the standard. As the minutes indicate, the approach chosen "to deal with a facility's under-utilization" was that:

> *After an agreed upon period of time . . . if a facility has not reached the utilization standard,* ***the department would be able to approve additional capacity to other facilities within that planning area that were at or above the utilization standard****.*

(Emphasis added.) This approach is good policy, ensuring that providers who actually meet the needs of the patient population are given the opportunity to meet those needs. As the operator of the under-performing facility, FMC falls outside the intent of the (5)(a) exception.

Furthermore, FMC had another remedy, "relocate the stations."

DaVita, Inc.

"This planning area is not open for approval of additional stations.

WAC 246-310-812(5) provides as follows:

> *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.*

Two Clark County dialysis facilities are operating below 4.5 in-center patients per station. FMC/Battle Ground is operating at 4.04 patients per station and DaVita/Battle Ground is operating at 3.20 patients per station. Therefore, Section 812(5) forbids approval of additional stations in this planning area at this time.

Section 812(5)(a) does not apply.

Fresenius argues that these two facilities should not be considered for purposes of the Section 812(5) requirement, because Section 812(5)(a) applies. That rule provides that "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: … All stations for a facility have been in operation for at least three years[.]"

Fresenius mistakenly states that both Battle Ground facilities "have been in operation for three or more years" and therefore should not be considered for purposes of Section 815(a).

Our understanding is that FMC/Battle Ground opened on June 20, 2014; therefore, Fresenius is correct that its Battle Ground facility has been open for more than three years. But with respect to DaVita/Battle Ground, Fresenius is mistaken. That facility opened on March 1, 2016, and accordingly has not been open for at least three years. Therefore, Section 812(5)(a) does not apply.

Section 812(5)(b) does not apply.

Although Fresenius relies upon Section 815(a), in the interest of thoroughness we note that Section 815(b) also is inapplicable here. That rule provides that "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: … Certificate of need approved stations for a facility have not become operational within the timeline as represented in the approved application."

This is determined by calculating the stated timeline from the first day the applicant is permitted to open the facility. "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." However, if the CON is challenged, the applicant is not required to open the facility until the resolution of legal proceedings and "[t]he eight months would start from the date of the final department or judicial order."

Here, DaVita identified a 7-month timeline in its Battle Ground application. As the Department is well aware, this application was the subject of a legal challenge resulting in a settlement agreement. Pursuant to the terms of that settlement agreement, the first day DaVita was permitted to open its facility was December 20, 2015. Calculating the 7-month timeline from that date, DaVita had to open its facility by July 20, 2016 in order for its facility to have "become operational within the timeline as represented in the approved application."

DaVita opened its facility on March 1, 2016, well before the July 20, 2016 deadline. Therefore, Section 812(5)(b) does not apply.

Fresenius's application must be denied under WAC 246-310-812(5) because DaVita/Battle Ground is not yet operating at 4.5 patients per station. Section 812(5)(a), the exception relied upon by Fresenius, does not apply because DaVita/Battle Ground has been open for less than three years, not more than three years as Fresenius mistakenly states in its application. Section 812(5)(b), the only other exception to the Section 812(5) utilization requirement, also does not apply, because DaVita/Battle Ground opened within the timeline stated in the approved application."

Rebuttal Comment
FMC provided separate rebuttal comments for PSKC and DaVita on this topic.

FMC Rebuttal Comments to PSKC Public Comments
"PSKC contends our application should be denied because our Battle Ground dialysis center was not meeting the utilization standard of 4.5 patients per station as of May 1, 2018, the date for letters of intent. PSKC's conclusion is incorrect; our application meets this applicable WAC.

Importantly, PSKC does not deny there existed unmet need for 26 stations in this Planning Area, nor could it, since it, too, filed a certificate of need application, which it later withdrew. This point is very important; PSKC is arguing a technical point not the larger issue whether or not need exists. Need does exist, as identified on the Department's website.

We stated in our second round of screening responses that we recognized FKC Battle Ground was operating below the 4.5 patient per station volume standard, as specified in WAC 246-310-812(5). However, WAC 246-310-812(5) also provides exceptions to this minimum patient volume standard for all planning area facilities. Situations where this standard is considered met include paragraph (a), which specifies that facilities in operation three or more years are considered to have met that 4.5 patient/station standard.

FKC Battle Ground meets this criterion in WAC 246-310-812(5)(a). It became operational June 20, 2014. In other words, FKC Battle Ground has been operational more than three years, thus meets the plain language of WAC 246-310-812(5)(a). FMC's application meets the applicable WACs for submittal of the FKC Fisher's Landing application at the time of filing.

In its rebuttal comments, FMC also provided recent information from Northwest Renal Network that is outside the scope of utilization data used for this review. That section of FMC's rebuttal comments are not included in this evaluation or considered in this review.

FMC Rebuttal Comments to DaVita Public Comments
"DaVita contends our application should be denied because its DVA Battle Ground dialysis center was not meeting the utilization standard of 4.5 patients per station and that the exemptions to the utilization standard do not apply. DaVita misinterprets the regulations and its failure to timely open DVA Battle Ground permits the Department to approve new stations in the planning area.

The CN regulations require existing stations in a planning area to be operating at or above 4.5 patients per station (the "Utilization Standard") before new stations are approved even if there is need for additional stations in the planning area exists. WAC 246-310-812(5). When the new ESRD regulations were adopted in 2017, the ESRD rules workgroup recommended and the Department adopted exemptions to the Utilization Standard to discourage certain operators from managing their projects in

a manner that prevented approval of new stations in planning areas where need clearly existed. The new regulations added two exemptions that apply when a CN recipient (1) operates for three years and fails to meet the Utilization Standard (WAC 246-310-812(5)(a)) or (2) fails to become operational within the approved timeline (WAC 246-310-812(5)(b)). This second exemption gives the applicant the time needed to build and open new stations per the timeline delineated in their CN application but removes the protection of the Utilization Standard if they fail to timely open. DVA failed to begin operations under the required timeline and the Department may approve new dialysis stations in the planning area.

WAC 246-310-812(5) states:
(5) Before the department approves new in-center kidney dialysis stations in a 4.8 planning area, all certificate of need counted stations at each facility in the planning area must be operating at 4.5 in-center patients per station. However, when a planning area has one or more facilities with stations not meeting the in-center patients per stations standard, the department will consider the 4.5 in-center patients per station standard met for those facilities when:
(a) All stations for a facility have been in operation for at least three years; or
(b) Certificate of need approved stations for a facility have not become operational within the timeline as represented in the approved application. For example, an applicant states the stations will be operational within eight months following the date of the certificate of need approval. The eight months would start from the date of an uncontested certificate of need approval. If the certificate of need approval is contested, the eight months would start from the date of the final department or judicial order.

However, the department, at its sole discretion, may approve a one-time modification of the timeline for purposes of this subsection upon submission of documentation that the applicant was prevented from meeting the initial timeline due to circumstances beyond its control.

DaVita confirmed in its public comment that its application had a 7-month timeline to open its Battle Ground facility. As acknowledged by DaVita, the project was subject to challenge and the CN was issued as a result of a settlement agreement dated March 12, 2013, the date CN #1500R was issued to DaVita to establish the 10-station facility in Battle Ground. DaVita also correctly stated that if a CN is challenged, the timeline starts from the date of the final department or judicial order. In this case, the timeline starts on March 12, 2013, the date of the final department order, and extends for the period specified in the settlement agreement for the facility to open. Under the settlement agreement, the facility may open on "the earlier of eighteen (18) months after the date PNRS Battle Ground Facility is certified by the Centers for Medicare and Medicaid Services (CMS) or December 31, 2015". PNRS Battle Ground was certified on June 20, 2014, and as indicated by DaVita in its public comment, DaVita was permitted to open its new facility as early as December 20, 2015. DaVita elected, however, to wait until March 1, 2016 to open.

The settlement agreement extended the timeline for DaVita to develop and open its facility from the 7-months described in DaVita's CN application to a timeline of approximately 33 months. The settlement agreement gave DaVita over 4 times the amount of time it indicated it needed to develop and open DVA Battle Ground, over 4 times the amount of time DaVita was protected under the Utilization Standard, yet DaVita failed to become operational by the specified open date and failed to offer an explanation why.

DaVita's interpretation, that under WAC 246-310-812(5)(b) it has an additional 7-month timeline after it is authorized to open to become operational, is inconsistent with the language in the regulation and the intent behind the exemption. The exemption says that unless the facility is operational within the

timeline as represented in the approved application, the utilization standard does not apply. In this case the settlement agreement extended that timeline from 7 months to the approved start date, December 20, 2015. It is important to note that we are not arguing that the Settlement Agreement required DaVita to open DVA Battle Ground on a date certain, but that to maintain the protection of the Utilization Standard and prevent the application of the exemption at WAC 246-310-812(5)(b), DaVita was required to meet a minimum timeline to become operational. DaVita elected not to open its facility by December 20, 2015, even though it had over 33 months after the date its CN was issued (the final department order) and consequently is not protected by the Utilization Standard.

DaVita's argument, that it had a 7-month timeline to develop and implement its project after December 2015, is further contradicted by the requirements on CN#1500R. The CN issued to DaVita for its Battle Ground facility required it to commence its project no later than March 13, 2015. If DaVita now asserts that it waited until December 31, 2015 to commence its project, we query whether DaVita's project was timely implemented before its CN expired.

The following table shows the relevant dates applicable to DaVita's Battle Ground project.

FMC Rebuttal Table 1

Table 1. DVA Battle Ground Timeline

March 12, 2013	Department issues DVA Battle Ground CN#1500.
June 2014	PNRS/FKC Battle Ground certified as of June 20, 2014.
December 20, 2015	Terms of the settlement agreement state that DVA Battle Ground can begin treating patients either: 1. 18 months after the PNRS/FKC Battle Ground is CMS certified (December 20, 2015); or 2. December 31, 2015; whichever date is earlier. Therefore, the applicable operational date for DVA Battle Ground is December 20, 2015.
March 1, 2016	Actual DVA Battle Ground 1st treatment date.

In summary, the exemption to the Utilization Standard at WAC 246-310-812(5)(b) applies to DVA Battle Ground because it was not operational in the approved timeline, thereby opening up the Clark County Planning Area to new in-center kidney dialysis stations. Our 26-station FKC Fisher's Landing application meets all applicable WACs and will address the tremendous unmet need (26 stations) currently existing in the Clark County Planning Area."

Rebuttal comments were also provided by PSKC that focused on public comments submitted by DaVita. PSKC's rebuttal comments are below.

PSKC Rebuttal Comments

"While PSKC concurs with most of the comments included in the DaVita letter, we are taking this opportunity to correct information DaVita submitted regarding the status of its Battle Ground facility vis-a-vis WAC 246-310-812(5)(b).

As DaVita notes, its DaVita Battle Ground facility was approved as the result of a settlement agreement entered into on March 12, 2013: Per paragraph 4 of the agreement, DaVita was approved to "open" its facility 18 months after PNRS was certified by CMS, or December 31, 2015, whichever date was

earlier. Because PNRS was certified on June 20, 2014, DaVita was permitted to open as early as 18 months later on December 20, 2015. Notably, even if PNRS had opened later, DaVita was still approved to open its new facility no later than December 31, 2015.

Notwithstanding the settlement language, DaVita suggests that the agreement did not contemplate that DaVita would actually open its new facility in December 2015. Rather, DaVita suggests that it was expected merely to begin development as of that date, and would then be permitted an additional seven months (the development timeline identified in its original CN submittal) - in addition to the litigation delays permitted under WAC 246-310-815(a), and the 18 month delay permitted under the settlement - before its facility would be deemed under WAC 246-310-812(5)(b) to have missed the timeline described in its application. This is not a correct reading of either the settlement or the WAC, and DaVita's suggestion that its calculation is consistent with the approach contemplated by WAC is a misstatement: DaVita knew when it entered the settlement on March 12, 2013, that its proposed Battle Ground facility would be allowed to open by December 31, 2015, at the latest. The seven months of development should have occurred prior to December 2015, not after. The bottom line is that DaVita Battle Ground failed to meet its timeline as required by WAC 246-310-812 (5)(b).

DaVita acknowledged, and PSKC concurs, that it did not open DaVita Battle Ground until March 2016. This was beyond the approved opening date of December 2015. Clearly, DaVita was late in opening its Battle Ground facility. While this issue is moot in the FMC application that is the subject of this rebuttal (because FMC itself was operating below 4.5), PSKC raises this issue now because it is important for all applicants to understand clearly how the CN Program is to evaluate CN approved projects consistent with WAC 246-310-812(5)(b). There needs to be clarity regarding the interpretation of timelines and when/how a project is deemed to have either met or missed the timeline that was outlined in the approved application."

Department Evaluation

WAC 246-310-812(5) states that the "*data used to make this calculation must be from the most recent quarterly modality report from the Northwest Renal Network as of the letter of intent submission date."*

The date of the letter of intent is May 1, 2018. The data available as of May 1, 2018, is December 31, 2017, end of year data that was available on February 15, 2018. The utilization of the five existing dialysis centers located in Clark County is shown below.

Department's Table 2
December 31, 2017, Utilization Data for Clark County

Facility Name	# of Stations	# of Patients	Patients/Station
DaVita Battle Ground	10	32	3.20
DaVita Vancouver	12	68	5.67
(FMC) PNRS Battle Ground	24	97	4.04
(FMC) PNRS Fort Vancouver	22	139	6.32
(FMC) PNRS Salmon Creek	16	91	5.69

The table above shows that two of the five facilities in Clark County are not operating above 4.5 in-center patients per station: FMC's Battle Ground facility and DaVita's Battle Ground facility. Before addressing this utilization issue, the department notes that the following two facts are not in dispute.

- FMC does not argue that its Battle Ground facility is operating above 4.5 in-center patients per station; and

- DaVita does not argue that its Battle Ground facility is operating above 4.5 in-center patients per station.

This evaluation will discuss comments on each of the two under-utilized facilities separately.

FMC Battle Ground

Both PSKC and DaVita assert that FMC is precluded from adding dialysis station capacity in Clark County because its own Battle Ground facility is below the utilization standard. PSKC provides historical rule-making information to support its claim that as the operator of the under-performing facility, FMC falls outside the intent of the WAC 246-310-812(5)(a) exception.

To evaluate the comments provided above, the department reviewed the historical rule making files focusing on the WAC 246-310-815(5). Historical documents reviewed include:

- October 17, 2013, Workshop Notes
- January 22, 2014, Workshop Notes
- March 19, 2014, Workshop Notes
- May 12, 2016, Stakeholder Meeting Notes

The notes reviewed by the department do not specifically state that the provider operating below the utilization standard should be precluded from adding stations in the planning area. Under the plain language of WAC 246-310-812(5), a provider with a facility not meeting the patients per station standard is eligible to apply for a new facility in the planning area if the under-utilized facility has been in operation for at least three years. To conclude otherwise would create the absurd result that if a planning area has need and only the provider with an under-utilized facility applied, the need would go unmet even though there might be rational reasons, such as poor location, to explain the low utilization.

DaVita Battle Ground

DaVita also asserts that its own facility has not been operating for at least three years in the planning area, therefore, FMC, or any other applicant, cannot apply to add dialysis station capacity in a non-special circumstance review. [WAC 246-310-812(5)(a)]

It is undisputed that DaVita's Battle Ground facility opened on March 1, 2016. Given that this application was submitted on June 1, 2018, the facility had not been operational for three years prior to submission of the FMC application.

PSKC and FMC assert that WAC 246-310-812(5)(b) applies to DaVita's Battle Ground facility because DaVita did not open the facility within the timeline stated in the application. DaVita states that under the previously discussed March 12, 2013, 'Dispute Resolution Agreement' (Agreement) specific to Clark County, DaVita could not open its facility before December 31, 2015.

Within its rebuttal comments, FMC provided a copy of the Agreement. Section #4 of the Agreement is restated below.

"The Department shall condition DaVita's Certificate of Need to specify that DaVita shall not open the DaVita Battle Ground Facility to serve patients until the earlier of eighteen (18) months after the date the PNRS Battle Ground Facility is certified by the Centers for Medicare and Medicaid Services (CMS) or December 31, 2015; provided, however that if the PNRS Battle Ground Facility is operating at 4.8 in-center patients per station as demonstrated by the Northwest Renal Network Quarterly Modality Report, or successor report, then the foregoing restrictions on the opening date of the DaVita Battle Ground Facility

shall no longer apply. The date that DaVita opens the DaVita Battle Ground Facility or December 31, 2015, whichever comes first, is referred to herein as the "DaVita Trigger Date."

The table below shows the calculations of specific dates under the Agreement.

June 20, 2014	FMC Battle Ground is certified[7]
December 20, 2015	18 Months From June 20, 2014
March 1, 2016	DaVita Battle Ground Opening Date[8]

In its initial application for the Battle Ground facility, DaVita stated it would open within 7 months from approval. Since DaVita was precluded from opening earlier than December 20, 2015, and it opened within four months of December 20, 2015, the department concludes that DaVita's opening was within the 7-month timeline stated in its application.

In conclusion, WAC 246-310-812(5)(a) applies to this project. DaVita's Battle Ground facility has not been operational for three years. Sub-section (5)(b) does not apply to this project because DaVita became operational within the combined timeline of the Dispute Resolution Agreement and DaVita's application. The department concludes that this project **does not meet the standard under WAC 245-310-812**.

(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 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

[7] This is the FMC Trigger Date as referenced in the Agreement.
[8] This is the DaVita Trigger Date as referenced in the Agreement.

third-party payer.[9] 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. Patients require access to the specific treatment modality and convenient hours of operation that meet their individual clinical and personal needs, which can be especially challenging if several of the existing facilities currently have high occupancies…and significant unmet need projected in the Planning Area….

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 all of our Washington facilities, and will include FKC Fisher's Landing as well.

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

A copy of our charity care policy is contained in Exhibit 6." [source: Application, p18]

FMC also provided the following policies for this project. [source: Application, Exhibits 6 and 7]
- Admission Policy
- Charity Care Policy

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, pdf20]

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

Department's Table 3
FKC-Fisher's Landing Projected Payer Mix

Source	Percentage of Patients by Payer	Percentage of Revenue by Payer
Medicare	46.6%	27.1%
Commercial	11.3%	39.8%
Medicaid	3.9%	1.9%
Medicaid ADV	31.2%	24.9%
Medicaid RISK	2.9%	1.8%
Miscellaneous Insurance	3.4%	2.7%
Self Pay	0.7%	0.7%
Old Revenue Accounts	0.0%	1.1%
Total	**100.0%**	**100.0%**

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 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, pp16-17 and September 28, 2018, screening responses, Revised Exhibit 8]

"The numeric need methodology set forth in WAC 246-310-812 estimates need for twenty-six (26) additional stations in the Clark County ESRD Planning Area. Based on the finding of need for 26 stations, we know that there is a correspondingly high number of patients who will require access to new services in the coming years. Our experience has shown that with such high need, new stations will get filled quickly. As new Clark County patients require dialysis care, they will utilize new stations consistent with the net need forecast for Clark County.

Fresenius is a well-known provider that already has a presence in the community and is well recognized for its quality. In fact, Fresenius recently achieved the highest percentage of four and five star rated clinics when compared to all other major dialysis providers in the country. Currently, Fresenius has the three highest rated dialysis facilities in Clark County according to Medicare's Dialysis Facility Compare webtool. FKC Salmon Creek and FKC Battle Ground have five star overall ratings [out of five], and FKC Fort Vancouver has a four star overall rating. Patients' nephrologists recognize this and, consequently, direct referrals to Fresenius facilities.

In light of these facts and findings, Table 6 below presents the projected utilization at FKC Fisher's Landing. All 26 stations are anticipated to be operational by July 2020, therefore, the first full year of operation will be CY2021. It is assumed the number of treatments per patient is 144 treatments per year."

Applicant's Table 6

Table 6. FKC Fisher's Landing Utilization Forecast, 2020 - 2023

	Begin Operations (July 2020)	Full Year 1 (2021)	Full Year 2 (2022)	Full Year 3 (2023)
Total in-center stations	26	26	26	26
Total in-center patients	76	103	122	134
Total in-center treatments	5,472	14,832	17,568	19,296
In-center Patients Per Station	2.92	3.96	4.69	5.15
In-center Occupancy (Assumes 6 Patient/Station Max)	48.7%	66.0%	78.2%	85.9%
Total home patients	7	11	15	19
Total home treatments	504	1,584	2,160	2,736

The payer mix assumptions below are based on the closest three comparable facilities for year 2017. The three facilities are FKC Battle Ground, FKC Fort Vancouver, and FKC Salmon Creek [source: Application p23]

Source	Percentage of Patients by Payer	Percentage of Revenue by Payer
Medicare	46.6%	27.1%
Commercial	11.3%	39.8%
Medicaid	3.9%	1.9%
Medicaid ADV	31.2%	24.9%
Medicaid RISK	2.9%	1.8%
Miscellaneous Insurance	3.4%	2.7%
Self Pay	0.7%	0.7%
Old Revenue Accounts	0.0%	1.1%
Total	**100.0%**	**100.0%**

FMC provided other financial assumptions used to prepare the Pro Forma Revenue and Expense Statement. [source: September 28, 2018, screening response, pp6-7, p12, and p15]

Patient Volumes

- Utilization projections, including the assumptions used to derive the forecasts, are presented in Table 6 and surrounding discussion within the main text of the application.
- It is assumed the number of treatments per patient is 144/year. There is an adjustment in 3Q-4Q2020 to reflect only 6 months of operation during the forecast time period.

Revenues

- In-center revenues are taken from three closest Washington State clinic actuals, given this is a new facility. Payer mix statistics have also been obtained from the three closest clinic actuals

for the most recent calendar year. Revenues are calculated by payer, by treatment and net revenues. 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).
- Net revenue: revenue for all patient care services less deductions from revenue
- Deductions from revenue: Reductions in gross revenue arising from bad debts, charity care, contractual adjustments (including negotiated rates), administrative courtesy and policy discounts.

Charity Care

- Calculated at the Self Pay treatment mix percentage. This percentage is multiplied by revenues, then summed for in-center and home.

Bad Debt

- Calculated on a per treatment basis (approximately $21.07/treatment) based on three closest clinic actuals.

Expenses

- Expenses have been calculated on a per treatment basis for variable expenses from three closest clinic actuals.
- Personnel expenses are based on identified patient to staff ratios and incorporates a 10% nonproductive factor
- Depreciation is straight-line; assumes 10 years on leaseholds and 8 years on equipment.
- Rent Expense is based on 'Monthly Base Rent' featured in section 3.1 of the lease agreement.
- Note Year 1 of the lease agreement is from March 2020 to February 2021.
- Other Property Expenses includes common area maintenance ("CAM"), allocated taxes, and insurance costs. Estimated at 5% of base Rent Expense.
- Start-Up Costs includes base rent prior to operational date (July 1, 2020). Therefore, the startup period spans four months from the commencement date (March 1, 2020) to June 30, 2020.
- The anticipated commencement date for the lease is March 2020. The table below provides a breakdown of the monthly *base rent* by lease year.

Applicant's Table

Table 5. FKC Fisher's Landing Lease – Monthly Base Rent

	March 2020 to Feb. 2021	March 2021 to Feb. 2022	March 2022 to Feb. 2023	March 2023 to Feb. 2024	March 2024 to Feb. 2025
Original Lease Term	Year 1	Year 2	Year 3	Year 4	Year 5
Base Rent	$ 29,282	$ 29,779	$ 30,286	$ 30,801	$ 31,324

Source: Section 3.1 of Lease Agreement

- Based on Table 5 above, Table 6 below maps the lease year terms to the pro forma forecast period featured in Exhibit 8 of our application. For instance, Full Year 1 (2021) is based on 2 months at Mar. 2020 – Feb. 2021 rates ($29,282 /month) and 10 months at Mar. 2021 – Feb. 2022 rates ($29,779 /month) for a total of $356,358.

Applicant's Table

Table 6. FKC Fisher's Landing Pro Forma Lease Expenses

	Pre-Operations (March 2020 to June 2020)	Start July 1, 2020	Full Year 1 (2021)	Full Year 2 (2022)	Full Year 3 (2023)
# of Months	4	6	12	12	12
Base Rent	$ 117,127	$ 175,690	$ 356,358	$ 362,416	$ 368,577

- Physician compensation is based on a fee of $50,000/year, starting in year 2020. There is no annual inflator to medical director fees included in the medical director agreement.
- 'G&A' includes: administrative allocations, which in turn is comprised of the expected contribution from FKC Fisher's Landing toward billing, computer costs, regional administration, finance center & financial coordinators, sales & account management, people management, and strategic business operations. It is calculated based on a per treatment statistic, which is held constant over the forecast period.
- 'Other Med' includes: leased medical equipment, repairs & maintenance to medical equipment, water treatment supplies, patient transportation, and unbillable lab and ancillary services.
- 'Admin Expenses' includes: taxes, transportation/lodging/misc. travel – mileage, telephone, recruiting, printing, meals, internet, bank charges, office supplies, professional development, promotion, postage, and freight.
- The wage and salary figures are based on FKC Fort Vancouver Dialysis Center actuals. They are held constant over the forecast period.
- Benefits are calculated at 29% of wages and salaries.

Based on the assumptions above, FMC projected the revenue, expenses, and net income for fiscal years 2020 through 2023.[10] Fiscal year 2020 is six months of operation and years 2021 through 2023 are full years. The projections are shown in Table 4. [source: September 28, 2018, screening response, Revised Exhibit 8]

Department's Table 4
FKC Fisher's Landing
Projected Revenue and Expenses for Fiscal Years 2020 - 2023

	FY 2020	FY 2021	FY 2022	FY 2023
Net Revenue	$2,657,719	$7,300,722	$8,773,674	$9,798,337
Total Expenses	$1,843,304	$4,426,971	$5,143,708	$5,633,919
Net Profit / (Loss)	**$814,415**	**$2,873,751**	**$3,629,966**	**$4,164,418**

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 26-station dialysis center.

Public Comment
None

[10] FMC's fiscal year is January through December.

Rebuttal Comment
None

Department Evaluation
FMC proposes a new 26 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(5) evaluated under WAC 246-310-210 (need). The fail of this project focused on the under-utilization of an existing provider, rather than need for the number of stations proposed in the application. For this reason and based on a review of the assumptions used for projecting utilization of the 26 station dialysis center, the department concludes the utilization projections are reasonable.

FMC provided a detailed description of the assumptions used for projecting revenue, expenses, and net income of proposed dialysis center located in Camas. FMC also provided the following specific documents with associated costs for this project.

- Executed Purchase and Sale Agreement [Application Exhibit 10A]
- Assignment of Purchase and Sale Agreement [September 28, 2018, screening response, Exhibit 18]
- Deed Transfer, Archery Holding, LLC to Vest Capital 2, LLC [November 30, 2018, Exhibit 20]
- Executed Lease Agreement [Application, Exhibit 10C]
- Draft Medical Director Agreement [Application, Exhibit 9][11]

With the exception of the Medical Director Agreement, all agreements listed above are executed. Further, the costs identified in all of the agreements referenced above can be substantiated in the Pro Forma Revenue and Expense Statement.

Further discussed in this evaluation is the draft Medical Director Agreement. FMC provided a revised draft Medical Director Agreement in its rebuttal responses (Exhibit 3). The revised agreement is intended to replace the agreement provided in Exhibit 9 of initial application. Since the draft Medical Director Agreement provided as Exhibit 9 in the application cannot be relied upon for this project or conditioned if this project is approved, and the revised draft Medical Director Agreement provided as Exhibit 3 of FMC's rebuttal comments cannot be used for this review, FMC did not provide a valid Medical Director Agreement with reliable costs. Based on this information, the department concludes that the immediate and long-range operating costs of the new Camas facility can 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.

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

Fresenius Medical Care
FMC provided the following information under this sub-criterion. [source: Application, pp22-23]

"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. [source: November 30, 2018, screening response, Revised 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 84.6% and commercial/other is 11.3%. Medicare and Medicaid reimbursement represents 55.7% 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 26 station facility is 4,949 square feet. FMC projects the actual treatment floor space will be 2,243. FMC's project does not exceed the maximum treatment floor area square footage allowable.

Based on the above information provided in the application, the department concludes that FMC's projected costs associated with 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 two tables related to the capital expenditure for this project and information about financing. FMC also provided audited financial statements. [source: Application, pp21-22 and Exhibit 14]

Department's Table 5
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] FMC also provided a Letter of Commitment from Camas Renal Construction to demonstrate confirmation of funding for the landlord's financial obligation for the capital expenditure identified above. [source: September 28, 2018, screening response]

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, provided documentation to demonstrate its financial commitment to the project. 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 need criteria in WAC 246-310-230 for this project.

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

Fresenius Medical Care
FMC provided the following staffing table showing projected staff for the new dialysis center. [source: September 28, 2018, screening response, p16]

Department's Table 6
Projected FTEs

Staff Type	Partial Year 2020	Full Year 2021 Increase	Full Year 2022 Increase	Full Year 2023 Increase	Total FTES Year 2023
Nurse Manager	1.10	0.00	0.00	0.00	1.10
Outpatient RN	4.20	1.50	1.00	0.70	7.40
Patient Care Tech	10.50	3.70	2.60	1.60	18.40
Equipment Tech	0.70	0.20	0.20	0.10	1.20
Medical Social Worker	0.70	0.20	0.20	0.10	1.20
Dietitian	0.70	0.20	0.20	0.10	1.20
Secretary	0.70	0.20	0.20	0.10	1.20
Home RN	0.40	0.20	0.20	0.20	1.00
Total	**19.00**	**6.20**	**4.60**	**2.90**	**32.70**

FMC provided the following clarification regarding the staffing table above. [source: Application, p25 and September 28, 2018, screening response, p2]

"RCG based its initial (i.e. 2020) staffing projections on its and its parent corporation's experience in developing dialysis facilities in Washington State. As illustrated above in Table 10, there are modest

FTE staffing increases for the project in its following years of development that correspond with utilization increases provided in Table 6."

"Fresenius Kidney Care bases staffing on patient census numbers. Subsequently, when projecting staffing needs for a new clinic it would mirror our existing centers' staffing projections in Clark County. They are one and the same process. Please see our response to question #14, below, where we detail our staff-to-patient ratios and other elements of our methodology for projecting needed staff and associated staff expenses."

Focusing on recruitment and retention of necessary staff, FMC provided the following information. [source: Application, p26 and September 28, 2018, screening response, p2]

"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.

Should we experience any difficulty in recruiting, we have the ability to relocate staff from one of our existing dialysis centers in the Planning Area (FKC/PNRS Fort Vancouver, FKC/PNRS Salmon Creek, FKC/PNRS Battle Ground) or from one of our other existing dialysis centers in Washington to assist while the recruitment efforts continue.

For the above reasons, RCG believes that we will be successful in putting into place a qualified, core staff to provide and promote quality of care at the new facility.

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

FMC also clarified that its medical director is under contract and not included in the table above.

Public Comment
None

Rebuttal Comment
None

Department Evaluation
With the establishment of a 26-station dialysis center in Camas, FMC expects to need approximately 33 FTEs by the end of year three (2023). 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 not 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
lemay	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/ Contruction 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, p28 and September 28, 2018, screening response, pp2-3]

"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.

The following is a representative list of such services that would be provided off-site by other FMC resources:

Accounting	*Executive Management*	*Marketing*
Billing Group	*Finance*	*Payroll*
Clinical Services	*Health Safety & Risk Management*	*Regulatory Affairs*
Clinical Education	*Help Desk*	*Real Estate & Construction*
Compliance	*Human Resources*	*Spectra Lab Services*

FMC also provided a draft Medical Director Agreement between Pacific Northwest Renal Services, LLC (a subsidiary of FMC) and Mandeep Sahani, MD. In addition to the draft agreement, FMC provided the following statements regarding medical director services for the new Clark County center. [source: Application, Exhibit 9 and November 30, 2018, screening response, p2]

"Mandeep Sahani, MD., the physician named in the Medical Director Agreement, has committed to being present in the state of Washington for the required Medical Director duties. He has a current WA license and is prepared to work in the state of WA."

Public Comment

During the review of this project, DaVita, Inc. provided comments regarding the FMC's Medical Director Agreement. DaVita's comments are below.

DaVita, Inc.

"FMC has not provided an acceptable Medical Director Agreement

It is axiomatic that the Department cannot determine that an applicant has satisfied the structure and process of care requirements unless the applicant provides assurance that the applicant's medical director agreement will satisfy the requirements of WAC 246-310-230. In this case, Fresenius has not done so.

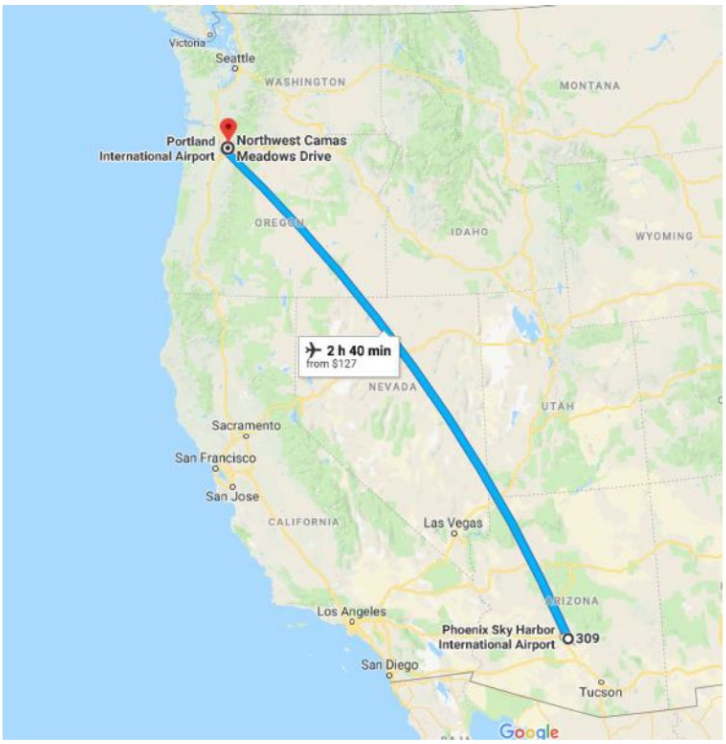
As the Department has noted in its screening questions, Fresenius proposes a medical director for its Fisher's Landing facility, Dr. Mandeep Sahini, who practices full-time as a nephrologist with Desert Kidney Associates ("DKA") in Mesa, Arizona, a suburb of Phoenix, Arizona. This is an experimental decision, to say the least. DaVita understands that Dr. Sahani will not be relocating to the Vancouver, Washington area, despite being licensed to practice in Washington. He is a senior partner in Mesa with DKA, with a long established practice and a "Top Doctor" award in Nephrology in Phoenix Magazine in 2009, per his DKA biography. This description is not the profile of a physician who relocates his life and gives up his partnership, existing medical practice, and community reputation in Arizona to assume a $50,000-per year medical directorship in Washington.

Fresenius admits as much in its response to the Department's second set of screening questions, dated November 30, 2018, where it states: "Mandeep Sahani, MD., the physician named in the Medical Director Agreement, has committed to being present in the state of Washington for the required Medical Director duties." In other words, Dr. Sahani will not be taking up residence in the State of Washington or anywhere nearby.

What are these medical director duties, exactly? Per Section 4.3.2 of the Medical Director Agreement, the medical director must "be available during all hours of operation of the Dialysis Operations for visits to and consultation regarding the Dialysis Operations and be on-call and working such additional time at or away from the Dialysis Operations as necessary to fulfill Medical Director's responsibilities under this Agreement, it being understood that a Medical Director needs to be available by phone and in person, as needed, at all times." Certainly, Dr. Sahani may be available by phone at all times. But because he is based in Phoenix, he clearly will not be "available during all hours of operation … for

visits to" the facility and "available … in person … at all times" as the MDA contemplates, given the travel time involved.

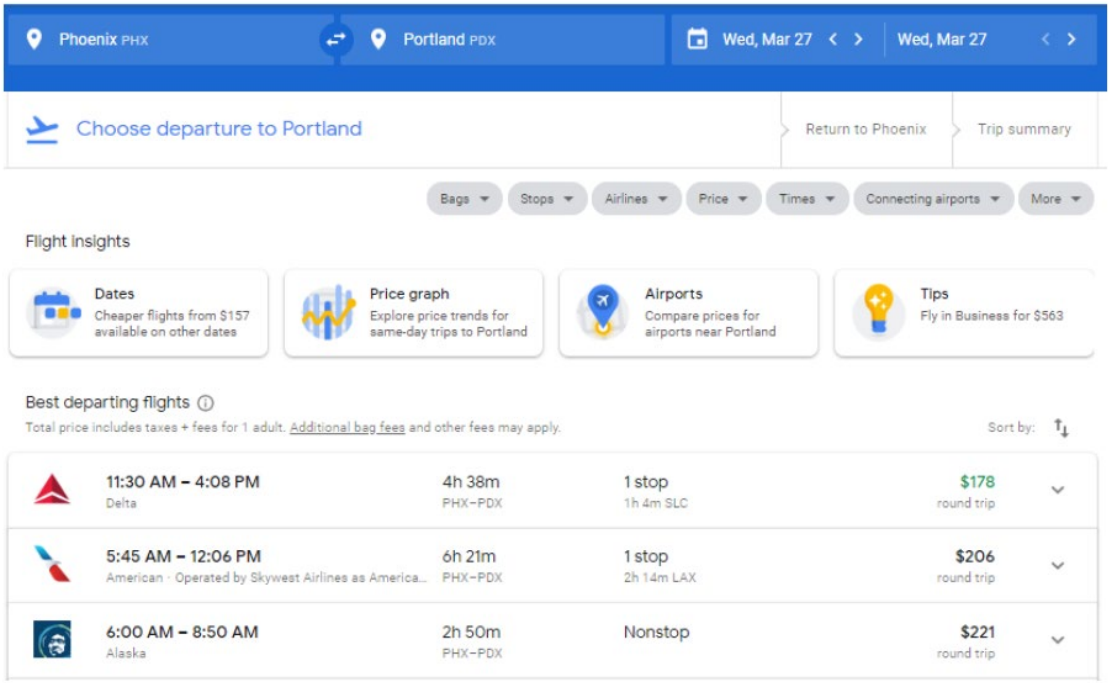
The travel involved is significant, both in terms of time and direct monetary expense. Let's first assess time. From Dr. Sahani's office (1450 S Dobson Rd. #309, Mesa, AZ 85202) to Phoenix Sky Harbor International Airport (PHX) is a drive of 12 minutes, per Google Maps as of 10:18 MST on 12/26/2018. Assuming Dr. Sahani arrives at the airport one and a half hours prior to his flight, he is now at ~1:45 minutes of travel time. A non-stop flight to Portland International Airport (PDX) takes two hours and fifty minutes on Alaska Airlines (AS 959). Upon arriving at PDX, Dr. Sahini collects his belongings, either rents a car or hails a ride-share, and heads to the FKC Fishers Landing facility. It takes Dr. Sahani approximately 30 or so minutes to collect his belongings and get to his chosen ground transportation. The drive itself takes 23 minutes, per Google Maps as of 11:24 PM PST on 12/26/2018. This means that his trip has taken an estimated total (at a time of night that by definition is during light traffic) of ~five hours and thirty minutes. Round-trip, that time is eleven hours. For reference, see the below map showing just the plane flight involved, from Google Maps.



Travel time is relevant for two reasons. First, Dr. Sahani has "committed to being present" for his medical director duties, which per the agreement provided, include "[being] available during all hours of operation of the Dialysis Operations for visits to … the Dialysis Operations." With an eleven-hour round trip to even make it to and from the facility, it is hard to believe Dr. Sahani will be able to satisfy this condition. Furthermore, FMC shows additional poor clinical judgment in its choice of medical director. The Centers for Medicare and Medicaid Services ("CMS"), which requires any dialysis facility receiving federal funding to name and contract with a Medical Director, provides guidance that a Medical Director position is considered in its annual financial report filings to require 0.25 full -time equivalent position ("FTE"), or approximately ten (10) hours per week. Given that Dr. Sahani is eleven hours from the proposed facility, a substantial portion of that time will necessarily be consumed just with travel, meaning that Dr. Sahani will potentially be able to spend less time in the Fishers Landing

facility than a comparably-skilled medical director from, say, Portland, Oregon, just across the Columbia River from the proposed facility.

From a monetary perspective, on a random day in March (3/27/2019), a flight that allows Dr. Sahani to fly in and out on the same day, avoiding hotel fees, but spending time in the facility, would be exemplified by the direct Alaska Airlines flight shown below, from 0600-0850. This flight, round-trip, runs $221. Assuming that Dr. Sahani is present in the Fishers Landing facility one day per month, this amounts to $2,652 annually, excluding any Uber, Lyft, rental car, parking, mileage, or hotel charges, or 5.3% of his proposed compensation, with no reimbursement clause.



It is also worth exploring why Dr. Sahani is considering taking the proposed medical directorship in Clark County, Washington, which will cost him thousands of dollars per year to maintain and more than a hundred hours just in travel if he visits in person once per month, and why FMC offered Dr. Sahani the position, if a comparable medical director might be found in Vancouver, WA, or perhaps Portland, OR, within a half hour or hour's drive of the facility, at most. DaVita understands that Dr. Sahani's medical group, DKA, is potentially locked out of the market for FMC medical directorships in Arizona by a larger group, Arizona Kidney Disease and Hypertension Centers ("AKDHC"), through a combination of noncompete agreements and rights of first refusal ("ROFRs") granted to AKDHC by FMC for any new FMC centers proposed in the state. It would appear that FMC is attempting to build a relationship with Dr. Sahani and his group by providing an out-of-state medical directorship option that circumvents these legal strictures.

But why should the Department treat this Certificate of Need application, and its claimed satisfaction of WAC 246-310-230, as anything more than an experiment, an experiment in remote medical directorship management that treats Washington State ESRD patients as test subjects? Let FMC test this model in other states, states which do not have WAC 246-310-230's protections. But the Department should not allow it to be tested on the Washington State ESRD patients who are legally under its protection.

Pacific Northwest Renal Services' Draft MDA Is Not Reliable

Fresenius applies as in this application as "Renal Care Group Northwest, Inc. ("RCG"). Its application uses this legal entity and its lease uses this legal entity. But Fresenius proposes a draft MDA with a different legal entity entirely. Instead, the draft MDA is between Dr. Sahani and Pacific Northwest Renal Services, L.L.C. ("PNRS"). Elsewhere in the application, Fresenius notes that RCG is responsible for the operation of PNRS facilities, but that PNRS is actually a joint venture between a second Fresenius subsidiary, Renal Care Group of the Northwest, Inc. ("RCGNW-I") and Oregon Health Sciences University ("OHSU").

On the signature page of the draft MDA that the Department has numbered "149," signatures are required from three parties: (1) Mandeep Sahani, M.D.; and the members of Pacific Northwest Renal Services, L.L.C., (2) Renal Care Group Northwest, Inc. and (3) Oregon Health & Science University. The applicant, RCG, is not a party to the MDA. Fresenius provides no explanation why the legal entity contracting with Dr. Sahani is not the applicant itself. Nor does it provide any evidence that a required signatory to the document, OHSU, has reviewed the document.

The Department requires a Medical Director Agreement ("MDA") that, if in draft form, may be conditioned for signature by time of facility opening, in keeping with CMS regulation. That is, the MDA must have been fully negotiated by the parties, and be ready for signature at time of submission to the Department. Here, the draft MDA is not between the applicant and the proposed medical director, and no evidence is provided that OHSU, whose signature is also apparently required for the MDA to take legal effect, has reviewed the MDA at all. Indeed, it seems odd that OHSU, which has the #23 ranked nephrology program in the country according to US News & World Report, would contract with a provider from Arizona, when it is located just across a bridge from the proposed facility.

Fresenius' proposed MDA appears to be contracting with the wrong entity, and it provides no evidence that all parties required to have negotiated and approved the MDA have done so. The MDA is not conditionable, and is not reliable on its face."

Rebuttal Comment

In response to DaVita's comments regarding the medical Director Agreement provided in the application, FMC provided the following rebuttal comments.

"In our draft MDA for FKC Fisher's Landing, we identified the parties, the proposed compensation and the term of the proposed MDA. This is what the Department requires for draft agreements, as DVA knows. However, DaVita criticizes our proposed MDA, stating, among other things, it is an "experimental decision." This is an unfair mis-characterization and, further, it is simply wrong. We agree that our proposed medical director, Dr. Mandeep Sahani, has a Phoenix, Arizona practice, a fact we disclosed in our Application.

The Department also had a question regarding our proposed MDA with Dr. Sahani in its August 22, 2018 screening questions (see #17). It asked the following question: "Page 1 of this agreement identifies that the medical director is a resident of Arizona. Provide the process the medical director would use to ensure necessary coverage for the dialysis services." Our response was that "Dr. Mandeep Sahani, the physician named in the Medical Director Agreement ("MDA"), has agreed to the requirements for a medical director as defined in the Fresenius MDA. Dr. Sahani is a licensed physician in Washington State. His active license number is MD6077161629." In our opinion, this response addresses the question of whether Dr. Sahani has agreed to provide all Medical Director duties and responsibilities as identified in our MDA. Very simply, Dr. Sahani has agreed to all of these duties.

Despite our screening response, DaVita assumes a number of things about this MDA and conveniently interprets this MDA to suit its arguments and recommendation for denial of our application based on the presumption that the physician cannot fulfill his duties. This presumption is wrong.

DaVita quotes the following text from Paragraph 4.3.2 of our MDA:
…the medical director must 'be available during all hours of operation of the Dialysis Operations for visits to and consultation regarding the Dialysis Operations and be on-call and working such additional time at or away from the Dialysis Operations as necessary to fulfill Medical Director's responsibilities under its Agreement, it being understood that a Medical Director need to be available by phone and in person as needed, at all times.

DaVita infers this language somehow means Dr. Sahani must be on-site for visits during all hours of the facility operations. It then goes into a lengthy discussion of the travel time and cost to fly from Phoenix to the proposed facility in Clark County. DaVita, however, ignores other provisions of the Agreement. Paragraph 4.1.2, Coverage, states: "if unavailable, the Medical Director shall arrange for coverage by a physician who meets the requirements hereunder … A Medical Director shall not be required to devote the entire working day to duties hereunder (with the exception of on-call responsibilities), but will continue the practice of medicine independently of the Company." There is nothing in paragraph 4.3.2 that requires continuous on-site presence, as DaVita suggests, but Dr. Sahani has already agreed to be available for any on-call responsibilities during the center's hours of operation, as required under Paragraph 4.3.2 in this MDA, as we stated above. Even DVA utilizes the services of out-of-state physicians for its clinics in Washington. See for example the DaVita application for a four-station facility in Longview, Cowlitz County, Washington, that was recently filed with the Department. In that CON request, it identifies its proposed medical director as Hongshi Xu, MD. However, this proposed physician has an office in Portland, Oregon. Based on an internet search, it is about one hour in travel time between Longview and Portland.

The Fresenius party to the Medical Director Agreement (MDA) is Pacific Northwest Renal Services, LLC. (PNRS). The CN applicant, Renal Care Group Northwest, Inc. (RCGN), is the majority owner of PNRS and Oregon Health Sciences University holds a minority interest in the entity. On a going forward basis, RCGN will replace PNRS as the Company under the MDA with no other changes to the agreement. Please see the MDA with RCGN attached as Exhibit 3."

As noted in its rebuttal responses, FMC also provided a revised Draft Medical Director Agreement.

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.

DaVita provided comments specific to FMC's draft Medical Director Agreement between Pacific Northwest Renal Services, LLC (a subsidiary of FMC) and Mandeep Sahani, MD.
DaVita raises two issues with the draft agreement.

1) The physician identified in the draft Medical Director Agreement is not a resident of Washington State. Rather, Dr. Sahani, practices full-time as a nephrologist with Desert Kidney Associates in Mesa, Arizona, a suburb of Phoenix, Arizona. FMC indicates that Dr. Sahani will not be relocating to Washington. DaVita questions whether the physician could perform the medical director duties as identified in the draft Medical Director Agreement. Specifically, section 4.3.2 of the agreement that states that the medical director must *"be available during all hours of operation of the Dialysis Operations for visits to and consultation regarding the Dialysis Operations and be on-call and*

working such additional time at or away from the Dialysis Operations as necessary to fulfill Medical Director's responsibilities under this Agreement, it being understood that a Medical Director needs to be available by phone and in person, as needed, at all times." DaVita also provides detailed information related to travel costs and time to and from Phoenix Arizona to demonstrate that the out-of-state physician could not meet the terms of the agreement as stated. On this topic, DaVita concludes that a medical director residing in Phoenix could not available by phone and in person, as needed, at all times as required in the agreement.

2) The draft Medical Director Agreement is not signed by the appropriate parties. Without the correct signatures, DaVita asserts that the agreement is not reliable because it provides no evidence that the appropriate parties have reviewed and agreed to the draft document. As a result, DaVita asserts that the agreement cannot be conditioned by Certificate of Need Program if the project is approved.

In response to DaVita's concerns about contracting with an out-of-state physician that will not be locating to Washington State, FMC asserts that it provided all of the information necessary in the agreement to demonstrate that the physician could meet the requirements of the Medical Director Agreement.

FMC also asserts that it responded to a screening question about using an out-of-state physician. Below is a restatement of the department's question #2 in its October 2, 2018, letter to FMC.

"Page 9 of the screening response clarifies that the proposed medical director is associated with a nephrology group known as Desert Kidney Associates. Since this nephrology group is located in Arizona and has no practice sites in Washington, provide a description of how this arrangement would work for the proposed Clark County facility."

FMC's response to the question is below. [source: November 30, 2018, screening response, p2]

"Mandeep Sahani, MD., the physician named in the Medical Director Agreement, has committed to being present in the state of Washington for the required Medical Director duties. He has a current WA license and is prepared to work in the state of WA."

It is clear from FMC's response above, that FMC did not provide a '*description of how this arrangement would work for the proposed Clark County facility'* as requested.

In addition to the draft agreement, FMC provided the following statements regarding medical director services for the new Clark County center. [source: Application, Exhibit 9 and November 30, 2018, screening response, p2]
"This Medical Director Agreement is with an individual physician, Mandeep Sahani, MD, not Desert Kidney Associates."

Medical Director Agreements, either in draft or executed form, are generally with a physician or nephrology group located in Washington State. Those that include out of state physicians or groups, are typically with the bordering states of Oregon or Idaho. For this facility, FMC has elected to enter into an agreement with a physician located in Arizona that does not intend to relocate to Washington State. For this reason, the department requested additional information from FMC on the process that would be used to ensure medical director coverage.

In FMC's screening response to the department's request to provide a description of how the arrangement would work for the proposed Clark County facility, FMC simply stated that the physician is committed to providing the medical director services. DaVita is correct in its assessment that FMC

did not provide a description of how the arrangement would work in is screening responses. FMC also does not provide a description of how the arrangement would work in rebuttal documents in response to DaVita's concerns.

While it is unusual that a dialysis provider would contract with a nephrologist or group that is further away than a border state, there is no a specific requirement for the dialysis provider to contract with a Washington State physician or group. However, FMC's lack of response on this topic is cause for concern. It is unclear why FMC would not provide a description of how this non-traditional medical director arrangement would ensure health and safety to the dialysis patient. The concerns raised by DaVita on the out of state medical director are not grounds for denial under WAC 246-310-230(2).

DaVita also questioned whether the draft agreement could be conditioned by the Certificate of Need Program if the project is approved because it will not be signed by the appropriate parties. Since it does not reference the appropriate parties, DaVita questions whether the appropriate parties have reviewed and agreed to the draft document.

In response, FMC provided a revised draft Medical Director Agreement that identifies the appropriate parties. FMC states that the only change in the revised draft is the replacement of PNRS with RCGN. FMC does not state that DaVita's comments are unfounded.

When the department receives public comment in opposition to a project, there is an expected process for rebuttal. In rebuttal, the department expects an applicant to identify where information can be found within the application or screening responses in order to refute claims made in public comment. In this case, the correct information did not exist in the draft Medical Director Agreement provided in the application and FMC provided a revised agreement in rebuttal.

This approach by FMC of providing a revised agreement in rebuttal goes beyond the scope of rebuttal. The Certificate of Need review is a public process – the department cannot rely on new information submitted in rebuttal, because the community and affected persons would not be afforded the opportunity to comment.

In summary, the draft Medical Director Agreement provided as Exhibit 9 in the application cannot be relied upon for this project or conditioned if this project is approved because it does not include the correct parties that must sign the agreement. This is demonstrated by FMC's submission of a revised draft agreement in rebuttal. The revised draft Medical Director Agreement provided as Exhibit 3 of FMC's rebuttal comments cannot be used for this review because it was submitted as improper rebuttal.

The department concludes that FMC did not provide sufficient information to demonstrate compliance with this sub-criterion. **This sub-criterion is not 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, p29]

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 2,627 facilities. Of the 2,627 facilities reporting to CMS by FMC, 601 do not have the necessary amount of data to compile a star rating. For the remaining 2,026 facilities with a star rating, the national average rating is 3.87. [source: CMS data July 2019]

CMS Star Rating for Washington State Centers
For Washington State, FMC owns, operates, or manages 23 facilities in 12 separate counties. All of the 23 centers are operational. The Washington State average rating is 3.65. [source: CMS data July 2019].

The department also focused on its own state survey data performed by the Department of Health's Office of Health Systems Oversight.

Washington State Survey Data
While all 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 Mandeep Sahani as the proposed Medical Director for the new facility. Dr. Sahani is credentialed in Washington State. Using data from the Medical Quality Assurance Commission, the department found that Dr. Sahani is compliant with state licensure and has no enforcement actions on the license. Given that FMC proposes a new facility, 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, pp28-29]

"The establishment of a new facility in the Clark County 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.

Fresenius currently has three existing facilities (FKC Fort Vancouver, FKC Salmon Creek, and FKC Battle Ground) in the Planning Area and is a 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. FKC Fisher's Landing will leverage these existing relationships that will allow it to quickly integrate into the healthcare system and greater community.

Further, there is tremendous need in the planning area that requires a significant 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 continuing the strong pattern and experience of collaboration that Fresenius has adopted in its existing operations at FKC Fort Vancouver, FKC Salmon Creek, and FKC Battle Ground.

As RCG has already done in the Planning Area and other communities in which we operate, prior to opening, FKC Fisher's Landing will establish relationships with area transit providers, nursing homes, and local hospitals.

FKC Fisher's Landing will also establish a transfer agreement with one or more local hospitals. See Exhibit 15 for a draft transfer agreement. If the requested project is approved, Fresenius will submit an executed version of this contract, consistent with the draft, prior to operating the facility."

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

Public Comment

None

Rebuttal Comment
None

Department Evaluation
FMC has been a provider of dialysis services in Washington State for many years. FMC also has a history of establishing relationships with existing healthcare networks in 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 where additional dialysis stations are needed. If approved, the project would 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 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 and 246-310-230. A review of step two is unnecessary for this project. However, Puget Sound Kidney Centers asserts in public comment that FMC had another alternative that should have been considered. PSKC states that the alternative is superior to submission of this application because of the low utilization of

FMC's Battle Ground facility. PSKC's specific comments are below. [source: PSKC public comments, pdf3-4]

Puget Sound Kidney Centers

"WAC 246-310-240(1) requires that a CN applicant demonstrate that superior alternatives, in terms of cost, efficiency or effectiveness are not available or practicable. If the Program is unable to determine that no superior alternatives exist, the proposed project fails for lack of cost containment.
The options identified by FMC in its application (p. 32) include:

1) *Establish a new 26-station facility (the project);*
2) *Do nothing;*
3) *Add 15-stations across the three existing facilities (Salmon Creek, Fort Vancouver and Battle Ground); or*
4) *Establish a 24 station facility (the original application).*

The option FMC failed to consider was a partial relocation of the under-performing facility (i.e., PNRS Battle Ground) to locate stations closer to where patients reside. This option would have redistributed stations, improved access and allowed for a competitive review process in Cycle 1 Non Special Circumstances of 2019. The relocation of some number of stations to either Fort Vancouver or Salmon Creek from Battle Ground was practicable and feasible: FMC's own alternative (Option 3 above) clearly suggests that Fort Vancouver and Salmon Creek had available space to add a number of stations. (FMC's option 3 does not describe how the 15 stations would be allocated across the facilities.) Table 1 provides an example of the effect that relocating four stations from Battle Ground to either Fort Vancouver or Salmon Creek would have on the utilization of all three facilities.

Puget Sound Kidney Centers Demonstrative Table

Table 1
Clark County Dialysis Planning Area Providers
Stations, Patients and Patients per Stations as of December 31, 2017

Facility	Number of Stations	12/31/2017 Number of Patients Per Quarterly In-Center Data	12/31/2017 Patients/ Station at current station capacity	Reduce Battle Ground by 4 stations and add 4 to either Salmon Creek or Fort Vancouver
PNRS Ft. Vancouver	24	139	5.79	At 28 stations, occupancy reduced to 4.96
PNRS Salmon Creek	16	91	5.69	At 20 stations, occupancy reduced to 4.55
PNRS Battle Ground	24	97	4.04	At 20 stations, occupancy increased to 4.85

Source: Northwest Renal Network Modality Reports, 12/31/2017

Relocating four (4) stations from FMC's under-performing facility at Battle Ground to its other facilities would thus have brought Battle Ground into the target utilization range. Adding the stations to FMC's other facilities, in particular the highly-utilized Ft. Vancouver location, would be an efficient manner of addressing patient need. FMC's failure to explore that superior alternative means that its application does not meet the requirements of WAC 246-310-240(1)."

FMC's rebuttal comments on this topic is below.

Rebuttal Comment

"PSKC stated the FKC Fisher's Landing CON fails to meet Cost Containment criterion (1), Superior Alternatives. It argues our application should be denied because we failed to consider a partial relocation, but no additional stations, for an under-performing facility (FKC Battle Ground) to locate patients closer to where patients reside.

The PSKC Public Comment paper stated: "This option would have redistributed stations, improved access and allowed for competitive review process in Cycle 1 Non Special Circumstances of 2019." As we stated above, initially PSKC also applied for a new dialysis facility in this Planning Area, but later withdrew its application. We think an underlying intent by PSKC to resubmit another request is driving its Public Comments regarding Cost Containment, since we addressed this Superior Alternatives criterion in our application and screening responses.

PSKC notes that in our application we evaluated four options, including:

- *Option One: Establish new 26-station facility- The Project*
- *Option Two: Postponing the request- Do Nothing*
- *Option Three: Add 15-stations spread across the existing Salmon Creek, Fort Vancouver, and Battle Ground facilities*

It fails to mention the extensive analysis we provided and the rationale for "doing something," i.e ., adding stations to the planning area.

We also added another option in response to a screening question from the Department:

- *Develop two new facilities to address total net need in the Clark County ESRD Planning Area.*

We did not include the PSKC preferred option of relocation—but no new stations—since there was demonstrated need for 26 stations in the planning area. The PSKC option of a partial relocation would do nothing to meet that large unmet need for additional dialysis capacity in this Planning Area. In this regard, PSKC's recommendation would have been the same as the "Do Nothing" option, which we evaluated and rejected, since it does not address need in the Planning Area to improve access, quality and continuity of care (avoid fragmentation). We addressed these disadvantages of this "Do Nothing" option extensively."

Step Three

Because FMC's project is the only application submitted for Clark County in this review cycle, no superiority analysis will be completed under this step.

Department Evaluation

FMC provided a comprehensive discussion of alternatives considered, including not submitting this application. However, with the low utilization of FMC's Battle Ground facility, the department concludes that FMC's better alternative may be to relocate some existing stations to Camas to allow for improved patient access to stations. Further, in the need section of this evaluation, FMC's project was denied because DaVita's Battle Ground facility was not operating at the required standard and it had not been operational for three years prior to submission of this application. **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 26 dialysis stations in the planning area. However, this project was denied under WAC 246-310-210 and WAC 246-310-230. **As a result, this sub-criterion is not met.**

APPENDIX A

Washington State Department of Health

2018
Clark County
ESRD Need Projection Methodology-Revised

	Planning Area	6 Year Utilization Data - Resident Incenter Patients					
	Clark	2012	2013	2014	2015	2016	2017
	Clark County	356	359	378	374	412	437
	TOTALS	356	359	378	374	412	437
246-310-812(4)(a)	**Rate of Change**		**0.84%**	**5.29%**	**-1.06%**	**10.16%**	**6.07%**
	6% Growth or Greater?		**FALSE**	**FALSE**	**FALSE**	**TRUE**	**TRUE**
	Regression Method:	**Linear**					
246-310-812(4)(c)			Year 1	Year 2	Year 3	Year 4	**Year 5**
			2018	2019	2020	2021	**2022**
Projected Resident Incenter Patients	from 246-310-812(4)(b)		449.00	468.00	487.00	506.00	**525.00**
Station Need for Patients	**Divide Resident Incenter by 4.8**		93.54	97.50	101.46	105.42	**109.38**
	Rounded to next whole number		**94**	**98**	**102**	**106**	**110**
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			94	98	102	106	**110**
Net Station Need			-10	-14	-18	-22	**-26**

Negative number indicates need for stations

Planning Area Facilities

Name of Center	# of Stations
DaVita Vancouver	12
PNRS Ft. Vancouver	24
PNRS Salmon Creek	16
DaVita Battle Ground	10
PNRS Clark County DC*	22
Total	84

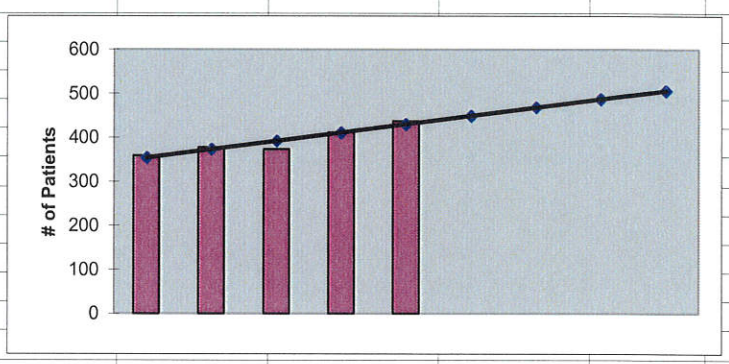
Source: Northwest Renal Network data 2012-2017
Most recent year-end data: 2017 posted 02/07/2018

PNRS Clark County Dialysis Clinic (Battle Ground) # of stations reduced from 24 to 22 based on 03/12/13 Dispute Resolution Agreement

Washington State Department of Health

2018
Clark County
ESRD Need Projection Methodology-Revised

x	y	Linear
2013	359	**354**
2014	378	**373**
2015	374	**392**
2016	412	**411**
2017	437	**430**
2018		**449.00**
2019		**468.00**
2020		**487.00**
2021		**506.00**
2022		**525.00**



SUMMARY OUTPUT

Regression Statistics	
Multiple R	0.945988058
R Square	0.894893406
Adjusted R Square	0.859857875
Standard Error	11.88836967
Observations	5

ANOVA

	df	*SS*	*MS*	*F*	*Significance F*
Regression	1	3610	3610	25.54245283	0.014945772
Residual	3	424	141.3333333		
Total	4	4034			

	Coefficients	*Standard Error*	*t Stat*	*P-value*	*Lower 95%*	*Upper 95%*	*ower 95.0%*	*Upper 95.0%*
Intercept	-37893	7575.258517	-5.002205524	0.015373841	-62000.85348	-13785.1465	-62000.9	-13785.1
X Variable 1	19	3.759432581	5.053954178	0.014945772	7.035807672	30.96419233	7.035808	30.96419