



STATE OF WASHINGTON
DEPARTMENT OF HEALTH
Olympia, Washington 98504

December 28, 2017

CERTIFIED MAIL # 7016 3010 0001 0575 0846

Ann Sullivan, Director of Operations
Fresenius Medical Care
702 South Park Drive
Puyallup, Washington 98373

RE: Certificate of Need Application #17-40

Dear Ms. Sullivan:

We have completed review of the Certificate of Need application submitted by Fresenius Medical Care proposing to add eight dialysis stations to FMC Aberdeen Dialysis Center located in Grays Harbor County. Enclosed is a written evaluation of the application.

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

Project Description:

This certificate approves the addition of 8 dialysis stations to the 16-station FMC Aberdeen Dialysis Center, for a facility total of 24 dialysis stations. At completion of the station addition, Fresenius Medical Care is approved to certify and operate 24 stations at FMC Aberdeen Dialysis Center. Services provided at FMC Aberdeen Dialysis Center include in-center hemodialysis, home hemodialysis and home peritoneal dialysis training and support for dialysis patients, a permanent bed station, an isolation station, and a shift beginning after 5:00 p.m. A breakdown of all stations at project completion is shown below:

Private Isolation Station	1
Permanent Bed Station	1
Other In-Center Stations	22
Total In-Center Stations	24

Conditions:

1. Approval of the project description as stated above. Fresenius Medical Care further agrees that any change to the project as described in the project description is a new project that requires a new Certificate of Need.

2. Prior to commencement of this project, Fresenius Medical Care must obtain approval for the relocation of FMC Aberdeen Dialysis Center under Washington Administrative Code 246-310-289(3).
3. Prior to providing services, Fresenius Medical Care will provide to the department for review and approval a copy of a signed, executed transfer agreement consistent with the agreement provided in the application.
4. Fresenius Medical Care shall finance this project using existing capital reserves, as described in the application.

Approved Costs:

The approved capital expenditure for this 8-station addition is \$241,947. This amount represents the total cost of \$423,347, minus the landlord's costs of \$181,400.

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

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

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

Mailing Address:

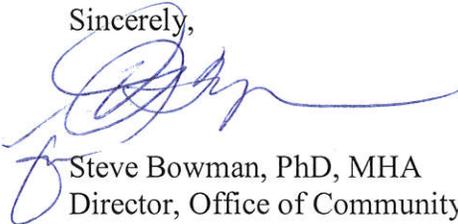
Department of Health
Certificate of Need Program
Mail Stop 47852
Olympia, WA 98504-7852

Physical Address:

Department of Health
Certificate of Need Program
111 Israel Road SE
Tumwater, WA 98501

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

Sincerely,



Steve Bowman, PhD, MHA
Director, Office of Community Health Systems

Enclosure

EXECUTIVE SUMMARY

EVALUATION DATED DECEMBER 28, 2017, FOR THREE CERTIFICATE OF NEED APPLICATIONS, EACH PROPOSING TO ADD DIALYSIS STATION CAPACITY TO GRAYS HARBOR COUNTY

BRIEF APPLICANT AND PROJECT DESCRIPTIONS

Fresenius Medical Care

Renal Care Group Northwest (RCGNW) is one of three entities owned by Renal Care Group, Inc. (RCG). RCGNW 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. FMC, through its subsidiaries, owns and operates 18 dialysis centers in Washington State.¹

Currently, FMC operates its Aberdeen Dialysis Center at 2012 Industrial Parkway in Aberdeen [98520], within Grays Harbor County. This application proposes to add 8 stations to the center after it is relocated. FMC intends to relocate the existing 16-station center to a new site in Grays Harbor County. If this project is approved, FMC Aberdeen Dialysis Center will be operating a 24-station center. The new site has not yet been assigned an address. FMC provided the following description of the new site in the county. [source: Application, p14]

“Parcel #: 02730000600, 02730000700; 02730000800; Lots 6, 7 and 8 of the Plat of Skyview, as per plat recorded in Volume 10 of Plats, pages 39 and 40, records of Grays Harbor County; Situated in the County of Grays Harbor, State of Washington.”

[source: Application, Exhibit 10]

The estimated capital expenditure associated with the 8-station addition is \$423,347; FMC’s portion of the cost is \$241,947. These costs include FMC’s portion of the building construction, fixed and moveable equipment, and architect / engineering fees. [source: Application, p14, & p27]

If approved, FMC anticipates the 24 station facility would be operational at the new site within one year of approval. Under this timeline, 2019 would be full calendar year one and 2021 would be calendar year three. [source: Application p17]

Kalpine Dialysis, LLC

Kalpine Dialysis, LLC (Kalpine) is a for profit service corporation that was registered with the Washington State Secretary of State on June 1, 2015. Kalpine is made up of three members with the following percentages of ownership. [source: Application, p4]

Name	Percentage Owned
DaVita (Total Renal Care, Inc.	79%
Vo Nguyen, MD	5%
Seth Thaler, MD	16%

¹ In the application, FMC refers to itself in a variety of ways: FMC, Fresenius Kidney Care or FKC, RCGNW, RCG, IN-RCG. Throughout this evaluation, the department will refer to the applicant as Fresenius Medical Care or FMC.

Kalpine proposes to establish an 8-station dialysis center in Elma, within Grays Harbor County. The dialysis center would be located at 351 East Main Street in Elma [98541]. Kalpine's Elma Dialysis Center would provide in-center hemodialysis, backup dialysis service, home hemodialysis and home peritoneal dialysis training, a dedicated isolation station, a permanent bed station, and shifts beginning after 5 pm. [source: Application, pp11-12]

The capital expenditure associated with establishing an 8-station center is \$2,474,094 and all costs would be paid by Kalpine. [source: Application, p10 and Appendix 7]

If this project is approved, Kalpine anticipates the 8-station center would be operational by January 1, 2021. Under this timeline, 2021 would be the facility's first full calendar year of operation and 2023 would be year three. [source: Application, p14]

DaVita Healthcare Partners, Inc.

In late 2012, DaVita, Inc. a for-profit end stage renal care provider was acquired by HealthCare Partners Holding, Inc. To reflect the combination of the two companies, DaVita, Inc. changed its name to DaVita HealthCare Partners Inc. Throughout this evaluation, DaVita HealthCare Partners Inc. will be referenced as 'DaVita.' [source: CN historical files]

DaVita's application proposes to establish an 8-station dialysis center in Elma, within Grays Harbor County. The dialysis center would be located at 351 East Main Street in Elma [98541]. DaVita's Elma Dialysis Center would provide in-center hemodialysis, backup dialysis service, home hemodialysis and home peritoneal dialysis training, a dedicated isolation station, a permanent bed station, and shifts beginning after 5 pm. [source: Application, pp10-11]

The capital expenditure associated with establishing an 8-station center is \$2,474,094 and all costs would be paid by DaVita. [source: Application, p9 and Appendix 7]

If this project is approved, DaVita anticipates the 8-station center would be operational by January 1, 2021. Under this timeline, 2021 would be the facility's first full calendar year of operation and 2023 would be year three. [source: Application, p13]

APPLICABILITY OF CERTIFICATE OF NEED LAW

These three projects are subject to Certificate of Need (CN) review because they propose one of the following:

- The construction, development, or other establishment of a healthcare 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); or
- An increase in the number of dialysis stations in a kidney disease center under provisions of RCW 70.38.105(4)(h) and WAC 246-310-020(1)(e).

CONCLUSIONS

Fresenius Medical Care

For the reasons stated in this evaluation, the application submitted by Fresenius Medical Care proposing to add eight dialysis stations to FMC Aberdeen Dialysis Center in Grays Harbor County is consistent with applicable criteria of the Certificate of Need Program. The approval requires agreement to the project description, conditions, and approved capital expenditure identified below.

Project Description:

This certificate approves the addition of 8 dialysis stations to the 16-station FMC Aberdeen Dialysis Center, for a facility total of 24 dialysis stations. At completion of the station addition, Fresenius Medical Care is approved to certify and operate 24 stations at FMC Aberdeen Dialysis Center. Services provided at FMC Aberdeen Dialysis Center include in-center hemodialysis, home hemodialysis and home peritoneal dialysis training and support for dialysis patients, a permanent bed station, an isolation station, and a shift beginning after 5:00 p.m. A breakdown of all stations at project completion is shown below:

Private Isolation Station	1
Permanent Bed Station	1
Other In-Center Stations	22
Total In-Center Stations	24

Conditions:

1. Approval of the project description as stated above. Fresenius Medical Care further agrees that any change to the project as described in the project description is a new project that requires a new Certificate of Need.
2. Prior to commencement of this project, Fresenius Medical Care must obtain approval for the relocation of FMC Aberdeen Dialysis Center under Washington Administrative Code 246-310-289(3).
3. Prior to providing services, Fresenius Medical Care will provide to the department for review and approval a copy of a signed, executed transfer agreement consistent with the agreement provided in the application.
4. Fresenius Medical Care shall finance this project using existing capital reserves, as described in the application.

Approved Costs:

The approved capital expenditure for this 8-station addition is \$241,947. This amount represents the total cost of \$423,347, minus the landlord's costs of \$181,400.

Kalpine Dialysis, LLC

For the reasons stated in this evaluation, the application submitted by Kalpine Dialysis, LLC proposing to establish an eight station dialysis facility in Elma, within the Grays Harbor County is not consistent with applicable criteria of the Certificate of Need Program.

DaVita HealthCare Partners, Inc.

For the reasons stated in this evaluation, the application submitted by DaVita HealthCare Partners, Inc. proposing to establish an eight station dialysis facility in Elma, within the Grays Harbor County is not consistent with applicable criteria of the Certificate of Need Program.

EVALUATION DATED DECEMBER 28, 2017, FOR THREE CERTIFICATE OF NEED APPLICATIONS, EACH PROPOSING TO ADD DIALYSIS STATION CAPACITY TO GRAYS HARBOR COUNTY

APPLICANT DESCRIPTION

Fresenius Medical Care

Renal Care Group Northwest (RCGNW) is one of three entities owned by Renal Care Group, Inc. (RCG). RCGNW 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, this evaluation shall refer to the applicant and all subsidiaries as Fresenius, or FMC. FMC operates outpatient dialysis centers in 48 states, the District of Columbia, and Puerto Rico through these subsidiaries. In Washington State, FMC owns, operates, or manages 23 kidney dialysis facilities. These facilities are listed below. [source: Application pp8-11 and CN historical files]

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 Gig Harbor

Fresenius Kidney Care Puyallup

Fresenius Kidney Care East Tacoma

Fresenius Kidney Care South Tacoma

Fresenius Kidney Care Mount Rainier

Spokane County

FMC Spokane Kidney Center

FMC Northpointe Dialysis 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

Kalpine Dialysis, LLC

Kalpine is a for profit service corporation that was registered with the Washington State Secretary of State on June 1, 2015. Kalpine is made up of three members with the following percentages of ownership. [source: Application, p4]

Name	Percentage Owned
DaVita (Total Renal Care, Inc.	79%
Vo Nguyen, MD	5%
Seth Thaler, MD	16%

Kalpine does not own or operate any healthcare facilities in Washington State or out-of-state. DaVita operates or provides administrative services in approximately 2,303 dialysis facilities located throughout the United States. Since DaVita’s ownership structure is identified below, it will not be repeated here.

The two owning nephrologist are two of five governing members of a nephrology group known as “Memorial Nephrology Associates, PLLC.” The nephrology group is located at 3525 Ensign Road Northeast in Olympia [98506]. The five governing members are listed below. [source: Washington State Secretary of State website]

Name
Julia Anuras
Lana Bur
Christopher Burtner
Vo Nguyen, MD
Seth Thaler, MD

Even though Drs. Nguyen and Thaler do not hold any ownership in any dialysis facilities, Dr. Thaler serves as the medical director for an FMC dialysis center located in Thurston County and Providence St. Peter Hospital’s acute dialysis program. Dr. Nguyen serves as medical director for FMC’s Aberdeen Dialysis Center, which is the FMC facility under concurrent review in this cycle. [source: Application, p5]

DaVita Healthcare Partners, Inc.

DaVita, Inc. is a for-profit end stage renal care provider that was acquired by HealthCare Partners Holding, Inc. in late 2012. To reflect the combination of the two companies, DaVita, Inc. changed its name to DaVita HealthCare Partners Inc. Throughout this evaluation, DaVita HealthCare Partners Inc. will be referenced as ‘DaVita.’

Currently DaVita operates or provides administrative services in approximately 2,303 dialysis facilities located in the United States. [source: Applications, p6] In Washington State, DaVita owns or operates 42² kidney dialysis facilities in 18 separate counties. Listed on the following page are the names of the facilities owned or operated by DaVita in Washington State. [source: CN historical files and Application, p7]

² As of the writing of this evaluation, two of DaVita’s CN approved dialysis facilities are not yet state surveyed and operational. The two facilities are: Lynnwood Dialysis Center [CN #1588 issued on October 21, 2016] and Wapato Dialysis Center [CN #1611 issued on August 18, 2017].

Benton

Chinook Dialysis Center
 Kennewick Dialysis Center

Clark

Vancouver Dialysis Center
 Battle Ground Dialysis Center

Chelan

Wenatchee Valley Dialysis Center

Douglas

East Wenatchee Dialysis Center

Franklin

Mid-Columbia Kidney Center

Island

Whidbey Island Dialysis Center

King

Bellevue Dialysis Center
 Federal Way Dialysis Center
 Kent Dialysis Center
 Olympic View Dialysis Center (management only)
 Renton Dialysis Center
 Redondo Heights Dialysis Center
 Westwood Dialysis Center

Kittitas

Ellensburg Dialysis Center

Lewis

Centralia Dialysis Center

Mason

Belfair Dialysis Center

Pacific

Seaview Dialysis Center

Pierce

Graham Dialysis Center
 Lakewood Community Dialysis Center
 Parkland Dialysis Center
 Puyallup Community Dialysis Center
 Rainier View Dialysis Center
 Redondo Heights
 Tacoma Dialysis Center

Skagit

Cascade Dialysis Center

Snohomish

Everett Dialysis Center
 Lynnwood Dialysis Center
 Mill Creek Dialysis Center
 Pilchuck Dialysis Center

Spokane

Downtown Spokane Renal Center
 North Spokane Renal Center
 Spokane Valley Renal Center

Stevens

Echo Valley Dialysis Center

Thurston

Olympia Dialysis Center
 Tumwater Dialysis Center

Yakima

Mt. Adams Dialysis Center
 Union Gap Dialysis Center
 Wapato Dialysis Center
 Yakima Dialysis Center
 Zillah Dialysis Center

PROJECT DESCRIPTIONS**Fresenius Medical Care**

Currently, FMC operates its Aberdeen Dialysis Center at 2012 Industrial Parkway in Aberdeen [98520], within Grays Harbor County. This application proposes to add 8 stations to the center after it is relocated. FMC intends to relocate the existing 16-station center to a new site in Grays Harbor County. If this project is approved, FMC Aberdeen Dialysis Center will be operating a 24-station center. The new site

has not yet been assigned an address. FMC provided the following description of the new site in the county. [source: Application, p14]

“Parcel #: 02730000600, 02730000700; 02730000800; Lots 6, 7 and 8 of the Plat of Skyview, as per plat recorded in Volume 10 of Plats, pages 39 and 40, records of Grays Harbor County; Situated in the County of Grays Harbor, State of Washington.”

[source: Application, Exhibit 10]

Services currently offered at FMC Aberdeen Dialysis Center include in-center hemodialysis, home hemodialysis and home peritoneal dialysis training, a dedicated isolation station, and a permanent bed station. FMC Aberdeen Dialysis Center also offers a shift beginning after 5:00 pm. [source: Application, p8 and p114; and July 31, 2017, screening response, p2]

The total project costs are broken down by relocation and station addition. The costs are also broken down by either FMC or Landlord responsibility. The table below shows a summary of the total costs.

Cost Breakdown	FMC Cost	Landlord Cost	Total	% of Total
Build-out Relocation of 16 stations	\$1,931,803	\$4,196,793	\$6,128,596	93.5%
Expand 8 stations	\$241,947	\$181,400	\$423,347	6.5%
Total Estimated Capital Cost	\$2,173,750	\$4,378,193	\$6,551,943	100.00%

As shown in the breakdown above, the landlord has agreed to pay \$181,400—or 43% of the total costs for the project. Included in FMC’s costs are its portion of the building construction, fixed and moveable equipment, and architect / engineering fees. [source: Application, p14, & p27]

If approved, FMC anticipates the 24 station facility would be operational at the new site within one year of approval. Under this timeline, 2019 would be full calendar year one and 2021 would be calendar year three. [source: Application p17]

Kalpine Dialysis, LLC

Kalpine proposes to establish an 8-station dialysis center in Elma, within Grays Harbor County. The dialysis center would be located at 351 East Main Street in Elma [98541]. Kalpine’s Elma Dialysis Center would provide in-center hemodialysis, backup dialysis service, home hemodialysis and home peritoneal dialysis training, a dedicated isolation station, a permanent bed station, and shifts beginning after 5 pm. [source: Application, pp11-12]

The capital expenditure associated with establishing an 8-station center is \$2,474,094. Of that amount, 67% is for construction and leasehold improvements; 25% is for fixed and moveable equipment, and the remaining 8% is for architect and engineering fees and costs associated with utility hook-ups. All costs would be paid by Kalpine. [source: Application, p10 and Appendix 7 and screening response, p8]

If this project is approved, Kalpine anticipates the 8-station center would be operational by January 1, 2021. Under this timeline, 2021 would be the facility’s first full calendar year of operation and 2023 would be year three. [source: Application, p14]

DaVita Healthcare Partners, Inc.

DaVita proposes to establish an 8-station dialysis center in Elma, within Grays Harbor County. The dialysis center would be located at 351 East Main Street in Elma [98541 DaVita's Elma Dialysis Center would provide in-center hemodialysis, backup dialysis service, home hemodialysis and home peritoneal dialysis training, a dedicated isolation station, a permanent bed station, and shifts beginning after 5 pm. [source: Application, pp10-11]

The capital expenditure associated with establishing an 8-station center is \$2,474,094. Of that amount, 67% is for construction and leasehold improvements; 25% is for fixed and moveable equipment, and the remaining 8% is for architect and engineering fees and costs associated with utility hook-ups. All costs would be paid by DaVita. [source: Application, pp9-10 and Appendix 7 and screening response, p4]

If this project is approved, DaVita anticipates the 8-station center would be operational by January 1, 2021. Under this timeline, 2021 would be the facility's first full calendar year of operation and 2023 would be year three. [source: Application, p13]

FMC Public Comment

During the review of these three projects, FMC submitted public comment focusing on the similarities of the Kalpine and DaVita applications. FMC's public comment on this topic is below. [source: FMC public comment on both Kalpine and DaVita projects, Executive Summary]

“DaVita ("DVA") submitted two certificate of need ("CON") applications for eight-station dialysis centers in Elma Washington, within the Grays Harbor ESRD Planning Area, in essence competing with itself. One application, by Kalpine Dialysis, LLC, ("Kalpine") is a proposed joint venture between DVA and two nephrologists, and the other, is a CON application submitted by DVA, alone. Curiously, the two DVA applications are virtually identical except for their ownership....”

Kalpine or DaVita Rebuttal Comment

No rebuttal comments on this topic were provided by Kalpine or DaVita.

Department Evaluation

It is clear from reading each of the applications submitted by Kalpine and DaVita that they are exactly the same. Similarities include, but are not limited to, the site, medical director, projected utilization, and costs to establish the dialysis center. Focusing on this topic, the Kalpine application provides the following statements. [source: Application, p3]

“Kalpine Dialysis LLC will have three members: The LLC Manager, Total Renal Care, Inc., a wholly owned subsidiary of DaVita Inc. (hereafter “DaVita”); Seth Thaler, MD; and Vo Nguyen, MD (the “Members”). Although all Members fully intend to move forward as described in this application, we note at the outset that the LLC has been structured in such a way that the project can move forward should the physician members withdraw from the LLC, fail to make capital contributions, or any other reason. DaVita is committed to establishing this new facility itself should that become necessary (i.e., as the sole member of Kalpine Dialysis LLC, should the physician members withdraw). This information can be referenced in Appendix 22.” [emphasis added]

Current CN rules and regulations do not prevent an applicant from submitting more than one application in a dialysis review cycle. The current rules and regulations also do not prevent an applicant from

requesting all of the projected station need in each application. DaVita has taken this approach in past applications. Further, DaVita does not dispute FMC's assertion that it essentially submitted two Certificate of Need applications for an eight-station dialysis center in Elma. The department will continue to review all three applications concurrently.

What is unusual, however, is for an applicant to submit two applications that identify the same site. For this reason, if the department concludes in this concurrent review that the eight station need should be divided between two providers at four stations each, the approval cannot be awarded to both Kalpine and DaVita. The rationale for this approach is that neither Kalpine nor DaVita provided any documentation in their respective applications that would demonstrate that the department's Investigations and Inspections Office (IIO) would recommend CMS certification for two separate dialysis centers at the same site.

Kalpine and DaVita Public Comment

Also during this review, Kalpine and DaVita submitted public comment focusing on the approach taken by FMC for its facility relocation and station addition. Kalpine and DaVita's public comment on this topic is below. [source: Kalpine public comment, p1; DaVita public comment, p1]

"The Department does not accept "single applications containing two or more reviewable projects." Department of Health Memorandum, May 17, 2011 (attached hereto as an Appendix).

Fresenius's proposal to relocate sixteen stations within the Grays Harbor planning area is a CON-reviewable project. A full-facility replacement within a planning area is exempt from CON review only if "no new stations are added to the replacement facility[.]" WAC 246-310-289(3)(b). Because Fresenius would add stations to the replacement facility, its proposed full-facility relocation constitutes the establishment of a new health care facility, a CON reviewable project. See WAC 246-310-020(1)(a) ("construction, development, or other establishment of a new health care facility" is subject to CON review); WAC 246-310-010(26) ("health care facility" includes "kidney disease treatment centers").

Fresenius's proposal to add six stations to its facility is a separate CON-reviewable project. See WAC 246-310-020(1)(e) ("[a]ny increase in the number of dialysis stations in a kidney disease center" is subject to CON review).

Therefore, Fresenius has included two reviewable projects in a single application: (1) establishing a new healthcare facility and (2) increasing the number of dialysis stations in a kidney dialysis facility. This is even reflected in the language that Fresenius itself uses in its application. (Application, p. 14 ("both actions are included in this application"). The Department should deny Fresenius's application consistent with the policy set forth in its May 17, 2011 memorandum."

FMC Rebuttal Comment

FMC provided the following rebuttal comments. [source: FMC rebuttal comment, pp6-7]

"The [Kalpine and DaVita] assertion is incorrect regarding FMC Aberdeen's current request. A review of the Department's evaluation history in years following the memorandum release, most notably a 2012 evaluation which will be described below, does not support [Kalpine and DaVita's] allegations. Further, prior to submitting our current application, Fresenius sought guidance from Certificate of Need program staff who specifically recommended to do what was done. As referenced above, a prior 2012 Department decision examined exactly the issue in question.

The Department's evaluation states DaVita submitted an application in August 2011 to "both relocate its existing dialysis center in Island County and add 3 stations to the new facility." Although the Department ultimately denied the expansion, it was due to the fact that the DaVita project was determined to be the inferior proposal, NOT due to the relocation and expansion combination.

Therefore, the FMC Aberdeen request is consistent with the Department's evaluative history and does not constitute the violations levied against it by [Kalpine and DaVita]; thus, allowing it to be subject to full Certificate of Need review.

Fresenius relocation is driven by flood plain issues, not new stations. [Kalpine and DaVita] state[s] in its public comment: On page 32, Fresenius admits that "the expansion necessitates relocation[.]" In other words, Fresenius cannot add eight new stations at its existing location. The only way Fresenius can add eight stations in this planning area is to spend \$6,551,943 to build a new facility.

What [Kalpine and DaVita] ignore[s] is that earlier in our application on page 25 we mention that "The project's requested expansion coincides with a site re-location, necessitated by need to move from a flood plain area." which we reiterate in our first screening response. Therefore, the capital expenditures associated with relocation should not attributed to the expansion, as they will be incurred regardless of whether the additional stations are approved."

Department Evaluation

For clarification, FMC's application proposes to add eight stations, not six as asserted by Kalpine and DaVita in their public comment.

Kalpine and DaVita assert that FMC's application includes two projects: a sixteen station relocation and an eight station addition. This is incorrect. WAC 246-310-289(3) allows an entire dialysis center to relocate within the same planning area, provided that:

- (a) The existing facility ceases operation;*
- (b) No new stations are added to the replacement facility;*
- (c) There is no break in service between the closure of the existing facility and the operation of the replacement facility;*
- (d) The existing facility has been in operation for at least five years at its present location; and*
- (e) The existing facility has not been purchased, sold or leased within the past five years.*

The process to obtain approval for a relocation under WAC 246-310-289(3) is submission of an exemption application with the appropriate review fee. FMC's Aberdeen Dialysis Center meets (a) – (e) above and would have qualified for the exemption had it been submitted. FMC's project currently under review is the 8-station addition and all costs and equipment related to the station addition. The costs for the relocation are not evaluated again in this project.

FMC states that it is taking the same approach that DaVita took in its Island County project when DaVita requested relocation of its dialysis center and a station addition at the new site. The difference between the two projects is subtle, but important. DaVita had not been operating its Island County facility for a least five years at the present location. DaVita did not qualify for the exemption under WAC 246-310-289(3) and, therefore, had to submit its relocation project as a full CN application, along with its station addition request.

In summary, FMC's project is not two projects in one. If the station addition project is approved, FMC must still submit an exemption application to relocate the 16 station facility. The costs for FMC's

relocation project will not be evaluated in this station addition application, because they were already evaluated and approved when FMC was issued CN #1260 approving an 8-station addition for a 16-station facility at its current site in Aberdeen.

APPLICABILITY OF CERTIFICATE OF NEED LAW

Fresenius Medical Care’s application proposes to add dialysis stations to a relocated dialysis center. This application is subject to review as an increase in the number of dialysis stations in a kidney disease center under provisions of RCW 70.38.105(4)(h) and WAC 246-310-020(1)(e).

The Kalpine and DaVita projects are subject to CN review as the construction, development, or other establishment of a healthcare 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.*

WAC 246-310-280 through 289 contain service or facility specific criteria for dialysis projects and must be used to make the required determinations.

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 these projects, each applicant must demonstrate compliance with applicable kidney disease treatment center criteria outlined in WAC 246-310-280 through 289.

TYPE OF REVIEW

As directed under WAC 246-310-282(1) the department accepted these three applications under the Kidney Disease Treatment Centers-Concurrent Review Cycle #2 for calendar year 2017. The chronologic summary of the concurrent review is contained in Appendix A, following this evaluation.

CHRONOLOGIC SUMMARY OF REVIEW

Action	Fresenius Medical Care	Kalpine Dialysis LLC	DaVita HealthCare Partners
Letter of Intent Submitted	April 28, 2017	April 28, 2017	April 28, 2017
Application Submitted	May 31, 2017	May 31, 2017	May 31, 2017
1 st Amendment Application Submitted	N/A	N/A	N/A
Department’s pre-review Activities <ul style="list-style-type: none"> • Department screening letter sent • Screening responses received 	June 30, 2017 July 31, 2017	June 30, 2017 July 31, 2017	June 30, 2017 July 31, 2017
Beginning of Review	August 16, 2017		
End of Public Comment <ul style="list-style-type: none"> • No public hearing conducted • Public comments accepted through the end of public comment 	October 16, 2017		
Rebuttal Comments Received	November 15, 2017		
Department's Anticipated Decision Date	January 2, 2018		
Department's Actual Decision Date	December 28, 2017		

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.*

Under concurrent review, each applicant is an affected person for the other applications. No other entities requested interested or affected person status for any of the three applications.

SOURCE INFORMATION REVIEWED

- Fresenius Medical Care Certificate of Need application received May 31, 2017
- Kalpine Dialysis, LLC Certificate of Need application received May 31, 2017
- DaVita HealthCare Partners, Inc. Certificate of Need application received May 31, 2017
- Fresenius Medical Care screening response received July 31, 2017
- Kalpine Dialysis, LLC screening response received July 31, 2017
- DaVita HealthCare Partners, Inc. screening response received July 31, 2017
- Fresenius Medical Care public comment received by 5:00pm on October 16, 2017
- Kalpine Dialysis, LLC public comment received by 5:00pm on October 16, 2017
- DaVita HealthCare Partners, Inc. public comment received by 5:00pm on October 16, 2017
- Fresenius Medical Care rebuttal comment received by 5:00pm on November 15, 2017
- Kalpine Dialysis, LLC rebuttal comment received by 5:00pm on November 15, 2017
- DaVita HealthCare Partners, Inc. rebuttal comment received by 5:00pm on November 15, 2017
- Years 2011 through 2016 historical kidney dialysis data obtained from the Northwest Renal Network
- Year 2016 Northwest Renal Network December 31, 2016 (fourth quarter) utilization data released February 15, 2017
- Licensing data provided by the Medical Quality Assurance Commission, Nursing Quality Assurance Commission, and Health Systems Quality Assurance Office of Customer Service
- Fresenius Medical Care website at www.freseniuskidneycare.com/
- DaVita HealthCare Partners, Inc. website at www.davitahealthpartners.com
- Northwest Renal Network website at www.nwrn.org
- Centers for Medicare and Medicaid website at www.medicare.gov/dialysisfacilitycompare
- Certificate of Need historical files

CONCLUSIONS

Fresenius Medical Care

For the reasons stated in this evaluation, the application submitted by Fresenius Medical Care proposing to add eight dialysis stations to FMC Aberdeen Dialysis Center in Grays Harbor County is consistent with applicable criteria of the Certificate of Need Program. The approval requires agreement to the project description, conditions, and approved capital expenditure identified below.

Project Description:

This certificate approves the addition of 8 dialysis stations to the 16-station FMC Aberdeen Dialysis Center, for a facility total of 24 dialysis stations. At completion of the station addition, Fresenius Medical Care is approved to certify and operate 24 stations at FMC Aberdeen Dialysis Center. Services provided at FMC Aberdeen Dialysis Center include in-center hemodialysis, home hemodialysis and home peritoneal dialysis training and support for dialysis patients, a permanent bed station, an isolation station, and a shift beginning after 5:00 p.m. A breakdown of all stations at project completion is shown below:

Private Isolation Station	1
Permanent Bed Station	1
Other In-Center Stations	22
Total In-Center Stations	24

Conditions:

1. Approval of the project description as stated above. Fresenius Medical Care further agrees that any change to the project as described in the project description is a new project that requires a new Certificate of Need.
2. Prior to commencement of this project, Fresenius Medical Care must obtain approval for the relocation of FMC Aberdeen Dialysis Center under Washington Administrative Code 246-310-289(3).
3. Prior to providing services, Fresenius Medical Care will provide to the department for review and approval a copy of a signed, executed transfer agreement consistent with the agreement provided in the application.
4. Fresenius Medical Care shall finance this project using existing capital reserves, as described in the application.

Approved Costs:

The approved capital expenditure for this 8-station addition is \$241,947. This amount represents the total cost of \$423,347, minus the landlord’s costs of \$181,400.

Kalpine Dialysis, LLC

For the reasons stated in this evaluation, the application submitted by Kalpine Dialysis, LLC proposing to establish an eight station dialysis facility in Elma, within the Grays Harbor County is not consistent with applicable criteria of the Certificate of Need Program.

DaVita HealthCare Partners, Inc.

For the reasons stated in this evaluation, the application submitted by DaVita HealthCare Partners, Inc. proposing to establish an eight station dialysis facility in Elma, within the Grays Harbor County is not consistent with applicable criteria of the Certificate of Need Program.

CRITERIA DETERMINATIONS

A. Need (WAC 246-310-210)

Fresenius Medical Care

Based on the source information reviewed and agreement to the conditions identified in the conclusion section of this evaluation, the department concludes that the Fresenius Medical Care project has met the need criteria in WAC 246-310-210, which includes the applicable kidney disease treatment facility criteria in WAC 246-310-280 through 289.

Kalpine Dialysis, LLC

Based on the source information reviewed, the department concludes that the Kalpine Dialysis, LLC project does not meet the need criteria in WAC 246-310-210, which includes the applicable kidney disease treatment facility criteria in WAC 246-310-280 through 289.

DaVita Healthcare Partners, Inc.

Based on the source information reviewed and agreement to the conditions identified in the conclusion section of this evaluation, the department concludes that the DaVita HealthCare Partners, Inc. project has met the need criteria in WAC 246-310-210, which includes the applicable kidney disease treatment facility criteria in WAC 246-310-280 through 289.

- (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 246-310-284 requires the department to evaluate kidney disease treatment center applications based on the populations 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 applied is detailed under WAC 246-310-284(4). WAC 246-310-210(1) criteria is also identified in WAC 246-310-284(5) and (6).

WAC 246-310-284 Kidney Disease Treatment Center Numeric Methodology

WAC 246-310-284 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 (NRN).³

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 246-310-284(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.⁴

³ Northwest Renal Network 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]

⁴ 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 2016.

In planning areas experiencing high rates of growth in the dialysis population (6% or greater growth in each of the last five annual change periods), the method uses exponential regression to project future need. In planning areas experiencing less than 6% growth in any of the last five annual change periods, linear regression is used to project need. 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 NRN data, again concluding with the base year. [WAC 246-310-284(4)(b) and (c)]

WAC 246-310-284(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 projection year, 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 246-310-284(4)(d)]

The department calculates the numeric methodology for each of the 57 planning areas and posts the results to its website. Below is a discussion of each applicant's numeric methodology. The department's evaluation of each methodology will be discussed at the end of this sub-criterion.

Fresenius Medical Care

Fresenius performed each of the steps of the methodology as described above and concluded need for 8 stations in Gray Harbor County by the end of year 2020. [source: Application pp20-22]

Public Comment

None

Rebuttal Comment

None

Kalpine Dialysis, LLC

Kalpine performed each of the steps of the methodology as described above and concluded need for 8 stations in Gray Harbor County by the end of year 2020. [source: Application pp18-19]

Public Comment

None

Rebuttal Comment

None

DaVita Healthcare Partners, Inc.

DaVita performed each of the steps of the methodology as described above and also concluded need for 8 stations in Gray Harbor County by the end of year 2020. [source: Application pp15-17]

Public Comment

None

Rebuttal Comment

None

Department Evaluation of the Numeric Methodology for the Applications

Based on the calculation of the annual growth rate in the planning area as described above, each applicant and the department used the linear regression to determine planning area need. The number of projected patients was divided by 4.8 to determine the number of stations needed in the planning area. The result of each applicant's and the department's numeric methodology is shown in Table 1 below.

**Table 1
Grays Harbor County Numeric Methodology Summary**

	4.8 in-center patients per station		
	2020 Projected # of stations	Minus Current # of stations	2020 Net Need or (Surplus)
Fresenius Medical Care	24	16	8
Kalpine Dialysis, LLC	24	16	8
DaVita HealthCare Partners	24	16	8
Department of Health	24	16	8

As shown in Table 1, the department's methodology showed a need for 24 dialysis stations in the planning area by the end of year 2020. Once the 16 existing stations are subtracted, Grays Harbor County shows a net need of 8 stations. The department's methodology is included in this evaluation as Appendix A.

The department concludes each applicant **met this numeric methodology standard.**

In addition to the numeric need, the department must determine whether other services and facilities of the type proposed are not or will not be sufficiently available or accessible to meet the dialysis station need.⁵ The department uses the standards in WAC 246-310-284(5) and WAC 246-310-284(6).

WAC 246-310-284(5)

WAC 246-310-284(5) requires all CN approved stations in the planning area be operating at a certain utilization before new stations are added. For Grays Harbor County, the utilization is 4.8 in-center patients per station.

The department's evaluation of each applicant's compliance with this standard will be discussed at the end of this standard.

⁵ WAC 246-310-210(1)(b).

Fresenius Medical Care

There is one facility operating in Grays Harbor County. It is FMC’s Aberdeen facility that currently operates with 16 stations. FMC relied on the NRN quarterly modality report for December 31, 2016, released on February 15, 2017 to demonstrate compliance with this standard. FMC provided a table showing that the utilization of its Aberdeen facility as of December 31, 2016 was 4.88 patients per station. [source: Application, p23]

Public Comment

None

Rebuttal Comment

None

Kalpine Dialysis, LLC

Kalpine relied on the NRN quarterly modality report for December 31, 2016, released on February 15, 2017 to demonstrate compliance with this standard. Kalpine provided a table showing that the utilization of FMC’s Aberdeen facility as of December 31, 2016 was 4.88 patients per station. [source: Application, p19]

Public Comment

None

Rebuttal Comment

None

DaVita Healthcare Partners, Inc.

DaVita also relied on the NRN quarterly modality report for December 31, 2016, released on February 15, 2017 to demonstrate compliance with this standard. DaVita also provided a table showing that the utilization of FMC’s Aberdeen facility as of December 31, 2016 was 4.88 patients per station. [source: Application, p17]

Public Comment

None

Rebuttal Comment

None

Department Evaluation of WAC 246-310-284(5) for all three applications

The department uses data *‘from the most recent quarterly modality report or successor report from the Northwest Renal Network as of the first day of the application submission period’* to evaluate this standard. For these three applications submitted on May 31, 2017, the most recent quarterly data is December 31, 2016, available as of February 15, 2017.

FMC’s 16-station Aberdeen Dialysis Center is the only facility operating in Grays Harbor County. Table 2 shows the operational status and a summary of the dialysis center.

**Table 2
Department's Facility Utilization Calculations**

Facility Name	# of Approved Stations	# of Operational Stations	# of Pts	# Pts/Station
FMC Aberdeen Dialysis Center	16	16	78	4.875

All three applicants acknowledged that FMC's Aberdeen Dialysis Center was operating above the required 4.8 patients per station standard. Table 2 above substantiates that the existing operational dialysis center in Grays Harbor County satisfies this standard. Meeting this standard indicates that the existing facility is effectively and appropriately serving the population. Meeting this standard also indicates stations are not or will not be sufficiently available to meet future need. **Each of the three applicants meets this standard for the planning area.**

WAC 246-310-284(6)

WAC 246-310-284(6) requires new in-center dialysis stations be operating at a required number of in-center patients per station by the end of the third full year of operation. For Grays Harbor County, the requirement is 4.80 in-center patients per approved station. [WAC 246-310-284(6)(a)]

The department's evaluation of each applicant's compliance with this standard will be discussed at the end of this standard.

Fresenius Medical Care

FMC provided the following statement related to the projected operation of its proposed 24 station facility. [source: Application, p17]

"This project will commence upon CN approval. Projected startup of the completed project is October 1, 2018."

Based on the statement above, year 2021 is FMC's Aberdeen Dialysis Center's third year of operation with 24 stations. FMC provided the following table in response to this sub-criterion. [source: Application, p24]

**Table 3
FMC Aberdeen Dialysis Center Projected Station Utilization**

Year 3	# of Stations	# of In-Center Patients	Patients/Station
2021	24	118	4.92

Public Comment

None

Rebuttal Comment

None

Kalpine Dialysis, LLC

Kalpine provided the following statements in response to this sub-criterion. [source: Application, p14]

"The table below outlines anticipated dates of commencement and completion of the project based on an approval date of January 2, 2018. Recognizing that a project's

timeline may be impacted by unforeseen variables, this is our best estimate according to our historical experience completing facility build-out projects.”

(Replicated) Table 8 Elma Dialysis Center Anticipated Dates of Commencement & Completion of Project			
Approval of Project	Construction Complete	1st Treatment	State Inspection & Certification
<i>January 2, 2018</i>	<i>September 25, 2020</i>	<i>November 25, 2020</i>	<i>December 30, 2020</i>

Based on the timeline above, Kalpine’s third year of operation is year 2023. Kalpine provided the following projections for the 8-station dialysis center for year three. [source: Application, p12]

**Table 4
Kalpine’s Elma Dialysis Center
Third Year Projected Facility Utilization**

Year 3	# of Stations	# of In-Center Patients	Patients/Station
2023	8	41	5.125

Public Comment

None

Rebuttal Comment

None

DaVita HealthCare Partners, Inc.

DaVita provided the following statements in response to this sub-criterion. [source: Application, p13]

“The table below outlines anticipated dates of commencement and completion of the project based on an approval date of January 2, 2018. Recognizing that a project’s timeline may be impacted by unforeseen variables, this is our best estimate according to our historical experience completing facility build-out projects.”

(Replicated) Table 8 Elma Dialysis Center Anticipated Dates of Commencement & Completion of Project			
Approval of Project	Construction Complete	1st Treatment	State Inspection & Certification
<i>January 2, 2018</i>	<i>September 25, 2020</i>	<i>November 25, 2020</i>	<i>December 30, 2020</i>

Based on the timeline above, DaVita’s third year of operation is year 2023. DaVita provided the following projections for the 8-station dialysis center for year three. [source: Application, p11]

**Table 5
DaVita’s Elma Dialysis Center
Third Year Projected Facility Utilization**

Year 3	# of Stations	# of In-Center Patients	Patients/Station
2023	8	41	5.125

Public Comment

None

Rebuttal Comment

None

Department Evaluation of WAC 246-310-284(6) for all three applications

Each of the three applications met the 4.8 patients per station utilization standard under WAC 246-310-284(6).

WAC 246-310-287

The department shall not approve new stations in a planning area if the projections in WAC 246-310-284(4) show no net need, and shall not approve more than the number of stations projected as needed unless:

- (1) All other applicable review criteria and standards have been met; and*
- (2) One or more of the following have been met:*
 - (a) The department finds the additional stations are needed to be located reasonably close to the people they serve; or*
 - (b) Existing dialysis stations in the dialysis facility are operating at six patients per station. Data used to make this calculation must be from the most recent quarterly modality report or successor report from the Northwest Renal Network as of the first day of the application submission period; or*
 - (c) The applicant can document a significant change in ESRD treatment practice has occurred, affecting dialysis station use in the planning area; and*
- (3) The department finds that exceptional circumstances exist within the planning area and explains the approval of additional stations in writing.*

Department Evaluation

This sub-criterion is not applicable to any of the three applications under review.

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

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

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

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

exceptions is Medicare coverage for patients with permanent kidney failure. Patients of any age with permanent kidney failure are eligible for Medicare coverage.

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

A facility's charity care policy should show a willingness of a provider to provide services to patients who have exhausted any third-party sources, including Medicare and Medicaid, and whose income is equal to or below 200% of the federal poverty standards, adjusted for family size or is otherwise not sufficient to enable them to pay for the care or to pay deductibles or coinsurance amounts required by a third-party payer.⁶ With the passage of the Affordable Care Act (ACA), the amount of charity care is expected to decrease, but not disappear. The policy should also include the process one must use to access charity care at the facility.

Fresenius Medical Care

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

“RCG and Fresenius have a documented and proven history of providing charity care in all of our Washington facilities. All individuals identified as needing dialysis services will continue having access to FKC Grays Harbor. FKC Grays Aberdeen's [sic] admission policies prohibit discrimination on the basis of race, income, ethnicity, sex or handicap. A copy of the admission policy is contained in Exhibit 12. A copy of our charity care policy is contained in Exhibit 13.”
[source: Application p25]

As stated above, the following policies were included with the application. [source: Application Exhibits 12 & 13, Screening Response Exhibit 12]

- Fresenius Medical Care Patient Admission Policy – Effective March 26, 2014
- Fresenius Medical Care Billing Waivers for Indigent Patients (charity care) Policy – Effective May 15, 2000

Medicare and Medicaid Programs

All operational FMC dialysis facilities in Washington State are currently Medicare and Medicaid certified. FMC provided its projected payer mix for FMC Aberdeen Dialysis Center in its application. During the review of this application, FMC provided a revised payer mix table with the following explanation for the revisions.

“Before discussion of [Kalpine and DaVita]'s comments, we would like to clarify assumptions used in FMC Aberdeen's financial projections. In FMC Aberdeen's screening response, we identified year-to-date 2017 (January to April) as the basis for the payer mix material presented in Table 4, which is an accurate statement. Our financial model in our application incorporated full year (CY2016) actuals, a more comprehensive set of payer mix statistics. See Revised Table 4 below for a revised payer mix that accurately identifies the anticipated percentage of treatment and revenue by payer, based on CY2016 actuals. Please note that none of the financial projections provided in our application or screening have changed as a result of Revised Table 4. This is due to the fact that the figures presented in Revised Table 4 were what were used to construct the financial model.
[emphasis added]

⁶ WAC 246-453-010(4).

**Revised Table 1, FKC Aberdeen Dialysis Historical (CY2016)
and Projected Payer Mix by Treatment and Revenue**

<i>Source</i>	<i>% of Treatment by Payer</i>	<i>% of Revenue by Payer</i>
<i>Medicare</i>	<i>79.30%</i>	<i>37.49%</i>
<i>Medicaid</i>	<i>9.50%</i>	<i>4.61%</i>
<i>Commercial</i>	<i>6.49%</i>	<i>54.04%</i>
<i>Other</i>	<i>4.70%</i>	<i>3.97%</i>
<i>Total</i>	<i>100.00%</i>	<i>100.00%</i>

Note: Medicare Advantage and Medicaid Risk-sponsored patients are included in Medicare and Medicaid, respectively. The "Other" payer group includes miscellaneous insurance, and self-pay sponsored patients. Source: Applicant, 2017.

While FMC’s initial payer mix table provided on page 16 of the application is different than the revised table above, because the table above reflects the payer mix used by FMC in its application, the department will use the revised table above.⁷ FMC provided the following statement to describe the assumptions used project the payer mix shown above. [source: FMC screening response, p2]

“These payer mix percentages were taken from FMC Aberdeen actuals for the period January 1-April 30, 2017.”

Kalpine and DaVita Public Comment

Both Kalpine and DaVita provided comments on FMC’s application that focus on patient access to dialysis services. Both Kalpine and DaVita provided the same public comments and they are restated below. [source: Kalpine public comment, pp5-6; DaVita public comment, pp5-6]

Geographic Access in the Planning area

“Currently, all sixteen dialysis stations in the planning area are in Aberdeen (zip code 98520). Fresenius proposes to add eight stations in the same location. In contrast, Kalpine’s proposed facility in Elma (zip code 98541) would improve geographic access in this large planning area.

Fresenius’s proposal fails to acknowledge an issue very important to patients – proximity of the facility to their home. The 6/30/2017 patient population data from the Network illustrates that although 98520 (Fresenius’s location) is home to 25 ESRD patients, zip code 98541 (Kalpine’s proposed location) is home to 14. Moreover, zip code 98541 has been growing since the 6/30/2015 data at a rate of 12.8% per year (from 11 ESRD patients), as opposed to just 9.5% per year for 98520 (from 20 ESRD patients). Kalpine’s proposal to build a new center in Elma would significantly improve geographic access in this planning area.

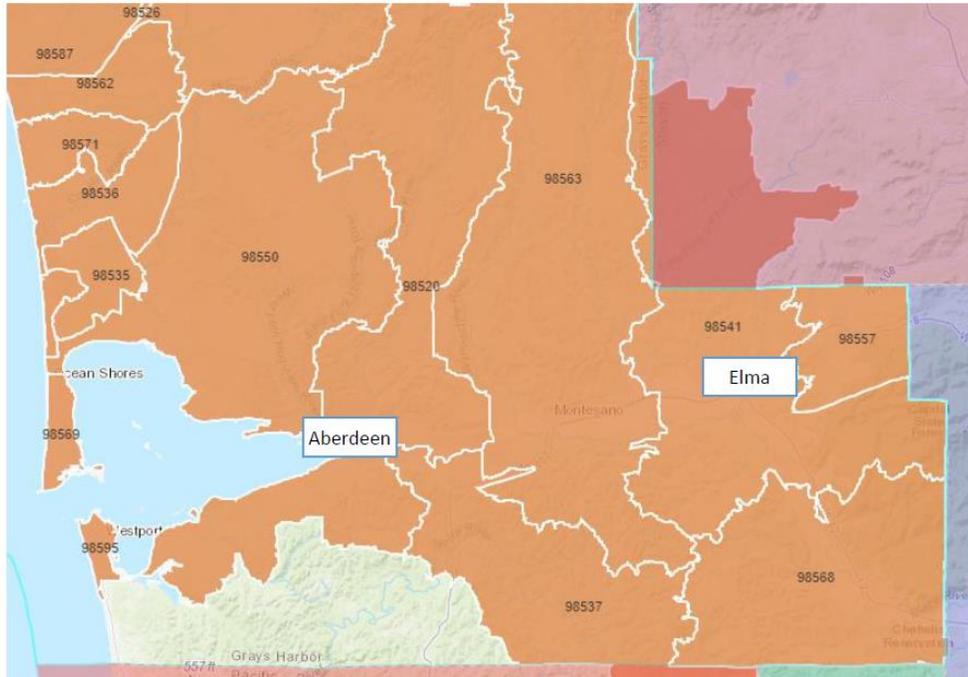
Below are the applicable zip codes from Grays Harbor County along with the corresponding patient census per the Network 16 data of 6/30/2017 and 6/30/2015.”

⁷ Note that if FMC had calculated its payer mix on the incorrect table provided in the application, then its projected Revenue and Expense Statement would also have been incorrect and unreliable. This type of change would not be appropriate revision for a review.

<i>Zip Code</i>	<i>Total ICHD, PD & HHD 6/30/2017</i>	<i>% Grays Harbor ESRD Population</i>	<i>Facilities</i>	<i>Total ICHD, PD & HHD 6/30/2015</i>	<i>Annual Growth</i>
98520	24	28%	Current & Proposed FMC	20	9.5%
98541	14	16%	Proposed Kalpine & DaVita	11	12.8%
<i>Grays Harbor Total</i>	85	100%		67	12.6%

* Current FMC Aberdeen is located at 2012 Industrial Pkwy, Aberdeen, WA 98520.

* Proposed Kalpine and/or DaVita facility would be located at 351 E Main St., Elma, WA 98541.



FMC Rebuttal Comment [source: FMC rebuttal comment, p4]

“[Kalpine and DaVita] overemphasizes its relative geographic access for Grays Harbor County residents. Patient origin data from the Northwest Renal Network shows that FMC Aberdeen’s facility offers the greatest geographic access to all residents of the county given its centralized location within Grays Harbor. [Kalpine and DaVita]’s proposal also offers less community access as indicated by its charity care forecast, comprising only a fraction what Fresenius proposes.”

Department Evaluation

FMC has been providing dialysis services to the residents of Washington State for many years. The admission policy states *“Where medically appropriate and consistent with this policy, facilities shall admit and treat patients needing dialysis without regard to race, creed or religion, color, age, sex, disability, national origin, marital status, diagnosis and/or sexual orientation..”* [source: Application Exhibit 12]

All operational FMC dialysis centers in Washington State are Medicare and Medicaid certified. Documentation provided in the application demonstrates that FMC Aberdeen Dialysis Center would continue its Medicare and Medicaid certification. FMC projected no changes in the Medicare,

Medicaid, or commercial/other revenues for FMC Aberdeen Dialysis Center with 8 additional stations.

FMC provided an “Indigence Policy” that provides the necessary information and process a patient would use to obtain charity care at an FMC Aberdeen Dialysis Center. A charity care line item was also included as a deduction from revenue within the pro forma financial data. [source: FMC screening Response, Revised Exhibit 14B]

As previously stated, in Washington State, most dialysis patients qualify for either Medicare or Medicaid services. Charity care is generally not used by dialysis providers. Typically, the department requires applicants to submit a copy of the charity care policy to demonstrate a willingness to provide charity care if necessary.

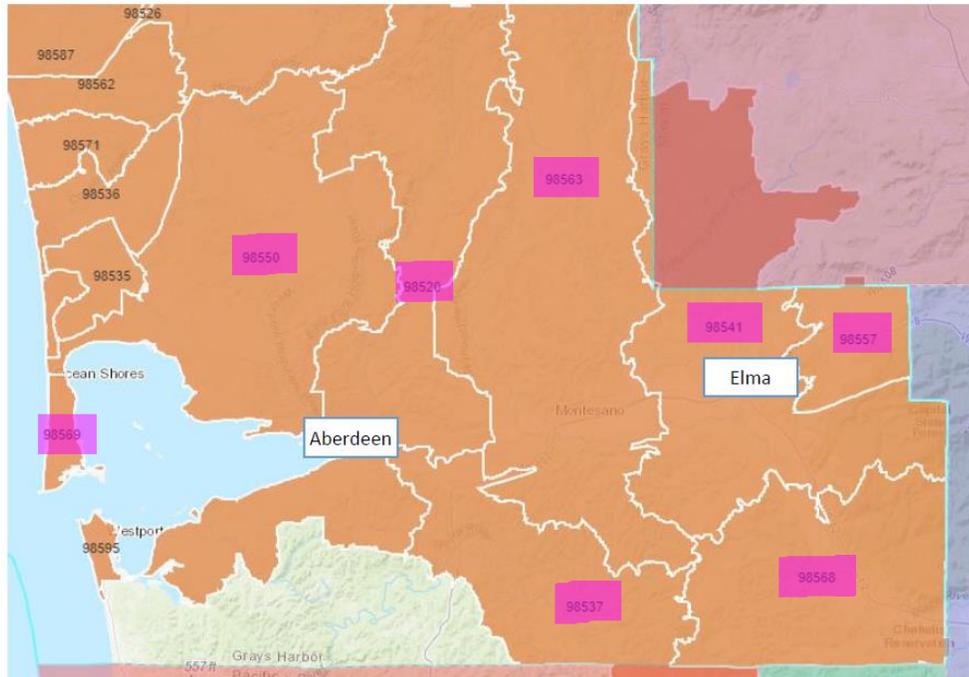
Both Kalpine and DaVita assert that adding stations to FMC’s existing facility in Aberdeen would not improve patient access because 16% of the Grays Harbor dialysis patients live in the Elma zip code of 98541. Information provided by Kalpine and DaVita show that Aberdeen and Elma zip codes make up a combined 44% of the patients dialyzing in Grays Harbor County.

To evaluate this information, the department compared the December 31, 2016, utilization data obtained from the Northwest Renal Network with Grays Harbor zip code data shown in the map provided by Kalpine and DaVita. A total of 75 patients have dialyzed from 8 of the 15 zip codes identified in the Grays Harbor County map. Table 8 shows the number of patients from each of the eight zip codes.

Table 8
December 31, 2016
Dialysis Utilization for Residents of Grays Harbor County

Zip	City/Town	Number of Patients	Percentage of Total
98520	Aberdeen	28	37.3%
98537	Cosmopolis	4	5.3%
98541	Elma	15	20.0%
98550	Hoquiam	14	18.7%
98557	McCleary	1	1.3%
98563	Montesano	6	8.0%
98568	Oakville	2	2.7%
98569	Ocean Shores	5	6.7%
	Totals	75	100.0%

Next, the department mapped the zip codes above using the map provided by Kalpine and DaVita. The pink zip codes are those with dialysis patients identified in the December 31, 2016, NRN data.



As shown in the map above, the majority of Grays Harbor Dialysis patients reside near either Aberdeen or Elma area. For many patients, an Aberdeen facility would be closer; for others, an Elma facility would be closer. Based on the information above, the department concludes that while a dialysis facility located in Elma could improve access for Grays Harbor dialysis patients, it is not a reason to consider an Elma project superior to an Aberdeen project.

The department concludes FMC’s project **meets this sub-criterion.**

Kalpine Dialysis, LLC

Kalpine provided the following statement related to this sub-criterion.

“The Department of Health knows, based on DaVita’s history of providing dialysis services at numerous locations throughout Washington State, that all ESRD patients have access to DaVita’s facilities, including members of the under-served groups referenced in the regulation. Appendix 14 includes a copy of the admission, patient financial evaluation, and patient involuntary transfer policies which documents that access is not denied due to indigence, racial or ethnic identity, gender or handicapped status.” [source: Application, p21]

Kalpine also provided copies of the following policies used at all existing dialysis centers owned and operated by DaVita. [source: Application, Appendix 14]

- Accepting End Stage Renal Disease Patient for Treatment [Admission Policy] – Revised and Approved December 2016
- Patient Financial Evaluation Policy – Reviewed and Approved April 2014
- Patient Behavior Agreements, 30 Day Discharge, Involuntary Discharge or Involuntary Transfer Policy – Reviewed and Approved May 2017

The department noted that the documents all reference DaVita. In response to the department’s question of how the documents could meet the above sub-criterion with no reference to Kalpine, Kalpine provided the following response. [source: Kalpine screening response, p9]

“Per the Management Services Agreement, as the Contractual Manager, DaVita has the responsibility to establish operational policies and procedures it deems to be necessary. The Indigent Care Policy & Involuntary Transfer Procedure is part of DaVita's standard Policies & Procedures used to manage operations.

"2. RIGHTS AND RESPONSIBILITIES OF CONTRACTUAL MANAGER. (b) Operational Policies; Quality Control. Contractual Manager shall establish all operational policies and procedures reasonably necessary for establishing the appropriate standards of patient care at the Center. ”

Medicare and Medicaid Programs

Kalpine states that its new Elma facility would be Medicare and Medicaid certified. Kalpine does not currently own or operate any dialysis centers, therefore, Kalpine provided DaVita’s company-wide percentages of revenues by payer and patient to be used for its facility. The percentages are shown in Table 7 below. [source: Application, p12]

Table 7
Kalpine Elma Dialysis Center Projected Payer Mix

Source	Revenue	Patient
Medicare	56.7%	78.9%
Medicaid	4.5%	7.7%
Insurance/HMO	38.8%	13.4%
Total	100.0%	100.0%

Kalpine also provided the following statement related to the table above. [source: Kalpine screening response, p4]

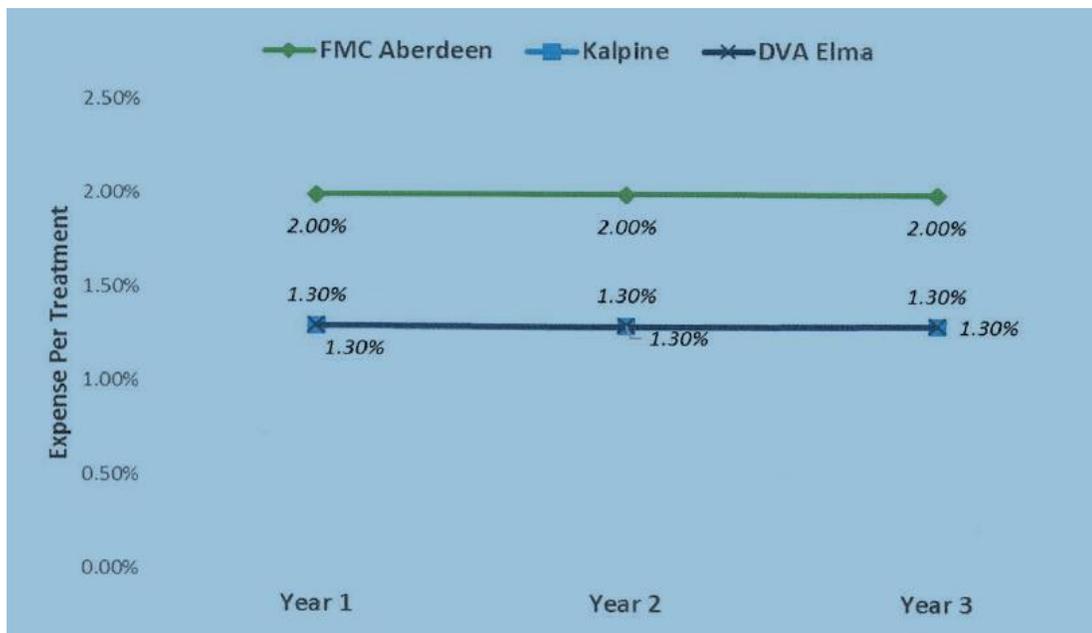
“These revenue sources are an actual company-wide average of revenue sources and percentage by payer type. No assumptions were made.”

FMC Public Comment

FMC provided public comment on Kalpine project, which is restated below by topic.

Community Access

“According to WAC 246-310-210(2), it is very important to evaluate measures of community access. One such key measure is the provision of charity care. All three applicants included charity care allowances in their financial pro forma projections, shown below in Figure 2.”



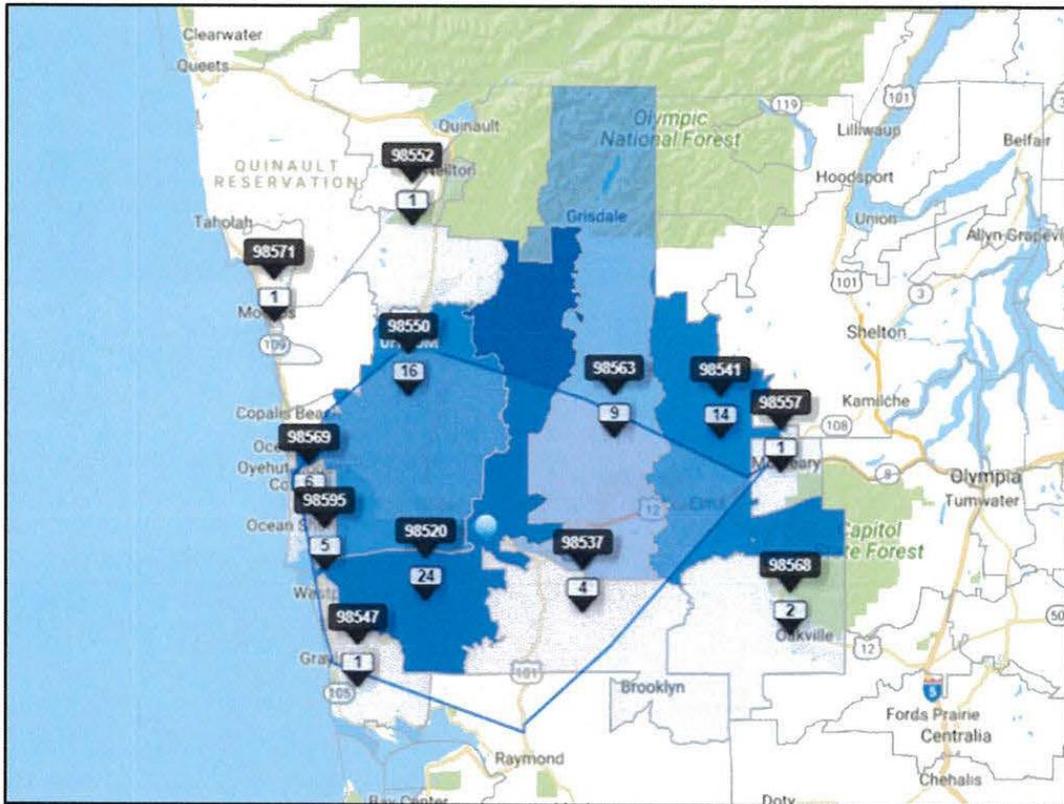
FMC Aberdeen: CN 17-40 Screening Response #1. Revised Exhibit 13B. Includes I/C and Home Net Revenue
 Kalpine Source: CN 17-44 Screening Response #1, Revised Appendix 9a, p. 63.
 DVA Elma source: CN 17-46, Appendix 9, p., 184.
 Kalpine and DaVita have identical charity care percentages that overlap on the chart.

“The applicants' data demonstrate sizeable differences in the amount of charity care each applicant anticipated. Based on the findings of Figure 2, FMC Aberdeen's charity care expenditures, as a percent of total revenues, would be approximately 54% greater ($2.0\% / 1.3\% = 1.54$) than Kalpine in each applicant's respective third year of operations. If this gap in charity care continues, FMC Aberdeen would be providing a significantly higher level of charity care to low-income persons, which demonstrates its request would provide greater community access.” [source: FMC public comment, p10]

Patient Access-Location of Dialysis Centers

“This is also a shortfall of the Kalpine Elma request in comparison to FMC's CON request. It would provide less patient access than the FMC proposal. There are three key problems with Kalpine's request: First, FMC's existing facility is located in closer proximity to Grays Harbor County patients who use dialysis, based on the most recent patient origin data from the Northwest Renal Network. Second, FMC will have its eight additional stations on-line a full two years before Kalpine would, providing much more timely access to care. The net need statistics for dialysis stations demonstrate need for additional stations almost immediately and well before Kalpine would become operational.” [source: FMC public comment, pp4-5]

“The proposed location in Elma is not where planning area patients reside. Thus, the Kalpine facility would not improve patient access. See Figure 1 below for a patient origin map featuring 2Q2017 Grays Harbor patient census data from the Northwest Renal Network. The black markers label the zip code and the number below denotes the sum of HD and IPD dialysis patients residing in the respective zip code. Further, the shaded polygon within Figure 1 represents a 30-minute drive time from Aberdeen (blue circle).”



(1) Number below zip code is the sum of HD and IPD patient residents

(2) Shaded polygon represents 30-minute drive time from Aberdeen (blue circle)

Source: Northwest Renal Network data -All Network patients as of June 30, 2017

“Figure 1 demonstrates that the preponderance of dialysis patients from Grays Harbor County reside within and immediately around Aberdeen. Kalpine may state that there is a considerable number of dialysis patients in their proposed location, Elma. However, this ignores the fact that the town center of Elma, where many of zip code 98541 residents live, is within FMC Aberdeen’s 30-minute drive time. Conversely, a Kalpine facility would provide inadequate access to address the future needs of patients in the western portion of the County that would be beyond a 30-minute drive to Kalpine’s proposed Elma facility. It is important to acknowledge that the requested stations are to address future unmet need. While Kalpine’s facility would be expected to serve the current base of Elma patients receiving care in Aberdeen, thus freeing up some capacity at FMC Aberdeen, any future unmet demand by Western Grays Harbor residents will be inappropriately burdened with long drive-times to any Kalpine facility in Elma when FMC Aberdeen reaches full capacity, if not approved for expansion. Again, all residents of Western Grays Harbor would be stretched to the limit with a drive time well over 30-minutes to Elma-this harms patient access.

In summary, FMC Aberdeen, by virtue of its central location within the county, will offer significantly greater geographical access to all residents of the county, including Elma residents and those to the west. Kalpine’s facility, on the other hand, could serve Eastern and Central Grays Harbor County patients, but would provide inadequate access for all future dialysis patients in western portions of the county.” [source: FMC public comment, pp8-9]

Patient Access-Timing of Operation

“Application of the methodology contained in WAC 246-310-284 identifies a need for an additional eight (8) stations in the Grays Harbor County Dialysis Planning Area by 2020, Projection Year 4. FMC Aberdeen is operating above the operating standard defined in WAC 246-310-284 (5), further demonstrating additional need for dialysis capacity in the Planning Area. The current situation is one where access must be improved quickly or FMC Aberdeen will reach maximum occupancy. When that happens, future Planning Area patients who need dialysis will be required to out-migrate to receive life-saving dialysis treatment.

There is a very significant difference between the three applicants who propose developing additional stations in the Grays Harbor Planning Area. Only the FMC application allows for timely access. The projected startup of FMC Aberdeen's completed project is October 1, 2018, whereas Kalpine Elma's projects are not expected to be operational until November 25, 2020. In other words, the proposed Kalpine facility would be operational two full years after FMC Aberdeen. See Table 1 below for a timeline outlining the three applicants' proposals matched to the calculated net need for additional dialysis stations according to the Department's numeric need methodology.”

FMC Table 1 - Recreated

	YE2018	YE2019	YE2020	YE2021
<i>Net Station Need</i>	5	7	8	10
<i>FMC Aberdeen(New Supply) [1]</i>	8	8	8	8
<i>Kalpine Dialysis (New Supply) [2]</i>	0	0	8	8
<i>Elma Dialysis (New Supply) [3]</i>	0	0	8	8

[1] Projected startup of FMC Aberdeen's completed project is October 1, 2018.

[2] Projected startup of Kalpine's completed project is November 25, 2020.

[3] Projected startup of DaVita's Elma project is November 25, 2020.

“Table 1 clearly shows the sizeable gap in timing between FMC Aberdeen and the other two requested projects. This finding shows planning area residents will be negatively impacted in the event Kalpine's project is approved over FMC Aberdeen because of untimely access to needed dialysis care. Without additional stations, FMC Aberdeen will continue operating at higher levels of occupancy year-over-year until it reaches full capacity, effectively limiting access for other Planning Area residents in need of dialysis services. When this happens, these residents will be forced to out-migrate for required dialysis treatment up until the time [Kalpine's new stations become operational in November 2020, two full years after FMC Aberdeen. Conversely, FMC Aberdeen is committed to addressing the current and projected need for additional stations on a timely basis with patients gaining greater access by October 2018.” [source: FMC public comment, pp9-10]

Kalpine Rebuttal Comment

Community Access

“Kalpine will provide a much-needed dialysis facility in an underserved part of Grays Harbor County. Currently, 100% of the dialysis stations are located in Aberdeen, but 31 % of patients reside in zip codes that are closer to Elma. Kalpine proposes to locate 33% of Grays Harbor County's total dialysis stations in Elma, closer to where these patients reside. Moreover, Kalpine is dedicated to caring for all patients, regardless of insurance status or ability to pay. FMC's arguments to the contrary are without merit.

The Kalpine facility would improve patient choice and geographic access. FMC argues that the Kalpine facility in Elma "is not where planning area patients reside," so the facility "would not improve patient access." FMC is wrong. Indeed, FMC's own graphic disproves its argument. According to FMC, too few Grays Harbor dialysis patients live close enough to Elma to warrant a facility there. Not so. According to the map FMC submitted with its comments, there are eighty-four dialysis patients in the planning area. As Figure 2 shows, fifty-eight of these patients live in zip codes clustered around Aberdeen, and twenty-six of the patients live in zip codes clustered around Elma. In other words, 69% of the patients live around Aberdeen and 31 % of the patients live around Elma. If granted, the Kalpine proposal would locate 33% of Grays Harbor's 24 dialysis stations in Elma.

Figure 2

Western Grays Harbor County		Eastern Grays Harbor County	
Zip Code	Dialysis Patients	Zip Code	Dialysis Patients
98571	1	98563	9
98552	1	98557	14
98550	16	98568	1
98569	6		2
98595	5		
98547	1		
98520	24		
98537	4		
Total	58	Total	26
Share of Total	69%	Share of Total	31%

Furthermore, the patients who currently live in and around Elma experience long drive times to access the dialysis facility in Aberdeen. This shown in Figure 3.

Figure 3

City/Town	Drive Time to Elma	Drive Time to Aberdeen
Oakville, WA (98568)	21 minutes	41 minutes
McCleary, WA (98557)	14 minutes	35 minutes
Malone Porter, WA (98541)	13 minutes	33 minutes
Brady, WA (98563)	9 minutes	18 minutes
Elma WA (98541)	0 minutes	26 minutes

It simply does not make sense to increase the number of dialysis stations in Aberdeen when a significant portion of the Grays Harbor dialysis patients live in eastern Grays Harbor County, close to Elma. Rather, to improve patient access and geographic access, the Program should grant Kalpine's proposal to add eight stations in Elma. FMC assumes, without citation, that all future dialysis patients will reside in the western part of Grays Harbor County, such that "any future unmet demand by Western Grays Harbor residents will be inappropriately burdened with long drive-times to any DVA Elma facility." That is incorrect. Aberdeen and Elma experienced similar growth rates over the past ten years, and it stands to reason that those similarities will continue. Compare Population.us, Population of Aberdeen, WA (last visited Nov. 6, 2017), with Population.us, Population of Elma, WA (last visited Nov. 6, 2017). Likewise, the number of new ESRD patients has increased by 16.77% since 2014 in zip code 98541, where the Kalpine facility will be located.

Kalpine's project, not FMC's, would add capacity where it is most needed in the planning area: Eastern Grays Harbor County. FMC's 16-station facility is located in Western Grays Harbor County, where 69% of the planning area's ESRD patients reside. Kalpine's 8-station facility would be located in Eastern Grays Harbor county, where 31% of the planning area's ESRD patients reside. In other words, approval of Kalpine's project would result in two-thirds of the stations (16/24) being in the part of the planning area where two-thirds of the patients reside, and one-third of the stations (8/24) being in the part of the planning area where one-third of the patients reside.” [source: Kalpine rebuttal comment, pp2-4]

Patient Access-Timing of Operation

“The Kalpine facility will be operational in 2020, the year in which need for additional stations in the Grays Harbor planning area reaches eight. In other words, construction of the Kalpine facility is perfectly timed to meet the identified need. Additionally, as discussed above, Kalpine proposes a facility in an underserved location within Grays Harbor County, while FMC proposes to keep all capacity in a single location in the western part of the planning area.” [source: Kalpine rebuttal comment, pp4-5]

Department Evaluation

Kalpine is a new provider for Washington State, so it does not have a history of providing dialysis services that the department can rely on to conclude conformance with this sub-criterion. On the other hand, Kalpine’s majority owner, DaVita, has been providing dialysis services to the residents of Washington State for many years. Kalpine’s admission policy is DaVita’s policy. The Accepting End Stage Renal Disease Patients for Treatment provides the assurance that Kalpine would accept patients for treatment without regard to “*race, color, national origin, gender, sexual orientation, age, religion, or disability...*” provided that the patient is a candidate for dialysis services. However, the admission policy includes no reference to Kalpine. As a DaVita policy with no Kalpine reference, the department cannot conclude that Kalpine’s Admission Policy meets this standard.

All DaVita dialysis centers are Medicare and Medicaid certified. Documentation provided in the application demonstrates that the Kalpine facility would be both Medicare and Medicaid certified. Kalpine projected the Medicare revenues for the new center to be 56.7% of total revenues. Pro forma financial data provided in the application shows Medicare revenues. Kalpine’s Medicaid revenues are projected to be 4.5% of total revenues. Pro forma financial data provided in the application shows Medicaid revenues.

Kalpine did not provide a policy specifically entitled “Charity Care.” However DaVita’s Patient Financial Evaluation Policy provides the necessary information and process a patient would use to obtain charity care at a DaVita facility. Kalpine provided this document. Kalpine further demonstrated its intent to provide charity care for patients by including a ‘charity’ line item as a deduction from revenue within the pro forma income statement.

FMC asserts that one measure of community access is provision of charity care by an applicant. For other types of healthcare projects, the department would agree with FMC’s statement and approach to superiority. However, in Washington State, most dialysis patients qualify for either Medicare or Medicaid services. Charity care is generally not used by dialysis providers. The department requires applicants to submit a copy of the charity care policy to demonstrate a willingness to provide charity care if necessary. Kalpine provided the charity care policy that has been used by DaVita at its centers. However, the charity care policy includes no reference to Kalpine. As a DaVita policy with no

Kalpine reference, the department cannot conclude that Kalpine's Charity Care Policy meets this standard.

FMC criticized Kalpine's location of its center in Elma stating that it's not where planning area patients reside. The department addressed this topic earlier in this evaluation and noted that the majority of patients reside in either Aberdeen or Elma and a dialysis facility located in Elma could improve access for Grays Harbor dialysis patients since FMC is already located in Aberdeen. The department also stated that the location of the center in Elma does not rise to the level of a project that would be superior to an Aberdeen project.

FMC noted a difference in the projected operational date for Kalpine's project when compared to FMC and concluded that the difference is significant for patient access. FMC's 24-station center is projected to be operational by the end of year 2018; Kalpine's 8-station facility is projected to be operational by the end of year 2020. Since FMC is proposing a station addition and Kalpine is proposing a new facility, the department would expect a difference in the operation timeline. However a two year difference is notable. It is unclear why Kalpine expects its facility to take almost 24 months from a January 2018 decision date to be operational. The timing difference could rise to the level of superiority.

Given that Kalpine would be operated and managed by DaVita, the policies provided in the application are executed policies used by DaVita in its Washington State facilities. There is no reference to Kalpine in any of the documents. As a result, no draft policies were provided by Kalpine. The department concludes Kalpine's project **does not meet this sub-criterion**.

DaVita HealthCare Partners, Inc.

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

"The Department of Health knows, based on DaVita's history of providing dialysis services at numerous locations throughout Washington State, that all ESRD patients have access to DaVita's facilities, including members of the under-served groups referenced in the regulation. Appendix 14 includes a copy of the admission, patient financial evaluation, and patient involuntary transfer policies which documents that access will not be denied at Elma Dialysis Center due to indigence, racial or ethnic identity, gender or handicapped status." [source: Application, p18]

DaVita provided copies of the following policies used at all DaVita dialysis centers, including the proposed Elma center. [source: Application, Appendix 14]

- Accepting End Stage Renal Disease Patient for Treatment [Admission Policy] – Revised and Approved December 2016
- Patient Financial Evaluation Policy – Reviewed and Approved April 2014
- Patient Behavior Agreements, 30 Day Discharge, Involuntary Discharge or Involuntary Transfer Policy – Reviewed and Approved May 2017

Medicare and Medicaid Programs

DaVita proposes that its new Elma facility would be Medicare and Medicaid certified. DaVita provided its company-wide percentages of revenues by payer and patient to be used for this facility. The percentages are shown in Table 9. [source: Application, p11]

**Table 9
DaVita Elma Dialysis Center Projected Payer Mix**

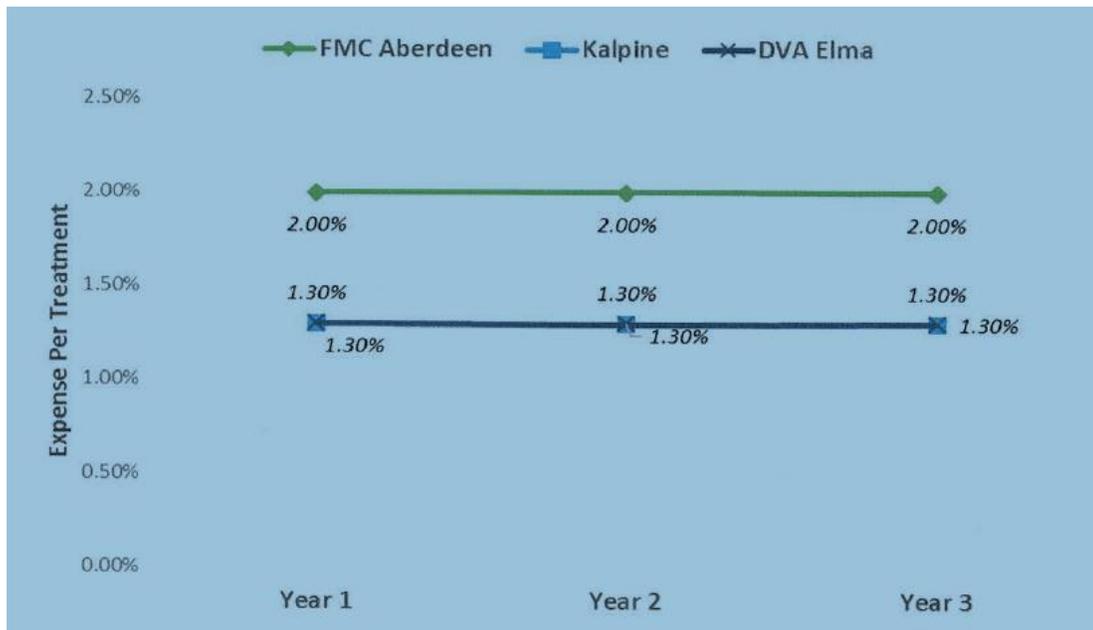
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Medicare	56.7%	78.9%
Medicaid	4.5%	7.7%
Insurance/HMO	38.8%	13.4%
Total	100.0%	100.0%

FMC Public Comment

FMC’s public comment is below by topic.

Community Access

“According to WAC 246-310-210(2), it is very important to evaluate measures of community access. One such key measure is the provision of charity care. All three applicants included charity care allowances in their financial pro forma projections, shown below in Figure 2.”



FMC Aberdeen: CN 17-40 Screening Response #1, Revised Exhibit 13B. Includes I/C and Home Net Revenue

Kalpine Source: CN 17-44 Screening Response #1, Revised Appendix 9a, p. 63.

DVA Elma source: CN 17-46, Appendix 9, p., 184.

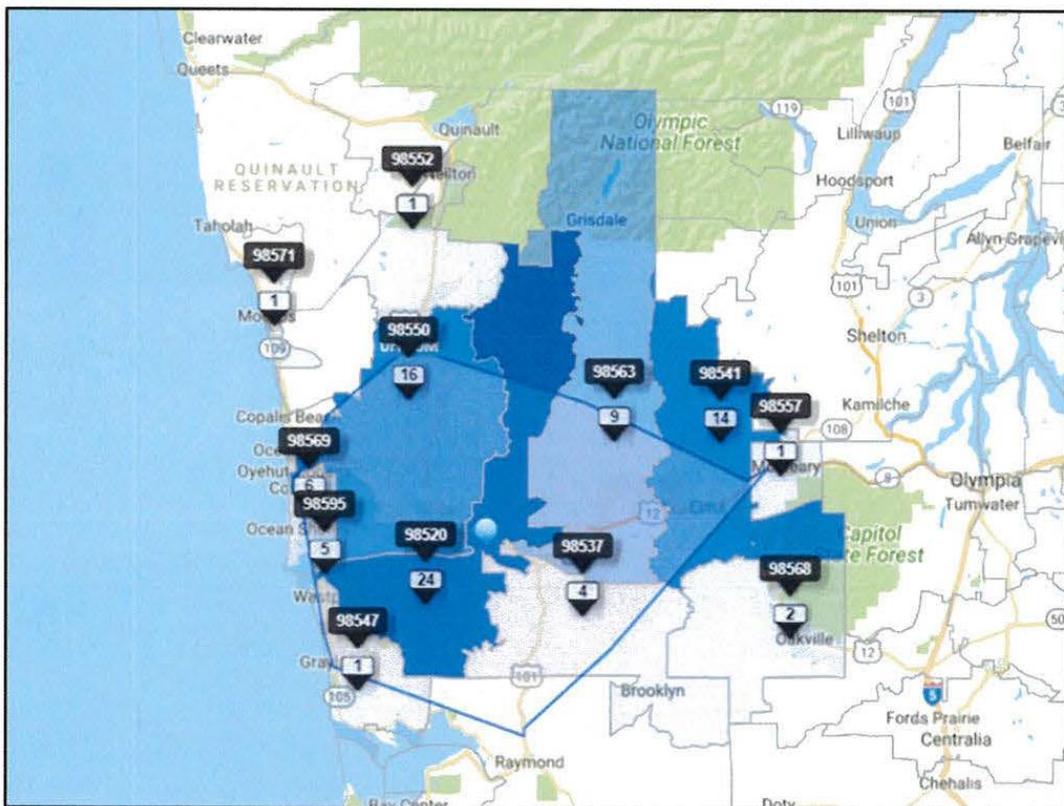
Kalpine and DaVita have identical charity care percentages that overlap on the chart.

“The applicants' data demonstrate sizeable differences in the amount of charity care each applicant anticipated. Based on the findings of Figure 2, FMC Aberdeen's charity care expenditures, as a percent of total revenues, would be approximately 54% greater ($2.0\% / 1.3\% = 1.54$) than DVA in each applicant's respective third year of operations. If this gap in charity care continues, FMC Aberdeen would be providing a significantly higher level of charity care to low-income persons, which demonstrates its request would provide greater community access.” [source: FMC public comment, pp9-10]

Patient Access-Location of Dialysis Centers

“This is also a shortfall of the DVA Elma request in comparison to FMC’s CON request. It would provide less patient access than the FMC proposal. There are three problems with DVA Elma’s request: First, FMC’s existing facility is located in closer proximity to Grays Harbor County patients who use dialysis, based on the most recent patient origin data from the Northwest Renal Network. Second, FMC will have its eight additional stations on-line a full two years before DVA Elma would, providing much more timely access to care. The net need statistics for dialysis stations demonstrate need for additional stations almost immediately and well before DVA would become operational.”
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“The proposed location in Elma is not where planning area patients reside. Thus, the DVA facility would not improve patient access. See Figure 1 below for a patient origin map featuring 2Q2017 Grays Harbor patient census data from the Northwest Renal Network. The black markers label the zip code and the number below denotes the sum of HD and IPD dialysis patients residing in the respective zip code. Further, the shaded polygon within Figure 1 represents a 30-minute drive time from Aberdeen (blue circle).”



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Source: Northwest Renal Network data -All Network patients as of June 30, 2017

“Figure 1 demonstrates that the preponderance of dialysis patients from Grays Harbor County reside within and immediately around Aberdeen. DVA may state that there is a considerable number of dialysis patients in their proposed location, Elma. However, this ignores the fact that the town center of Elma, where many of zip code 98541 residents live, is within FMC Aberdeen’s 30-minute drive time. Conversely, a DVA facility would provide inadequate access to address the future needs of patients in the western portion of the County that would be beyond a 30-minute drive to DVA’s

proposed Elma facility. It is important to acknowledge that the requested stations are to address future unmet need. While DVA's facility would be expected to serve the current base of Elma patients receiving care in Aberdeen, thus freeing up some capacity at FMC Aberdeen, any future unmet demand by Western Grays Harbor residents will be inappropriately burdened with long drive-times to any DVA facility in Elma when FMC Aberdeen reaches full capacity, if not approved for expansion. Again, all residents of Western Grays Harbor would be stretched to the limit with a drive time well over 30-minutes to Elma-this harms patient access.

In summary, FMC Aberdeen, by virtue of its central location within the county, will offer significantly greater geographical access to all residents of the county, including Elma residents and those to the west. DVA's facility, on the other hand, could serve Eastern and Central Grays Harbor County patients, but would provide inadequate access for all future dialysis patients in western portions of the county.” [source: FMC public comment, pp8-9]

Patient Access-Timing of Operation

“Application of the methodology contained in WAC 246-310-284 identifies a need for an additional eight (8) stations in the Grays Harbor County Dialysis Planning Area by 2020, Projection Year 4. FMC Aberdeen is operating above the operating standard defined in WAC 246-310-284 (5), further demonstrating additional need for dialysis capacity in the Planning Area. The current situation is one where access must be improved quickly or FMC Aberdeen will reach maximum occupancy. When that happens, future Planning Area patients who need dialysis will be required to out-migrate to receive life-saving dialysis treatment.

There is a very significant difference between the three applicants who propose developing additional stations in the Grays Harbor Planning Area. Only the FMC application allows for timely access. The projected startup of FMC Aberdeen's completed project is October 1, 2018, whereas DVA Elma's projects are not expected to be operational until November 25, 2020. In other words, the proposed DVA facility would be operational two full years after FMC Aberdeen. See Table 1 below for a timeline outlining the three applicants' proposals matched to the calculated net need for additional dialysis stations according to the Department's numeric need methodology.”

FMC Table 1 - Recreated

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<i>Net Station Need</i>	5	7	8	10
<i>FMC Aberdeen(New Supply) [1]</i>	8	8	8	8
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[1] Projected startup of FMC Aberdeen's completed project is October 1, 2018.

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“Table 1 clearly shows the sizeable gap in timing between FMC Aberdeen and the other two requested projects. This finding shows planning area residents will be negatively impacted in the event DVA's project is approved over FMC Aberdeen because of untimely access to needed dialysis care. Without additional stations, FMC Aberdeen will continue operating at higher levels of occupancy year-over-year until it reaches full capacity, effectively limiting access for other Planning Area residents in need of dialysis services. When this happens, these residents will be forced to out-migrate for required dialysis treatment up until the time DVA's new stations become operational in November 2020, two full years after FMC Aberdeen. Conversely, FMC Aberdeen is committed to

addressing the current and projected need for additional stations on a timely basis with patients gaining greater access by October 2018.” [source: FMC public comment, pp9-10]

DaVita Rebuttal Comment

Community Access

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FMC argues that the DaVita facility in Elma "is not where planning area patients reside," so the facility "would not improve patient access." FMC Pub. Comments at 8. FMC is wrong. Indeed, FMC's own graphic disproves its argument. According to FMC, too few Grays Harbor dialysis patients live close enough to Elma to warrant a facility there. Not so. According to the map FMC submitted with its comments, there are eighty-four dialysis patients in the planning area. As Figure 2 shows, fifty-eight of these patients live in zip codes clustered around Aberdeen, and twenty-six of the patients live in zip codes clustered around Elma. In other words, 69% of the patients live around Aberdeen and 31 % of the patients live around Elma. If granted, the DaVita proposal would locate 33% of Grays Harbor's 24 dialysis stations in Elma.

Figure 2

Western Grays Harbor County		Eastern Grays Harbor County	
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Total	58	Total	26
Share of Total	69%	Share of Total	31%

Furthermore, the patients who currently live in and around Elma experience long drive times to access the dialysis facility in Aberdeen. This shown in Figure 3.

Figure 3

City/Town	Drive Time to Elma	Drive Time to Aberdeen
Oakville, WA (98568)	21 minutes	41 minutes
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It simply does not make sense to increase the number of dialysis stations in Aberdeen when a significant portion of the Grays Harbor dialysis patients live in eastern Grays Harbor County, close to Elma. Rather, to improve patient access and geographic access, the Program should grant DaVita's proposal to add eight stations in Elma.

FMC assumes, without citation, that all future dialysis patients will reside in the western part of Grays Harbor County, such that "any future unmet demand by Western Grays Harbor residents will be inappropriately burdened with long drive-times to any DVA Elma facility." That is incorrect. Aberdeen and Elma experienced similar growth rates over the past ten years, and it stands to reason that those similarities will continue. Compare Population.us, Population of Aberdeen, WA (last visited Nov. 6, 2017), with Population.us, Population of Elma, WA (last visited Nov. 6, 2017). Likewise, the number of new ESRD patients has increased by 16.77% since 2014 in zip code 98541, where the DaVita facility will be located.

DaVita's project, not FMC's, would add capacity where it is most needed in the planning area: Eastern Grays Harbor County. FMC's 16-station facility is located in Western Grays Harbor County, where 69% of the planning area's ESRD patients reside. DaVita's 8-station facility would be located in Eastern Grays Harbor county, where 31 % of the planning area's ESRD patients reside. In other words, approval of DaVita's project would result in two-thirds of the stations (16/24) being in the part of the planning area where two-thirds of the patients reside, and one-third of the stations (8/24) being in the part of the planning area where one-third of the patients reside."

[source: DaVita rebuttal comment, p2, pp4-5]

Patient Access-Timing of Operation

"The DaVita facility will be operational in 2020, the year in which need for additional stations in the Grays Harbor planning area reaches eight. In other words, construction of the DaVita facility is perfectly timed to meet the identified need. Additionally, as discussed above, DaVita proposes a facility in an underserved location within Grays Harbor County, while FMC proposes to keep all capacity in a single location in the western part of the planning area."

[source: DaVita rebuttal, pp5-6]

Department Evaluation

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

All DaVita dialysis centers are Medicare and Medicaid certified. Documentation provided in the application demonstrates that Elma facility would be both Medicare and Medicaid certified. DaVita projected the Medicare revenues for the new center to be 56.7% of total revenues. Pro forma financial data provided in the application shows Medicare revenues. DaVita's Medicaid revenues are projected to be 4.5% of total revenues. Pro forma financial data provided in the application shows Medicaid revenues.

DaVita did not provide a policy specifically entitled "Charity Care." However DaVita's Patient Financial Evaluation Policy provides the necessary information and process a patient would use to obtain charity care at a DaVita facility. DaVita further demonstrated its intent to provide charity

care for patients by including a ‘charity’ line item as a deduction from revenue within the pro forma income statement.

FMC asserts that one measure of community access is provision of charity care by an applicant. For other types of healthcare projects, the department would agree with FMC’s statement and approach to superiority. However, in Washington State, most dialysis patients qualify for either Medicare or Medicaid services. Charity care is generally not used by dialysis providers. The department requires applicants to submit a copy of the charity care policy to demonstrate a willingness to provide charity care if necessary. DaVita provided the charity care policy that has been used by DaVita at its centers. This approach is acceptable.

FMC criticized DaVita’s location of its center in Elma stating that it’s not where planning area patients reside. The department addressed this topic earlier in this evaluation and noted that the majority of patients reside in either Aberdeen or Elma and a dialysis facility located in Elma could improve access for Grays Harbor dialysis patients since FMC is already located in Aberdeen. The department also stated that the location of the center in Elma does not rise to the level of a project that would be superior to an Aberdeen project.

FMC noted a difference in the projected operational date for DaVita’s project when compared to FMC and concluded that the difference is significant for patient access. FMC’s 24-station center is projected to be operational by the end of year 2018; DaVita’s 8-station facility is projected to be operational by the end of year 2020. Since FMC is proposing a station addition and DaVita is proposing a new facility, the department would expect a difference in the operation timeline. However a two year difference is notable. It is unclear why DaVita expects its facility to take almost 24 months from a January 2018 decision date to be operational. The timing difference could rise to the level of superiority.

Given that DaVita currently operates dialysis centers in Washington State and uses the same policies and procedures at each center, the policies provided in the application are executed policies used by DaVita in its Washington State facilities. As a result, no draft policies were provided by DaVita. The department concludes DaVita’s project **meets this sub-criterion**.

- (3) The applicant has substantiated any of the following special needs and circumstances the proposed project is to serve.
 - (a) The special needs and circumstances of entities such as medical and other health professions schools, multidisciplinary clinics and specialty centers providing a substantial portion of their services or resources, or both, to individuals not residing in the health service areas in which the entities are located or in adjacent health service areas.

Department Evaluation

This sub-criterion is not applicable to any of the three applications.

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

Department Evaluation

This sub-criterion is not applicable to any of the three applications.

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

Department Evaluation

This sub-criterion is not applicable to any of the three applications.

- (4) The project will not have an adverse effect on health professional schools and training programs. The assessment of the conformance of a project with this criterion shall include consideration of:
- (a) The effect of the means proposed for the delivery of health services on the clinical needs of health professional training programs in the area in which the services are to be provided.

Department Evaluation

This sub-criterion is not applicable to any of the three applications.

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

Department Evaluation

This sub-criterion is not applicable to any of the three applications.

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

Department Evaluation

This sub-criterion is not applicable to any of the three applications.

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

Fresenius Medical Care

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

Kalpine Dialysis, LLC

Based on the source information reviewed, the department concludes that the Kalpine Dialysis, LLC project does not meet the financial feasibility criteria in WAC 246-310-220.

DaVita Healthcare Partners, Inc.

Based on the source information reviewed and agreement to the conditions identified in the conclusion section of this evaluation, the department concludes that the DaVita HealthCare Partners, Inc. project 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 does not contain specific WAC 246-310-220(1) financial feasibility 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 the operating revenues and expenses should

be for a project of this type and size. Therefore, using its experience and expertise the department evaluates if the applicant's pro forma income statements reasonably project the proposed project is meeting its immediate and long-range capital and operating costs by the end of the third complete year of operation.

Fresenius Medical Care

FMC currently operates FMC Aberdeen Dialysis Center with 16 dialysis stations. The relocation and station addition project described in this application is proposed to be complete in October 2018. Under this timeline, October through December 2018 would be the facility's first partial year of operation with 24 stations. The first full calendar year of operation is year 2019 and 2021 is year three.

FMC provided the assumptions used to project in-center and home treatments and patients for calendar years 2018 through 2021. Below is a summary of these assumptions. [source: FMC screening response, Revised Exhibit 14B]

- *The number of in-center patients is currently at 78 patients as of December 31, 2016. This is expected to increase to 85 patients in October 2018, then increase to 100 in-center patients in 2019, 110 patients in 2020, then to 118 patients in 2021, the third full year of operations.*
- *The number of home patients is expected to be much smaller, reaching 14 patients in year 3 (2021). As of December 31, 2016, there were 6 home patients cared for by this center.*
- *It is assumed the number of treatments per patient is 144/year. There is adjustment for the "ramp" over each period.*

Using the assumptions above, FMC projected the number of treatments to be provided in the projection years. [source: FMC screening response, Revised Exhibit 14B]

**Table 10
FMC Aberdeen Projected Patients and Treatments**

	2018⁸	2019	2020	2021
Stations	24	24	24	24
Total In-Center Patients	85	100	110	118
Total In-Center Treatments	3,060	14,400	15,840	16,992
Total Home Treatments	288	1,440	1,728	2,016
Total Treatments	3,348	15,840	17,568	19,008

The assumptions FMC used to project revenue, expenses, and net income for FMC Aberdeen Dialysis Center for years 2018-2021 are restated below.[source: FMC screening response, Revised Exhibit 14B]

- *In-center gross and net revenues are taken from FMC Aberdeen Dialysis Center actuals, given this center has been operational for a number of years. Revenues are calculated by payer, by treatment for both gross and net revenues.*
- *Charity Care: 2.0% of Net Revenue/Treatment*
- *Bad Debt: Calculated on a per treatment basis for in-center and home treatments from FMC Aberdeen actuals.*

⁸ Partial year only (October to December).

- Expenses have been calculated on a per treatment basis for variable expenses from FMC Aberdeen actuals.
- Depreciation is straight-line; assumes 10 years on leaseholds and 8 years on equipment.
- The lease agreement specifies lease costs begin effective at operations start-up, October 1, 2016. Base rent starts at \$33.69/sf in year one and inflates 1, 7% per year thereafter.
- The signed lease agreement specifies a common area maintenance and allocated taxes and insurance costs. The year one figure is \$5.50/sf. It is held constant thereafter, since future CAM costs are not known.
- [The pro forma statements] includes monthly costs of \$5,000 from lease signing until start-up. The total cost is \$80,000. It is a pre-operations [start up] expense and would be paid monthly, but is included in its entirety in 201[8] in the interest of financial conservatism.
- Medical Director fees were calculated as follows: In 2017, annualized FMC Aberdeen was allocated a cost of \$97,276 by FMC finance. For simplicity, and based on the agreement, this 2017 figure was inflated 2% per year, thereafter.

Using the assumptions listed above, FMC projected the revenue, expenses, and net income for FMC Aberdeen Dialysis Center with 24 stations. [source: FMC screening response, Revised Exhibit 14B]

Table 11
FMC Aberdeen
Projected Revenue and Expense Summary

	CY 2018	CY 2019	CY 2020	CY 2021
Net Revenue	\$1,793,011	\$8,478,748	\$9,403,742	\$10,174,583
Total Expenses	\$1,112,500	\$4,392,641	\$4,792,278	\$5,178,438
Net Profit / (Loss)	\$680,511	\$4,086,107	\$4,611,464	\$4,996,145

All numbers shown above are rounded to nearest whole dollar.

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

The “Total Expenses” line item includes expenses related to operation of FMC Aberdeen, including allocated costs and depreciation. The line item also includes medical director costs consistent with the Medical Director Agreement provided in the application. [source: FMC screening response, Revised Exhibit 14B]

The site for the relocated dialysis center was purchased by the landlord and FMC provided a copy of the executed Purchase and Sale Agreement. The seller is Frank Martin Franciscovich d/b/a Grenville Properties located in Aberdeen. The purchaser is Aberdeen Renal Construction, LLC located in Dallas, Texas. The agreement was executed on May 5, 2017. FMC intends to repay the land purchase through a lease agreement.

FMC also provided a copy of the executed Lease Agreement between FMC and Aberdeen Renal Construction, LLC, a Colorado limited liability company. The lease agreement outlines roles and responsibilities for both entities. Specifically, the landlord will purchase the land, construct the building and complete ‘certain’ improvements to the space ensure it is usable as a dialysis center. The agreement provides specific timelines for completion of various items or stages in the construction. The agreement includes single line drawings showing 24 dialysis stations and space for support and ancillary areas. Once completed and ready for occupancy, FMC will lease the space from Aberdeen Renal Construction, LLC. The lease agreement identifies 15 years with three 5-year

options for renewal. The agreement identifies the base rent, which is consistent with the amounts identified by FMC in its pro forma revenue and expense statement. [source: FMC screening response, Exhibit 11C, Exhibit 9, Exhibit 11]

Kalpine and DaVita Public Comment

Both Kalpine and DaVita provided public comments related to this sub-criterion. The public comment from both is below.

Financial Projections

“It is axiomatic that the Department cannot determine that an applicant has satisfied the financial feasibility and cost containment criteria unless the applicant provides reliable financial projections and cost information.

Fresenius projects that in 2021 (full year three), it will have 16,992 in-center treatments. (Screening Responses, p. 22.) Fresenius states that 5.24% of the treatments are reimbursed through commercial insurance. (Application, p. 16.) Therefore, 890 of its in-center treatments in 2021 are projected to be reimbursed through commercial insurance. (16,992 x .0524 = 890.)

Fresenius projects that in 2021, its in-center treatments will generate \$9,502,629 of in-center revenue. (Screening Responses, p. 22.) Fresenius states that 41.47% of its revenue relates to commercially-insured patients. (Application, p. 16.) Therefore, \$3,940,740 of its in-center revenue in 2021 is expected to come from commercially-insured patients. (\$9,502,629 x .4147 = \$3,940,740.)

*Dividing Fresenius’s projected year-three commercial revenue for in-center patients (\$3,940,740) by Fresenius’s projected year-three total treatments for commercially-insured in-center patients (890) results in a commercial insurance revenue per treatment figure of **\$4,428**.*

Fresenius’s application materials state that the revenue projections and the payor mix each are based on historical data from its existing Grays Harbor facility. (Screening Responses, p. 23 [“In-center gross and net revenues are taken from FMC Aberdeen Dialysis Center actuals, given this center has been operational for a number of years. Revenues are calculated by payer, by treatment for both gross and net revenues.”].) Therefore, this revenue per treatment calculation is using consistent data.

Fresenius projects that it will have approximately six commercially-insured patients in 2021. (.0524 x 118 = 6.18.) Its pro forma financial projection depends on the assumption that its reimbursement for these six patients will be \$4,428 per treatment, which is \$637,632 per year. (\$4,428 x 144 = \$637,632.) The following table presents this revenue per treatment calculation for each of the four categories of payer identified by Fresenius (Medicare, Medicaid, Commercial, and Other):

	<i>In-center Revenue</i>	<i>In-center Patients</i>	<i>In-center treatments</i>	<i>Revenue per Treatment</i>
<i>Total</i>	\$9,502,629	118	16,992	\$559
<i>Medicare</i>	\$4,146,947 (43.64%)	91 (77.05%)	13,092 (77.05%)	\$317
<i>Medicaid</i>	\$668,985 (7.04%)	13 (11.02%)	1,873 (11.02%)	\$357
<i>Commercial</i>	\$3,940,740	6	890	\$4,428

	(41.47%)	(5.24%)	(5.24%)	
Other	\$745,956 (7.85%)	8 (6.69%)	1,137 (6.69%)	\$656

source: Application, p.16 (payer mix); screening responses, p22 (revised pro forma)

We do not see how Fresenius is able to achieve a reimbursement rate of **\$4,428** per treatment for commercially-insured patients at this facility. Even if Fresenius really is charging this much currently, we do not see how Fresenius can realistically project that it will be able to continue to do so for at least another four years (i.e., through 2021), and for a growing number of patients.

The Department should deny Fresenius’s application because the financial projections provided by Fresenius are based on unrealistic assumptions and are unreliable.” [source: Kalpine public comment, pp1-3; DaVita public comment, pp1-3]

Project Timeline

“Fresenius’s application also presents an unreliable project schedule. On page 17 of its application, Fresenius states that its proposed new facility will become operational on October 1, 2018. Fresenius’s financial feasibility and cost estimates are based on this opening date. (Application, p. 30 [staffing], Exhibit 14B [pro forma]; Screening Responses, p. 13 [rent forecast], Exhibit 14B [revised pro forma].)

We do not see how Fresenius could possibly build and open this new dialysis facility only nine months after the Department’s expected decision date. Like its capital expenditures, Fresenius’s project timeline—which drives its financial feasibility and cost estimates—is unreliable.” [source: Kalpine public comment, pp3-4; DaVita public comment, pp3-4]

FMC Rebuttal Comment

FMC provided rebuttal comment on the issues raised by Kalpine and DaVita. FMC’s rebuttal comment is below by topic.

Financial Projections

“Contrary to [Kalpine and DaVita]’s assertion that Fresenius financial projections include unrealistic net revenues per treatment rates by commercial payer, these rates were derived from CY2016 financial actuals from the existing FMC Aberdeen facility. Therefore, [Kalpine and DaVita]’s comments regarding revenue projections are misinformed. FMC Aberdeen’s revenue assumptions are by definition reliable and realistic as they were based on historical Planning Area-specific financial data. In addition, comparative review of the three applicants’ financial projections demonstrate Fresenius’ request is much more cost effective, given that it would expend a fraction of what either Kalpine or DVA Elma proposes to spend. Further, there are several issues with [Kalpine and DaVita]’s own financial projections, including but not limited to: failure to use relevant local data, inconsistent volume assumptions, and failure to fully document binding site control which alone disqualifies the [Kalpine and DaVita] project from being able to demonstrate financial feasibility.” [source: FMC rebuttal comment, p4]

“Before discussion of [Kalpine and DaVita]’s comments, we would like to clarify assumptions used in FMC Aberdeen’s financial projections. In FMC Aberdeen’s screening response, we identified year-to-date 2017 (January to April) as the basis for the payer mix material presented in Table 4, which is an accurate statement. Our financial model in our application incorporated full year (CY2016) actuals, a more comprehensive set of payer mix statistics. See Revised Table 4 below for

a revised payer mix that accurately identifies the anticipated percentage of treatment and revenue by payer, based on CY2016 actuals. Please note that none of the financial projections provided in our application or screening have changed as a result of Revised Table 4. This is due to the fact that the figures presented in Revised Table 4 were what were used to construct the financial model.

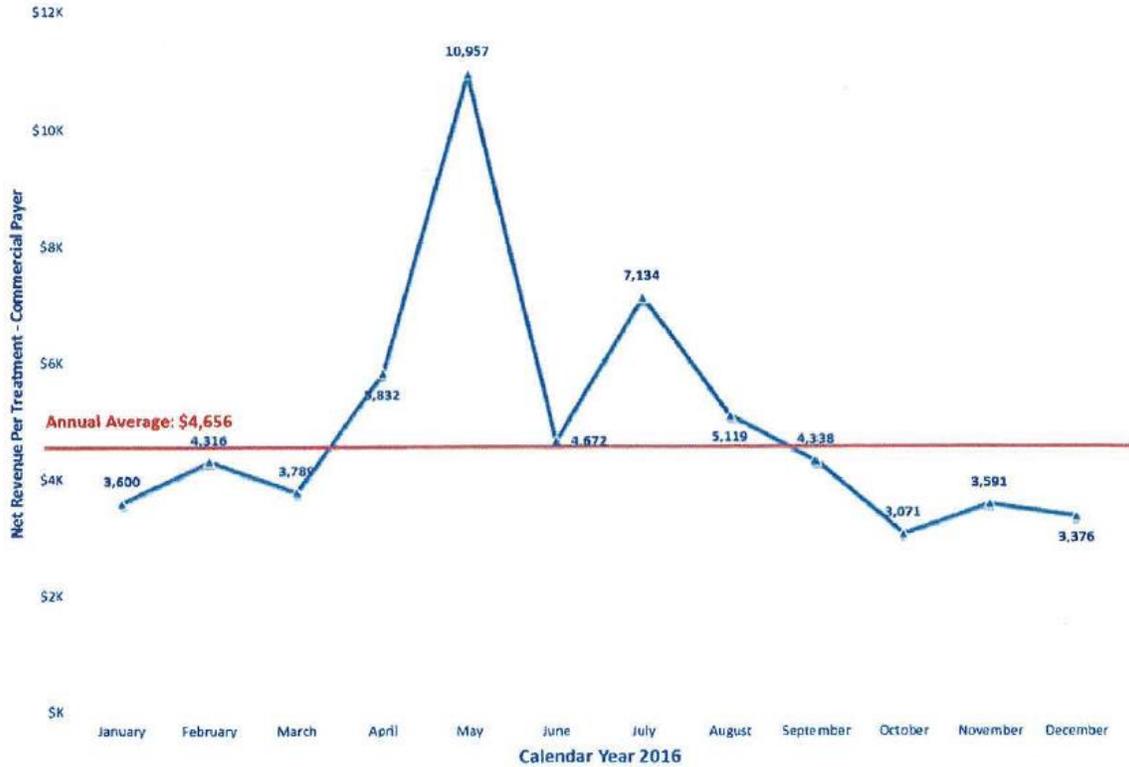
Revised Table 1, FKC Aberdeen Dialysis Historical (CY2016) and Projected Payer Mix by Treatment and Revenue

Source	% of Treatment by Payer	% of Revenue by Payer
<i>Medicare</i>	79.30%	37.49%
<i>Medicaid</i>	9.50%	4.61%
<i>Commercial</i>	6.49%	54.04%
<i>Other</i>	4.70%	3.97%
Total	100.00%	100.00%

Note: Medicare Advantage and Medicaid Risk-sponsored patients are included in Medicare and Medicaid, respectively. The "Other" payer group includes miscellaneous insurance, and self-pay sponsored patients. Source: Applicant, 2017.

[Kalpine and DaVita] states FMC Aberdeen's financial projections are unreliable. [Kalpine and DaVita] is misinformed and, consequently, has arrived at wrong conclusions with respect to the FMC Aberdeen financial model. The basis of [Kalpine and DaVita]'s contention is a purportedly unrealistic treatment revenue rate for patients with commercial insurance incorporated into the FMC Aberdeen projections. [Kalpine and DaVita]'s entire argument of the 'unrealistic' nature of FMC's rate directly contrasts with actual evidence. As described above, the payer-specific, gross and net revenues are taken from FMC Aberdeen actuals for the most recent calendar year (CY2016). Further, this rate is not a statistical anomaly of one outlier month in CY2016 that skewed the commercial rate incorporated into the final model, but rather is a consistent rate in FMC Aberdeen's operating history. Figure 1 displays the CY2016 monthly history of net revenue per treatment by commercial payers at FMC Aberdeen, as well as a red line which shows the annual average used in our application. Figure 1 clearly shows that the rate incorporated in our financial projections is well supported and reflects Planning Area specific data for FMC."

Figure 1. FMC Aberdeen – CY2016 Net Revenue Per Treatment by Commercial Payers



Source: Internal FMC data – CY2016

[source: FMC rebuttal comment, pp7-8]

Project Timeline

“[Kalpine and DaVita] raises doubts of FMC Aberdeen's projected timeline for the new site to become operational by October 1, 2018. Specifically, [Kalpine and DaVita] does not "see how Fresenius could possibly build and open this new dialysis facility only nine months after the Department's expected decision date".

[Kalpine and DaVita]'s skepticism does not account for the fact that Fresenius has been planning the relocation for quite some time due to the need for relocation due to flood plain issues as described above. Unlike other CN applications for new facilities, where the outcome is uncertain, Fresenius knew beforehand that it would require a new site and has proactively taken steps to streamline operationalizing the new site location.” [source: FMC rebuttal comment, pp8-9]

Department Evaluation

Kalpine and DaVita question the validity of the assumptions FMC used to determine the number of patients and treatments at FMC Aberdeen Dialysis Center. FMC based the projected payer mix on the current payer mix at Aberdeen Dialysis Center. Since the facility has been in operation for many years, this is a sound and reasonable approach by FMC.

Kalpine and DaVita further question the assumptions used by FMC to project revenues and expenses at the dialysis center. Specifically, both Kalpine and DaVita commented on FMC’s net revenue per treatment for commercial payers. In response, FMC provided a chart for full year 2016 showing

each of the twelve months separately to demonstrate its commercial net revenue per treatment is not an anomaly.

However, Kalpine and DaVita do not seem to assert that FMC’s projected commercial net revenue per treatment is higher than competitors (DaVita). Rather, Kalpine and DaVita question whether it is achievable on the long term. Since the value is based on FMC actuals, the department concludes that the assumptions used by FMC to project revenues are acceptable.

Both Kalpine and DaVita question whether FMC’s timeline of relocation and station addition is achievable. They do not trust that FMC can build and open the new center within nine months of CN approval. To evaluate this concern, the department reviewed past CN approvals for FMC. The data reviewed is FMC’s projected operational date identified in its application compared with FMC’s actual operational date provided in its quarterly progress reports. The table below shows the comparison review.

**Table 12
FMC Historical Project Comparison**

FMC Facility	Project	Projected Operation Date	Actual Operation Date	Comments
Leah Layne Dialysis Center	Add 4 stations	August 2010	October 2011	CN decision was 5 months late
Colville Dialysis Center	Add 2 stations	August 2010	June 2011	CN decision was 7 months late
Thurston County Dialysis Center	Establish 6-station center	September 2013	September 2014	
Moses Lake Dialysis Center	Relocate to a new site	June 2014	June 2014	
Chehalis Dialysis Center	Relocate to a new site	June 2015	May 2015	
North Pointe Dialysis Center	Relocate to a new site	November 2015	October 2016	FMC did not submit progress reports for first nine months after approval
Columbia Basin Dialysis Center	Relocate to a new site	March 2017	March 2017	

Table 12 above provides an overview of FMC’s ability to meet its projected timelines outlined in its historical applications. Of the seven projects reviewed, the department can verify that three of them—Moses Lake, Chehalis, and Columbia Basin—were completed within the identified timeline. This is less than 50% of the projects approved for FMC.

The department’s decision for both Leah Layne and Colville were five and seven months late, respectively. Specific to Leah Layne, FMC projected the station addition would be completed the same month the CN decision was due—August 2010. The CN decision was released in late December 2010, and the additional stations were operational six months later—in October 2011. FMC’s expectation that a station addition project would be completed the same month as CN approval is unrealistic considering the additional stations require, at minimum, a survey by the department’s Investigations and Inspections Office (IIO).

For Colville, the department's decision was scheduled for August 2010 and FMC projected the additional stations would be operational in August 2010. The decision was released in March 2011 and the additional stations were operational three months later—in June 2011. For the same reasons stated above, FMC's projected timeline is unrealistic.

For FMC's Thurston County project, it is unclear why completion was delayed for 12 months. The quarterly progress reports do not provide sufficient information to make that determination. For FMC's North Pointe project, since FMC did not complete and return its quarterly progress reports for the first nine months after approval, it is unclear why this project was delayed.⁹

In summary, Kalpine and DaVita raised valid concerns regarding FMC's timeline for completion of this project. Further, FMC may have provided unrealistic timelines in past applications. While the issue raises to the level of ensuring FMC's projected timelines are reasonable and achievable, it does not raise to the level of denial of FMC's project.

Based on the information above, the department concludes the assumptions used by FMC to project revenues and expenses can be substantiated. **This sub-criterion is met.**

Kalpine Dialysis, LLC

Kalpine proposes a new 8-station facility in Elma. The center would be leased by Kalpine from Palestra Real Estate Partners, Inc. The new center would be managed by the majority owner, DaVita. Kalpine provided the assumptions used to project in-center and home treatments and patients for calendar years 2020 through 2023. Below is a summary of the assumptions. [source: Application, pp18-19]

- The new facility would become operational near end of year 2020.
- Year 2021 is the full calendar year one for the dialysis center; year 2023 is full calendar year three.
- Utilization is based on the projected number of patients and treatments in Grays Harbor County. [department's numeric methodology]
- In-center treatments are based on an assumption of 3 treatments per week per patient for 52 weeks with a 5% allowance for missed treatments.

Using the assumptions stated above, Kalpine's projected number of in-center and home dialyses and patients for the 8-station facility is shown in Table 13 below. [source: Kalpine screening response, Revised Appendix 9A]

⁹ Once approval is issued, the department monitors the approved project through completion or the two year validity of the approval, whichever is longer. If a certificate holder does not complete and return progress reports quarterly as requested, the department cannot provide valuable technical assistance or guidance if a project is delayed. By not submitting progress reports, FMC also risks potential loss of its approval if the project is delayed beyond the validity period.

Table 13
Kalpine Elma Dialysis Center
Projected Patients and Dialyses for Years 2021-2023

	CY 2021	CY 2022	CY 2023
# of Stations	8	8	8
Total Treatments	4,303	5,690	6423
Total Patients	161	172	184

Kalpine provided the following assumptions used to project revenue, expenses, and net income for its 8-station center. [source: Kalpine screening response, pp8-11]

- *We used DaVita’s historical experience operating facilities in the state of Washington to estimate the future revenue and expenses for the Elma facility. We projected revenue for the new facility by multiplying the average net revenue per treatment for the existing DaVita facilities in the surrounding region by the estimated number of treatments at the new facility. These estimates are primarily driven by census assumptions from current Network 16 ESRD patient data as well as patients’ geographic locations and likely preferences. This methodology is consistent with how the pro-forma has been prepared for new DaVita facilities that the Department has approved in the past.*
- *The “G & A Allocation” for this facility is \$18 per treatment. This is the standard G & A assumption used by DaVita in previous applications.*
- *Per the Draft Dialysis Management Services Agreement in Appendix 24, the Contractual Manager will charge Kalpine Dialysis LLC a Management Fee as a percentage of the Net Revenues for services rendered. Find attached a revised pro-forma that includes a line item for the Management Fee in Appendix 9a: Detailed Projected Operating Statement (Pro Forma).*
- *The costs associated with the Joint Venture are 1) the management fee (explained in answer to Question #28) and 2) the development fee. The management fee, as mentioned in answer to Question #28, is represented in the pro-forma as a percentage of Net Revenues. The development fee, a capital expense, is a percentage of the total development costs associated with the center. The Dialysis Management Services Agreement Exhibit A Section B in **Appendix 24** states,*
‘As consideration for the services rendered by Contractual Manager prior to the opening of the Center, Owner shall pay Contractual Manager seven percent (7%) of the total development costs incurred to renovate/construct the Center, (the "Development Management Fee") ...’
- *The "Lease Expenses" line item in the pro-forma refers to the building lease due to Palestra Real Estate Partners, Inc. and is composed of two items 1) the base rent and 2) taxes and common area maintenance fees (CAM). The base rent amount is called out in Section 3 of the lease agreement with Palestra Real Estate Partners, Inc. The taxes and CAM are calculated at a per square foot rate of \$4.50. For example, Lease Expense for 2021 is base rent (\$192,000) plus Taxes and CAM (\$36,000) for a total of \$228,000, which matches the proforma.*
- *The cost associated with the ground lease is only incurred during the time period before the pro forma. As mentioned above, the ground lease is transferred to Palestra Real Estate Partners, Inc. and the associated costs are passed along to the Contractual manager as part of the base rent, which is included in the pro forma above.*

Based on the assumptions above, Kalpine projected the revenue, expenses, and net income for its 8-station dialysis center for years 2021 through 2025. A summary of the projections for years 2021 through 2023 is in Table 14 below. [source: Kalpine, screening response, Revised Appendix 9A]

Table 14
Kalpine Elma Dialysis Center
Projected Revenue and Expenses for Years 2021-2023

	CY 2021	CY 2022	CY 2023
Net Revenue	\$2,055,902	\$2,755,811	\$3,153,655
Total Expenses	\$1,919,249	\$2,279,312	\$2,545,049
Net Profit / (Loss)	\$136,653	\$476,499	\$608,606

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

The ‘Total Expenses’ line item includes all expenses related to the projected operation of the new 8-station facility, including allocated costs. The line item also includes medical director costs consistent with the draft Medical Director Agreement provided in the application. The line item also includes all expenses for management services, ground lease, and building lease expenses [source: Kalpine screening response, pp8-11 and Revised Appendix 9A]

FMC Public Comment

“Documentation of site control is a requirement for any applicant. Kalpine failed to provide a signed, binding letter of intent between the builder of the facility [Palestra Real Estate Partners, Inc.] to be operated by Kalpine and the DaVita entity that would lease the facility [Total Renal Care]. Instead, Kalpine only provided a draft build-to-suit lease agreement between Palestra and Total Renal Care that does not constitute a legally binding agreement. There is no signed documentation that is legally enforceable, that shows Total Renal Care has a binding agreement with the proposed landlord and that the landlord is bound to provide the space in the event a CON is awarded. Without this signed document, the applicant, Kalpine, does not have binding site control, as required. [source: FMC public comment, p4]

For the purposes of the Kalpine project, there are three primary actors:

<i>SVK Investments, LLC</i>	<i>Current owner of site</i>
<i>Palestra Reals Estate Partners, Inc.</i>	<i>Future owner if Kalpine is approved. Will build Kalpine facility and act as landlord.</i>
<i>Total Renal Care, Inc.</i>	<i>DaVita entity. Will act as Tenant to lease the facility to be operated by Kalpine.</i>

The applicant is required to show documentation that the seller of the site is in fact the legal owner of the property. Kalpine has provided required documents demonstrating SVK Investments is the rightful owner of the site and is able to enter into a contract leasing the site. Kalpine Dialysis also provided a signed ground lease agreement between SVK Investments and Total Renal Care. However, this alone does not document site control for the Kalpine project, as Kalpine failed to provide a signed, binding letter of intent between the builder of the facility [Palestra Real Estate Partners, Inc.] to be operated by Kalpine and the DaVita entity that would lease the facility [Total

Renal Care]. Instead, Kalpine has only provided a draft build-to-suit lease agreement between Palestra and Total Renal Care that does not constitute a legally binding agreement. There is no signed documentation that is legally enforceable, that shows Total Renal Care has a binding agreement with the proposed landlord, Palestra Real Estate Partners. A draft lease is insufficient; there must be a signed letter of intent to lease that binds both parties in the event a certificate of need is awarded. Without this signed document, the applicant, Kalpine (or Total Renal Care), does not have binding site control, as required. Consequently, its project should be denied.” [source: FMC public comment, pp6-7]

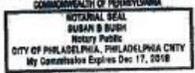
Kalpine Rebuttal Comment

“Consistent with Department precedent, the draft lease provided by Kalpine satisfies site control. Moreover, the draft lease subsequently was signed by Kalpine and Palestra Real Estate Partners. Contrary to FMC's argument, Kalpine adequately demonstrated site control with a complete, draft lease. Moreover, Kalpine and Palestra Partners signed the draft lease in May 2017.

On October 30, 2017, the Review Officer, the Department's final decision-maker in CON matters, ruled that a complete, draft lease may be accepted to establish site control. See In the Matter of Certificate of Need #1580 Issued to US HealthVest, LLC, Master Case No. M2016-876, Findings of Fact, Conclusions of Law, and Final Order, at 4 (Oct. 30, 2017) (“[A]ccepting a draft (but complete) lease during the CN application and evaluation stage is acceptable as long as a successful CN is conditioned upon submission of a copy of an executed lease consistent with the draft reviewed by the Program.”). Kalpine submitted with its application a draft lease that contains all required elements: It shows the parties to the lease (Palestra Real Estate Partners and Total Renal Care, Inc.), the project site (the Northeast corner of Highway 8 and Highway 12 in Elma, Washington), and rent (\$192,000 per year for the first five years). This lease demonstrated site control consistent with the standard explained by the Review Officer in her October 30 order.

Furthermore, Kalpine and Palestra Real Estate Partners signed the lease in May 2017. Figure 1 below shows the signature pages. The signed lease is identical to the unsigned lease Kalpine submitted with its application materials.

Figure 1

<p>IN TESTIMONY WHEREOF, Landlord and Tenant have caused this Lease to be executed as a sealed instrument, effective as of the day and year first above written.</p>	
<p>LANDLORD:</p> <p>PALESTRA REAL ESTATE PARTNERS, INC., a Pennsylvania corporation</p> <p>By: <u>[Signature]</u> Name: <u>Vincent Curran, Jr.</u> Title: <u>President</u> Date: <u>May 30, 2017</u></p> <p>STATE OF <u>Pennsylvania</u>)) SS COUNTY OF <u>Philadelphia</u>)</p> <p>I, <u>Susan B. Bush</u>, a Notary Public in and for the County and State aforesaid, do hereby certify that <u>VINCENT CURRAN, JR.</u>, the <u>PRESIDENT</u> of <u>PALESTRA REAL ESTATE PARTNERS, INC.</u>, who is personally known to me to be the same person whose name is subscribed to the foregoing instrument, appeared before me in person and acknowledged that he/she signed, sealed and delivered the said instrument as his/her own free and voluntary act and as the free and voluntary act of said <u>President</u>, for the uses and purposes therein set forth.</p> <p>Given under my hand and notarial seal this <u>30th</u> day of <u>May</u>, 2017. <u>[Signature]</u> Notary Public</p> <p>My Commission Expires: <u>Dec. 17, 2018</u></p> <p></p> <p>Elma, WA (Facility #TBD) ACTIVE#49302117.v2-5/25/17</p>	
<p>TENANT:</p> <p>TOTAL RENAL CARE, INC. a California corporation</p> <p>By: <u>[Signature]</u> Name: <u>Teresa Bush</u> Title: <u>DVP</u> Date: <u>5/31/17</u></p> <p>FOR TENANT'S INTERNAL PURPOSES ONLY:</p> <p>APPROVED AS TO FORM ONLY:</p> <p>By: _____ Name: _____ Title: _____</p> <p>STATE OF <u>Washington</u>)) SS COUNTY OF <u>Kearney</u>)</p> <p>I, <u>Susan B. Bush</u>, a Notary Public in and for the County and State aforesaid, do hereby certify that <u>Teresa Bush</u>, the <u>DVP</u> of <u>TOTAL RENAL CARE, INC.</u>, who is personally known to me to be the same person whose name is subscribed to the foregoing instrument, appeared before me in person and acknowledged that he/she signed, sealed and delivered the said instrument as his/her own free and voluntary act and as the free and voluntary act of said <u>DVP</u>, for the uses and purposes therein set forth.</p> <p>Given under my hand and notarial seal this <u>31st</u> day of <u>May</u>, 2017. <u>[Signature]</u> Notary Public</p> <p>My Commission Expires: <u>Dec 17, 2018</u></p> <p></p> <p>Elma, WA (Facility #TBD) ACTIVE#49302117.v2-5/25/17</p>	

Therefore, it is indisputable that Kalpine established site control. The draft lease submitted with the application was sufficient and, even if it were not, it subsequently was signed.” [source: Kalpine rebuttal comment, pp1-3]

Department Evaluation

Since Kalpine does not have a history of providing dialysis services in Washington State, Kalpine relied on the history and expertise of its majority owner—DaVita to determine a reasonable payer mix. Based on DaVita’s experience, the department concludes this approach by Kalpine is reasonable.

FMC does not dispute Kalpine’s assumptions used to project its revenue and expenses for the new dialysis center in Elma. However, FMC asserts that Kalpine did not provide sufficient documentation to demonstrate site control. Further, FMC points out that if Kalpine does not have site control, it cannot substantiate its expenses identified in the projected statements.

Kalpine provided the following two documents related to the site. Draft Lease Agreement and the Executed Ground Lease. [source: Application, Appendix 15] Below is a review of both documents.

Draft Lease Agreement

- This agreement is between Palestra Real Estate Partners, Inc. (landlord) and Total Renal Care (tenant) for space at “the northeast corner of Highway 8 and Highway 12, Elma Washington.”
- The agreement references a ‘Ground Lease’ with SVK Investments, LLC.

- The Lease Agreement states that the tenant (Total Renal Care) intends to assign its interest in the Ground Lease to the Landlord (Palestra Real Estate Partners, Inc.) and subject to such assignment (the “Assignment”), and Tenant’s issuance of a Notice to Proceed (defined in the lease agreement), Landlord desires to demise, lease and rent to the Tenant a to be constructed building (the “Building”), consisting of approximately 8,000 rentable square feet (the “Building Rentable Area”), as shown in Exhibit B attached to the Lease Agreement, and the Property, plus all easements, declarations, and rights of way, and the use of the Common Areas within the Center subject to the terms of the Ground Lease.
- The draft Lease Agreement states: *“It is understood and agreed by and between the parties hereto that the existence of this Lease is dependent and conditioned upon: (i) the continued existence of the Ground Lease, or (ii) Landlord’s purchase of the Property in accordance with the terms and conditions of the Ground Lease (such purchase shall be referred to as the “Release”).”*
- The term for this lease is 180 months (15 years) beginning whichever is earlier:
 - (a) four months following the ‘actual possession date’ or
 - (b) the date the tenant has obtained all licenses and permits necessary to operate a dialysis clinic at the site.
- The tenant has the right to renew the lease for three additional 5 year periods.
- All costs associated with the lease and substantiated in the pro forma revenue and expense statements.
- The lease has a “no assignment or sub-letting” clause; however, it can be transferred with permission by the landlord.
- The draft lease includes the appropriate zoning information.

Ground Lease

- This agreement is dated May 24, 2017 between SVK Investments, LLC (landlord) and Total Renal Care (tenant) for space at *“the northeast corner of Highway 8 and Highway 12, Elma Washington.”*
- The ground lease allows the landlord to lease to the tenant the site for the dialysis center. The premises are part of a larger shopping center of 350,349 square feet in a commercial development known as Eagle’s Landing. The site for the dialysis center is an approximate 8,000 square foot building.
- The term for this lease is 50 years (600 months) beginning when the tenant issues the “Notice to Proceed” as defined in the Ground Lease
- All costs associated with the lease and substantiated in the pro forma revenue and expense statements.

The Executed Ground Lease allows for Total Renal Care to lease the site and the building from the owner SVK Investments. Since this lease is executed, the department concludes that Total Renal Care has ‘site control’ for the property and the building.

The draft Lease Agreement between Palestra Real Estate Partners, Inc. (landlord) and Total Renal Care (tenant) allows the Total Renal Care to assign its interest in the Ground Lease to Palestra Real Estate Partners, Inc. This assignment allows the landlord to build out the building to make it useable as a dialysis center. Once the building is completed by Palestra Real Estate Partners, Inc. this draft Lease Agreement also allows the completed building to be lease the tenant (Total Renal Care).

In its rebuttal, Kalpine makes two assertions:

- 1) *Kalpine adequately demonstrated site control with a complete, draft lease; and*
- 2) *Kalpine and Palestra Real Estate Partners signed the [ground] lease in May 2017.*

Both of these statements are incorrect. First, Kalpine is not mentioned anywhere in the signed Ground Lease. Only Total Renal Care (DaVita) is identified in the lease and a representative of Total Renal Care signed the lease. Second, Kalpine is not mentioned anywhere in the draft Lease Agreement with Palestra Real Estate Partners, Inc. Again, only Total Renal Care is identified in the lease.

Even though DaVita is a majority owner of Kalpine, Kalpine Dialysis, LLC is a separate legal entity from DaVita and Total Renal Care based on the Washington State Secretary of State information provided in the application. As a result, only a representative of Kalpine can sign a legal document for Kalpine Dialysis, LLC.

For these reasons, the department concludes that Kalpine did not demonstrate site control for the dialysis center in Elma. As a result, the assumptions used by Kalpine to project their expenses (and consequently their net income) cannot be substantiated because they did not demonstrate control of their proposed site. **Kalpine does not meet this sub-criterion.**

DaVita HealthCare Partners, Inc.

DaVita proposes a new 8-station facility in Elma that would be operational in late year 2020. The center would be leased by DaVita from Palestra Real Estate Partners, Inc. DaVita provided the assumptions used to project in-center and home treatments and patients for calendar years 2020 through 2023. Below is a summary of the assumptions. [source: Application, pp13-15 and DaVita screening response, p2]

- The new facility would become operational near end of year 2020.
- Year 2021 is the full calendar year one for the dialysis center; year 2023 is full calendar year three.
- Utilization is based on the projected number of patients and treatments in Grays Harbor County. [department’s numeric methodology]
- In-center treatments are based on an assumption of 3 treatments per week per patient for 52 weeks with a 5% allowance for missed treatments.

Using the assumptions stated above, DaVita’s projected number of in-center and home dialyses and patients for the 8-station facility is shown in Table 15 below. [source: Application, p11 and Appendix 9]

Table 15
DaVita Elma Dialysis Center
Projected Patients and Dialyses for Years 2021-2023

	CY 2021	CY 2022	CY 2023
# of Stations	8	8	8
Total Treatments	4,303	5,690	6423
Total Patients	161	172	184

DaVita provided the following assumptions used to project revenue, expenses, and net income for its 8-station center. [source: DaVita screening response, pp4-6]

- *We used DaVita’s historical experience operating facilities in the state of Washington to estimate the future revenue and expenses for the Elma facility. We projected revenue for the new facility by multiplying the average net revenue per treatment for the existing DaVita facilities in the surrounding region by the estimated number of treatments at the new facility. These estimates are primarily driven by census assumptions from current Network 16 ESRD patient data as well as patients' geographic locations and likely preferences. This methodology is consistent with how the pro-forma has been prepared for new DaVita facilities that the Department has approved in the past.*
- *The “G & A Allocation” for this facility is \$18 per treatment. This is the standard G & A assumption used by DaVita in previous applications.*
- *The "Lease Expenses" line item in the pro-forma refers to the building lease due to Palestra Real Estate Partners, Inc. and is composed of two items 1) the base rent and 2) taxes and common area maintenance fees (CAM). The base rent amount is called out in Section 3 of the lease agreement with Palestra Real Estate Partners, Inc. The taxes and CAM are calculated at a per square foot rate of \$4.50. For example, Lease Expense for 2021 is base rent (\$192,000) plus Taxes and CAM (\$36,000) for a total of \$228,000, which matches the proforma.*
- *The cost associated with the ground lease is only incurred during the time period before the pro forma. As mentioned above, the ground lease is transferred to Palestra Real Estate Partners, Inc. and the associated costs are passed along to the Contractual manager as part of the base rent, which is included in the pro forma above.*

Based on the assumptions above, DaVita projected the revenue, expenses, and net income for its 8-station dialysis center for years 2021 through 2025. A summary of the projections for years 2021 through 2023 is in Table 16 below. [source: Application Appendix 9]

Table 16
DaVita Elma Dialysis Center
Projected Revenue and Expenses for Years 2021-2023

	CY 2021	CY 2022	CY 2023
Net Revenue	\$2,055,902	\$2,755,811	\$3,153,655
Total Expenses	\$1,713,659	\$2,003,731	\$2,229,684
Net Profit / (Loss)	\$342,243	\$752,080	\$923,971

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

The ‘Total Expenses’ line item includes all expenses related to the projected operation of the new 8-station facility, including allocated costs. The line item also includes medical director costs consistent with the draft Medical Director Agreement provided in the application. The line item also includes all expenses for ground lease and building lease expenses [source: DaVita screening response, pp4-6 and Appendix 9]

FMC Public Comment

“Documentation of site control is a requirement for any applicant. DVA failed to provide a signed, binding letter of intent between the builder of the facility [Palestra Real Estate Partners, Inc.] to be operated by DVA and the DaVita entity that would lease the facility [Total Renal Care]. Instead, DVA Elma only provided a draft build-to-suit lease agreement between Palestra and Total Renal

Care that does not constitute a legally binding agreement. There is no signed documentation that is legally enforceable, that shows Total Renal Care has a binding agreement with the proposed landlord and that the landlord is bound to provide the space in the event a CON is awarded. Without this signed document, the applicant, DVA Elma, does not have binding site control, as required. [source: FMC public comment, p4]

For the purposes of the DVA Elma project, there are three primary actors:

<i>SVK Investments, LLC</i>	<i>Current owner of site</i>
<i>Palestra Reals Estate Partners, Inc.</i>	<i>Future owner if DVA Elma is approved. Will build DVA Elma facility and act as landlord.</i>
<i>Total Renal Care, Inc.</i>	<i>DaVita entity. Will act as Tenant to lease the facility to be operated by DVA Elma.</i>

The applicant is required to show documentation that the seller of the site is in fact the legal owner of the property. DVA Elma has provided required documents demonstrating SVK Investments is the rightful owner of the site and is able to enter into a contract leasing the site. DVA Elma also provided a signed ground lease agreement between SVK Investments and Total Renal Care. However, this alone does not document site control for the DVA Elma project, as DVA Elma failed to provide a signed, binding letter of intent between the builder of the facility [Palestra Real Estate Partners, Inc.] to be operated by DVA Elma and the DaVita entity that would lease the facility [Total Renal Care]. Instead, DVA Elma has only provided a draft build-to-suit lease agreement between Palestra and Total Renal Care that does not constitute a legally binding agreement. There is no signed documentation that is legally enforceable, that shows Total Renal Care has a binding agreement with the proposed landlord, Palestra Real Estate Partners. A draft lease is insufficient; there must be a signed letter of intent to lease that binds both parties in the event a certificate of need is awarded. Without this signed document, the applicant, DVA Elma (or Total Renal Care), does not have binding site control, as required. Consequently, its project should be denied.” [source: FMC public comment, pp6-7]

DaVita Rebuttal Comment

“Consistent with Department precedent, the draft lease provided by DaVita satisfies site control. Moreover, the draft lease subsequently was signed by DaVita and Palestra Real Estate Partners. Contrary to FMC’s argument, DaVita adequately demonstrated site control with a complete, draft lease. Moreover DaVita and Palestra Partners signed the draft lease in May 2017.

On October 30, 2017, the Review Officer, the Department’s final decision-maker in CON matters, ruled that a complete, draft lease may be accepted to establish site control. See In the Matter of Certificate of Need #1580 Issued to US HealthVest, LLC, Master Case No. M2016-876, Findings of Fact, Conclusions of Law, and Final Order, at 4 (Oct. 30, 2017) (“[A]ccepting a draft (but complete) lease during the CN application and evaluation stage is acceptable as long as a successful CN is conditioned upon submission of a copy of an executed lease consistent with the draft reviewed by the Program .”). DaVita submitted with its application a draft lease that contains all required elements: It shows the parties to the lease (Palestra Real Estate Partners and Total Renal Care, Inc.), the project site (the Northeast corner of Highway 8 and Highway 12 in Elma, Washington), and rent (\$192,000 per year for the first five years). This lease demonstrated site control consistent with the standard explained by the Review Officer in her October 30 order.

- This agreement is between Palestra Real Estate Partners, Inc. (landlord) and Total Renal Care (tenant) for space at “*the northeast corner of Highway 8 and Highway 12, Elma Washington.*”
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- The draft Lease Agreement states: “*It is understood and agreed by and between the parties hereto that the existence of this Lease is dependent and conditioned upon: (i) the continued existence of the Ground Lease, or (ii) Landlord’s purchase of the Property in accordance with the terms and conditions of the Ground Lease (such purchase shall be referred to as the “Release”).*”
- The term for this lease is 180 months (15 years) beginning whichever is earlier:
 - (a) four months following the ‘actual possession date’ or
 - (b) the date the tenant has obtained all licenses and permits necessary to operate a dialysis clinic at the site.
- The tenant has the right to renew the lease for three additional 5 year periods.
- All costs associated with the lease and substantiated in the pro forma revenue and expense statements.
- The lease has a “no assignment or sub-letting” clause; however, it can be transferred with permission by the landlord.
- The draft lease includes the appropriate zoning information.

Ground Lease

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- The term for this lease is 50 years (600 months) beginning when the tenant issues the “Notice to Proceed” as defined in the Ground Lease
- All costs associated with the lease and substantiated in the pro forma revenue and expense statements.

The Executed Ground Lease allows for Total Renal Care to lease the site and the building from the owner SVK Investments. Since this lease is executed, the department concludes that Total Renal Care has ‘site control’ for the property and the building.

The draft Lease Agreement between Palestra Real Estate Partners, Inc. (landlord) and Total Renal Care (tenant) allows the Total Renal Care to assign its interest in the Ground Lease to Palestra Real Estate Partners, Inc. This assignment allows the landlord to build out the building to make it useable

as a dialysis center. Once the building is completed by Palestra Real Estate Partners, Inc. this draft Lease Agreement also allows the completed building to be lease the tenant (Total Renal Care).

In its rebuttal, DaVita makes two assertions:

- 3) *DaVita adequately demonstrated site control with a complete, draft lease; and*
- 4) *DaVita and Palestra Real Estate Partners signed the [ground] lease in May 2017.*

Both of these statements are correct because DaVita or Total Renal Care is identified throughout each document. Further, a representative of Total Renal Care signed the Ground Lease Agreement in May 2017.

The department concludes that DaVita demonstrated site control for the dialysis center in Elma. The lease costs can be verified in the pro forma Revenue and Expense Statement provided in the application. Further the department concludes that the assumptions used by DaVita to project the payer mix, projected patients and dialyses, and revenue/expenses for the proposed 8-station dialysis center in Elma can be substantiated.

If DaVita's project is approved, the department would include a condition requiring DaVita to provide a copy of the executed Lease Agreement consistent with the draft agreement provided in the application. With the following condition, the department concludes DaVita's project **meets this sub-criterion**.

- Prior to commencing the project, DaVita HealthCare Partners, Inc. will provide to the department for review and approval a copy of an executed lease agreement for the site. The executed agreement must be consistent with the draft agreement provided in the application.

- (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 does not contain specific WAC 246-310-220(2) financial feasibility 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 an unreasonable impact on costs and charges would be for a project of this type and size. Therefore, using its experience and expertise the department compared the proposed project's costs with those previously considered by the department.

Fresenius Medical Care

FMC proposes to relocate FMC Aberdeen Dialysis Center and add 8 stations, for a facility total of 24 stations. FMC has been operating the dialysis center at the current site in Aberdeen at 2012 Industrial Parkway since approximately November 2004. For this project, FMC proposes to relocate the facility to a new site in Aberdeen. FMC purchased the site for the new facility, however, the building must be constructed. The postmaster has not assigned an address for the site. The executed lease agreement provides a parcel number and a description of "*approximately +/- 56,628 square foot parcel located at the corner of Skyview Lane and Basich Boulevard, Aberdeen, WA 98520.*" [source: FMC screening response, Revised Exhibit 11C]

Given that the dialysis center will be relocated to the new site before stations are added, FMC identified all costs for the project, which includes relocation of the existing 16 station facility and costs to add 8 stations. The total costs to relocate and add stations is \$6,551,943. Information

provided in the application shows that the landlord agreed to be financially responsible for 66%—or \$4,378,193—of the \$6,551,943 necessary costs to relocate FMC Aberdeen and add eight stations.

Table 17 below shows the capital costs for the relocation and station addition that FMC will be required to pay. [source: Application, p27]

Table 17
FMC Aberdeen Dialysis Center - FMC's Portion of the Costs

Item	Relocate	Add 8 Stations	Total w/ 24 Stations
Land Purchase	\$0	\$0	\$0
Land/Building Improvements	\$0	\$0	\$0
Building Construction (tenant improvements)	\$1,456,426	\$182,409	\$1,638,835
Fixed Equipment	\$351,073	\$43,970	\$395,043
Moveable Equipment	\$0	\$0	\$0
Architect/Engineering Fees	\$124,304	\$15,568	\$139,872
Consulting Fees	\$0	\$0	\$0
Site Preparation	\$0	\$0	\$0
Supervision & Inspection	\$0	\$0	\$0
Costs of Securing Financing	\$0	\$0	\$0
Sales Tax	\$0	\$0	\$0
Other-Permits/Fees	\$0	\$0	\$0
Other-Real Estate Commission	\$0	\$0	\$0
Other-Legal Fees	\$0	\$0	\$0
Total Capital Expenditure	\$1,931,803	\$241,947	\$2,173,750

Table 18 below shows the capital costs for the relocation and station addition that the landlord agreed to pay. [source: Application, p27]

Table 18
FMC Aberdeen Dialysis Center - Landlord's Portion of the Costs

Item	Relocate	Add 8 Stations	Total w/ 24 Stations
Land Purchase	\$1,132,500	\$0	\$1,132,500
Land/Building Improvements	\$2,161,262	\$181,400	\$2,342,662
Building Construction (tenant improvements)	\$0	\$0	\$0
Fixed Equipment	\$0	\$0	\$0
Moveable Equipment	\$0	\$0	\$0
Architect/Engineering Fees	\$177,213	\$0	\$177,213
Consulting Fees	\$83,500	\$0	\$83,500
Site Preparation	\$0	\$0	\$0
Supervision & Inspection	\$64,109	\$0	\$64,109
Costs of Securing Financing	\$213,209	\$0	\$213,209
Sales Tax	\$0	\$0	\$0
Other-Permits/Fees	\$175,000	\$0	\$175,000
Other-Real Estate Commission	\$125,000	\$0	\$125,000
Other-Legal Fees	\$65,000	\$0	\$65,000
Total Capital Expenditure	\$4,196,793	\$181,400	\$4,378,193

In addition to the two tables above, FMC provided the following statement related to this sub-criterion, specifically related to costs and charges. [source: Application, pp27-28]

“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. Further, it is important to understand the basis for FKC reimbursement, given this Department question, which raises the issue of capital expenditures and their potential effect on costs and charges for health services.

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 FKC.

In the case of private sector payers, FKC 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").

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

As a follow-up to this question regarding impacts on costs, charges and reimbursement, and what elements make up reimbursement, which is what the question focuses on, it should be noted that CMS has implemented QIP with the express purpose of linking payment for care directly to providers' performance on quality of care measures. Over time, all payers will adapt some or all of these same standards, and will increasingly tie reimbursement to TPS measures.”

Kalpine and DaVita Public Comment

Both Kalpine and DaVita submitted public comments related to this sub-criterion. [source: Kalpine public comment, p4; DaVita public comment, p4]

*“It is unclear what Fresenius’s capital expenditures will be, because Fresenius uses different figures throughout its application. On page 1, Fresenius says that its capital expenditures will be “**\$6.551 million.**” But on page 6, Fresenius says that its capital expenditures will be “**6.476 million.**” On page 14, Fresenius again says that “[t]otal estimated capital expenditures are **\$6.476 million.**” But then in Table 2, immediately following that statement, Fresenius identifies “total capital expenditures” of “**\$6,551,943.**” The higher figure also is repeated in Table 12 on page 27.*

*What are Fresenius’s capital expenditures? Are they **\$6.551 million**, the figure used on page 1 and in Tables 2 and 12? Or are they **\$6.476 million**, the figure used on page 6 and page 14? Fresenius’s failure to provide a reliable cost figure means the Department cannot know what figure it should use*

for purposes of its financial feasibility and cost containment analysis, or even what capital budget to include in the CON should it approve this project.”

FMC Rebuttal Comment

FMC does not specifically provide rebuttal comment on this topic. Rather, FMC provides a table showing a comparison of the three applicants’ capital expenditure. [see below]

	<i>FKC Aberdeen</i>	<i>Kalpine Dialysis</i>	<i>DaVita Elma</i>
<i>Capital Expenditures</i>	<i>\$423,348</i>	<i>\$2,747,094</i>	<i>\$2,747,094</i>
<i># of stations</i>	<i>8</i>	<i>8</i>	<i>8</i>
<i>Capital (\$) Per Station</i>	<i>\$52,919</i>	<i>\$309,262</i>	<i>\$309,262</i>

The table shows FMC’s costs at \$423,348, which is total amount to be paid by FMC and the landlord to add 8 stations to the Aberdeen facility. FMC’s amount is \$241,947 and the landlord’s amount is 181,400. Under the lease agreement, FMC repays the landlord for its portion of the costs. [source: FMC rebuttal comment, p11]

Department Evaluation

Kalpine and DaVita criticize FMC for not consistently identifying the correct capital expenditure for its project. The criticisms are well founded, especially since FMC did not provide clarification during rebuttal. A review of FMC’s application shows that the \$6.476 amount was referenced twice: once in the Executive Summary and once preceding a table on page 12 of the application. The table, however, correctly adds to the \$6,551,943 amount. All other areas in the application, screening response, and rebuttal documents identify \$6,551,943 for the capital expenditure.

During the screening of FMC’s application, the department inadvertently did not notice the \$6.476 reference, and did not ask FMC to clarify. On the other hand, during rebuttal FMC could have, and should have, provided clarification on Kalpine and DaVita’s assertions. However, it is clear throughout the application that the \$6,551,943 is the correct amount. In this instance, the incorrect reference could be considered a typographical error and should not be grounds for denial of FMC’s project.

FMC’s \$6,551,943 capital expenditure is the combined costs for FMC and the landlord to relocate the 16 station dialysis center and add 8 stations. As stated in the project description section of this evaluation, the costs for the relocation are not included in this review. The costs evaluated in this project are the costs associated with FMC’s portion of the 8 station addition. Those costs are shown in Table 19 below.

Table 19
FMC Aberdeen Dialysis Center - FMC’s Capital Costs

Item	Add 8 Stations
Building Construction (tenant improvements)	\$182,409
Fixed Equipment	\$43,970
Architect/Engineering Fees	\$15,568
Total Capital Expenditure	\$241,947

Documentation provided in the application shows that FMC Aberdeen Dialysis Center’s Medicare and Medicaid reimbursements are projected to equal 42.1% of the revenue at the dialysis center. The department noted that the Medicare/Medicaid and “Other” percentages are different than the other

two applicants, with a seemingly disproportionate amount of revenue coming from commercial payers. FMC offered the following statement related to their assumptions:

“In FMC Aberdeen’s screening response, we identified year-to-date 2017 (January to April) as the basis for the payer mix material presented in Table 4, which is an accurate statement. Our financial model in our application incorporated full year (CY2016) actuals, a more comprehensive set of payer mix statistics.” [source: FMC rebuttal comment, p4]

Furthermore, FMC identified that 88.8% of their patient mix would be comprised of Medicare or Medicaid patients.

The department notes that Medicare and Medicaid patients typically make up the largest percentage of patients served by a dialysis facility. CMS implemented an ESRD Prospective Payment System (PPS). Under the new ESRD PPS, Medicare pays dialysis facilities a bundled rate per treatment. The rate is not the same for each facility.

Each facility, within a given geographic area, may receive the same base rate. However, there are a number of adjustments both at the facility and at patient-specific level that affects the final reimbursement rate each facility will receive. What a dialysis facility receives from its commercial payers will also vary. Even if two different dialysis providers billed the same commercial payer the same amount, the actual payment to each facility will depend on the negotiated discount rate obtained by the commercial payer from each individual provider. The department does not have an adopted standard on what constitutes an unreasonable impact on charges for health services. Based on department’s understanding of how dialysis patients may qualify for Medicare payments, the department concludes that the information presented by FMC about its revenue indicates this project may not have an unreasonable impact on charges for Medicare and Medicaid, since that revenue is dependent upon cost based reimbursement. The remaining 57.7% of FMC Aberdeen’s revenue will be derived through a variety of reimbursement sources such as private insurance. [source: FMC rebuttal comment, p4]

Based on the above information provided in the application, the department concludes that the costs associated with the addition of eight stations to FMC Aberdeen Dialysis Center would probably not have an unreasonable impact on the costs and charges for healthcare services in Grays Harbor County. **This sub-criterion is met.**

Kalpine Dialysis, LLC

Kalpine identified the costs for this project, which includes construction costs for the 8-station facility. The capital cost breakdown is shown in Table 20 below. [source: Application, Appendix 7 and Kalpine screening response, p8]

Table 20
Kalpine Elma Dialysis Center -Estimated Capital Costs

Item	Totals
Construction/Leasehold Improvements	\$1,671,000
Professional Service/Architect Fees	\$193,000
Fixed and Moveable Equipment	\$610,094
Architect/Engineering Fees	\$0
Real Estate Commission	\$0
Total Estimated Capital Costs	\$2,474,094

Kalpine provided the following statements related to the estimated construction costs and equipment costs. [source: Application, p24]

“Elma Dialysis Center’s capital expenditures have been estimated based on DaVita’s historical experience. DaVita has constructed many dialysis facilities locally and throughout the United States. ‘Professional service fees’ includes any architecture and engineering costs as well as the costs associated with utilities hook-ups.”

Kalpine provided the following statements related to this sub-criterion. [source: Application, p21]

“No existing facility is expected to lose volume or market share below Certificate of Need standards as a result of this project. The proposed facility will operate at utilization levels consistent with required utilization levels. Reimbursements for dialysis services are not subject to or affected by capital improvements and expenditures by providers; the proposed project will have no impact on increases in charges for services within the ESRD planning area.”

FMC Public Comment

“The Kalpine project will be much more costly on a per station basis than FMC. In other words, the FMC project will be more efficient, i.e., lower cost and will have a lower impact on patient costs and charges. See Table 2 below for a comparison of the three applicants' capital expenditures and per-unit statistics to compare relative costs, i.e., efficiency in terms of cost per unit of service. As shown below, Kalpine and DVA Elma's proposed developments are considerably more costly, with capital costs per station just under six times more expensive than FMC Aberdeen's requested expansion (\$309,262/\$52,919 = 5.84).”

Table 2 Comparison

	FKC Aberdeen	Kalpine Dialysis	DaVita Elma
Capital Expenditures	\$423,348	\$2,747,094	\$2,747,094
# of stations	8	8	8
Capital (\$) Per Station	\$52,919	\$309,262	\$309,262
Patients-Year 3	132	46	46
Capital (\$) Per Patient – Year 3	\$3,207	\$53,785	\$53,785
Treatments – Year 3	19,008	6,423	6,423
Capital (\$) Per Treatment – Year 3	\$3	\$48	\$48

FMC Aberdeen Source: CN 17-40, Screening Response #1 , p 3.

Kalpine Source: CN 17-44 Application, p. 10.

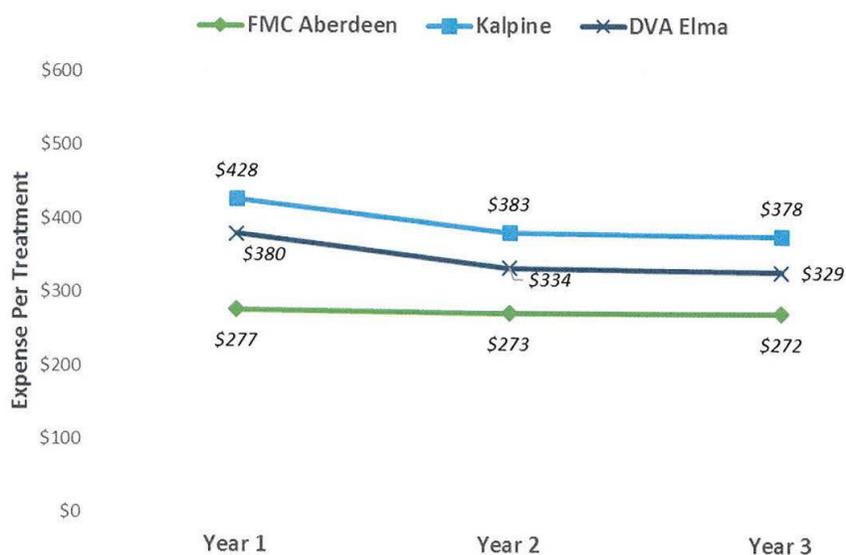
DVA Source: CN 17-46 Application, p. 9.

“Operating expense per unit of measure is a second metric routinely used to evaluate and compare the relative efficiency, per unit of service, of the three applicants. Lower operating expenses per treatment demonstrates greater efficiency by FMC Aberdeen, thus, superior conformance to the guiding principles of efficiency and cost effectiveness for CON review. Figure 3 below shows the total direct expenses per treatment for [full] years 1-3 for each applicant's respective project. Based on this evaluation, Kalpine is the least efficient, i.e. highest average cost, of any of the Grays Harbor ESRD applicants, and FMC Aberdeen, the most efficient.

- *Kalpine's projected expense per treatment in its third full year of operation is 38.8% more (\$378/\$272 = 138.8%) than FMC Aberdeen in its third full year of operation;*

- *Kalpine's projected average expenses would even be 14.8% more than the proposed DVA Elma facility in each facility's third full year of operation (\$378/\$329 = 114.8%).*
- *The proposed DVA Elma facility has projected average expenses that are 20.8% greater than FMC Aberdeen (\$329/\$272 = 120.8%) in each organization's third full year of operation.*

FMC Aberdeen is projected to be the most efficient, i.e., able to achieve lower per unit expenses, because of its comparative advantage capturing economies of scale, which is the result of expanding existing capacity to 24 stations in the event its project is approved. It is also due to the fact that Kalpine and DVA are proposing a facility that is much larger than actually needed, creating idle capacity and, by definition, a relatively less efficient operation compared to FMC. This is further detailed below. [source: FMC public comment, pp11-12]



FMC Aberdeen: CN 17-40, Screening Response #1, Revised Exhibit 138 (p 207). Includes physician compensation.

Kalpine Source: CN 17-44, Screening Response #1, Revised Appendix 9a, p. 63.

DVA Source: CN 17-46, Application, Appendix 9, p. 184.

“Kalpine proposes an 8,000 sq. ft. facility, which is clearly too large for only 8 stations. This creates unnecessary project costs which in recent decisions, the Department has not allowed.

The single line drawing provided in Appendix 16 of CN #17-44 shows expansion space for 2 additional stations beyond its current request for 8 stations, with total facility build-out capacity of 10 dialysis stations. Further, there is significantly more space identified in the single line drawing, which clearly shows the proposed facility would have a large amount of idle space. In other words, the facility is being overbuilt, which increases capital costs.

The Department has recently denied several CN applications that have included too much expansion space in the facility single line drawing. In a recent decision regarding DaVita's CN #15-06A2 requesting six stations for a new dialysis facility in the Lewis County service area, in its evaluation, where it denied the DVA request, the Department stated the following:

'In reviewing the line drawing supplied by DaVita, the project is a 13-station dialysis facility rather than a six station facility. The department has historically approved dialysis projects containing some shelled-in space for reasonable future expansion. This space has been intended to allow for cost-effective expansions where a small number of become needed in a planning area. In this case the number of stations for expansion exceeds the needed stations by over two times. Also this expansion space is integral to the treatment space proposed for this project. The department generally views expansion space as a separate unfinished space that could be finished in the future for expansion. This project does not seem to fit this concept. It appears from the line drawing that the expansion space would need to be finished as part of this project. This expansion space will need to be paid for by the costs and charges for dialysis treatments provided in the six stations until such time as an expansion would be approved. It does not seem cost-effective to over build a project to this extent. The department concludes that this project is overbuilt for the projected need in this dialysis planning area ... these rates are higher than necessary to support the unnecessary capital and operating costs of this over built facility.'

This determination by the department caused it to fail the DVA application on Financial Feasibility grounds, and its application was denied. In 2016, in a settlement with the department over this Lewis County denial, DVA agreed to eliminate this excess space and to build out a facility for only six stations, which was the net planning area need.

In the cases of the Kalpine facility, DVA is proposing essentially the type of project build-out that was denied by the department in Lewis County in 2015-an overbuilt facility with significant idle capacity. The Kalpine single line drawing shows that all of the additional stations would be located in the main treatment area. Its drawing shows space for two additional stations would be finished, while "shell" space would also be constructed, which appears to include additional space for two or three more stations. The space for all of these expansion stations would need to be constructed and would add to the capital costs, whether it's the two shown on the drawings or it's those two stations plus an additional two-three stations, for a total expansion of four-five stations. Kalpine has not explained whether it planned to utilize space allocated for all of these future stations productively and cost-effectively, or if it will leave this space as idle capacity. Based on existing, available information, it appears this space will be idle, and in part, shelled space.

The over-built facility proposed by Kalpine is a poor choice for patients in the Grays Harbor Planning Area and it raises costs. In light of the Department's recent stance on expansion space, Kalpine's proposed project fails CN Financial Feasibility criteria and its project should be denied. [source: FMC public comment, pp13-14]

Kalpine Rebuttal Comment

FMC's argument that its proposed facility will be more efficient in terms of capital expenses fails to take into account FMC's total required expenditure for the relocation and expansion. When Kalpine's costs are compared against FMC's total costs, the capital and operating expenditures per station and treatment are comparable. FMC includes in its comments a chart that purportedly compares "the three applicants' total capital expenditures and per-station statistics to compare relative cost control." FMC uses this chart to argue that Kalpine's capital cost per station is substantially higher than FMC's. This is incorrect. FMC includes in its chart only the capital costs for its proposed expansion; it omits the costs for the relocation, which are significant (\$6,128,595). As FMC admits on page 32 of its application, "the expansion necessitates relocation." In other words, FMC cannot add these eight stations in the planning area without incurring the total cost to relocate its existing

facility to a new, larger location. When FMC's calculations are corrected to compare the total cost of FMC's project against the total cost of the Kalpine project, the chart shows that the capital costs per station are comparable.

Figure 4

	FMC-FKC Aberdeen	Kalpine Dialysis, LLC
Capital Expenditures	\$6,551,943	\$2,474,094
# of Stations	24	8
Capital (\$) Per Station	\$272,997	\$309,262

FMC also criticizes Kalpine's anticipated operating costs, but this criticism is again misplaced. FMC makes much of the fact that Kalpine's anticipated operating costs per treatment are slightly higher than FMC's anticipated operating costs per treatment. But in reality, both providers' projected operating expenses are within a reasonable range.

Furthermore, the size of FMC's proposed facility (24 stations compared to 8 at Kalpine's proposed facility) dilutes both capital costs and operating costs, on a per-station basis, because certain expenses that any dialysis facility would need, regardless of size, are divided between more stations. Moreover, if this were given the undue weight FMC advocates, the Program's analysis would always favor the largest possible facility. Recent experience shows that this is not the case. In Pierce 5, for example, the Program approved several smaller facilities (rather than one large facility) to, among other reasons, improve geographic access. See Wash. State Dep't of Health, Evaluation Dated March 30, 2017 for Six Certificate of Need Applications, Each Proposing to add Dialysis Station Capacity to Pierce County Planning Area #5 (Mar. 30, 2017) (approving several small facilities in Pierce County planning area No. 5 to meet a 44-station need). Kalpine's eight-station facility will serve patients where they live. It is the better choice." [source: Kalpine rebuttal comment, pp6-7]

Department Evaluation

FMC's comments focus on a comparison of capital expenditures among itself, Kalpine, and DaVita. While the comments are pertinent for this sub-criterion, the difference in the costs identified by FMC in the table is not grounds for denial of Kalpine's project.

FMC also asserts that Kalpine's floor plans shows space to accommodate at least two more stations, for a facility total of ten. FMC also notes that the facility would have a 'large amount of idle capacity' that should be considered an over-build of space. Kalpine's rebuttal does not address this topic, rather it focuses on the cost comparison for the three projects.

While it is true that the department has denied projects for proposing an over-build of space, generally the over build has been double the amount of stations requested in the application. Kalpine is not requesting to build space for a 16 or more station facility and then only operate 8 stations. The floor plans for Kalpine's project appears to include a reasonable amount of space for future station addition and expanded support staff. The issues raised by FMC are not grounds for denial of Kalpine's project.

The costs for establishing its 8-station facility in Elma is \$2,474,094. The costs are comparable to those reviewed in past applications for similar size facility. The department does not consider the capital expenditure to be excessive for this project.

Documentation provided in the application shows that Kalpine’s Elma facility projects Medicare and Medicaid reimbursements equal 56.7% of the revenue at the dialysis center. This amount is consistent with percentages reviewed and approved in past DaVita projects.

The department notes that Medicare and Medicaid patients typically make up the largest percentage of patients served by a dialysis facility. CMS implemented an ESRD Prospective Payment System (PPS). Under the new ESRD PPS, Medicare pays dialysis facilities a bundled rate per treatment. The rate is not the same for each facility.

Each facility, within a given geographic area, may receive the same base rate. However, there are a number of adjustments both at the facility and at patient-specific level that affects the final reimbursement rate each facility will receive. What a dialysis facility receives from its commercial payers will also vary. Even if two different dialysis providers billed the same commercial payer the same amount, the actual payment to each facility will depend on the negotiated discount rate obtained by the commercial payer from each individual provider. The department does not have an adopted standard on what constitutes an unreasonable impact on charges for health services. Based on department’s understanding of how dialysis patients may qualify for Medicare payments, the department concludes that the information presented by Kalpine about its revenue indicates this project may not have an unreasonable impact on charges for Medicare and Medicaid, since that revenue is dependent upon cost based reimbursement. The remaining 61.2% of revenue is combined commercial and other revenues.

Based on the above information provided in the application, the department concludes that Kalpine’s projected costs associated with the establishment of an 8-station dialysis center in Elma would probably not have an unreasonable impact on the costs and charges for healthcare services in Grays Harbor County. **This sub-criterion is met.**

DaVita HealthCare Partners

DaVita identified the costs for this project, which includes construction costs for the 8-station facility. The capital cost breakdown is shown in Table 21 below. [source: Application, Appendix 7 and DaVita screening response, p4]

Table 21
DaVita Elma Dialysis Center - Estimated Capital Costs

Item	Totals
Construction/Leasehold Improvements	\$1,671,000
Professional Service/Architect Fees	\$193,000
Fixed and Moveable Equipment	\$610,094
Architect/Engineering Fees	\$0
Real Estate Commission	\$0
Total Estimated Capital Costs	\$2,474,094

DaVita provided the following statements related to the estimated construction costs and equipment costs. [source: Application, p19 and DaVita screening response, p4]

“DaVita Elma Dialysis Center’s capital expenditures have been estimated based on DaVita’s historical experience. DaVita has constructed many dialysis facilities locally and throughout the United States. ‘Professional service fees’ includes any architecture and engineering costs as well as the costs associated with utilities hook-ups.”

“No existing facility is expected to lose volume or market share below Certificate of Need standards as a result of this project. The proposed facility will operate at utilization levels consistent with required utilization levels. Reimbursements for dialysis services are not subject to or affected by capital improvements and expenditures by providers; the proposed project will have no impact on increases in charges for services within the ESRD planning area.”

FMC Public Comment

“The DVA Elma project will be much more costly on a per station basis than FMC. In other words, the FMC project will be more efficient, i.e., lower cost and will have a lower impact on patient costs and charges. The DVA Elma CN request does not meet the following Financial Feasibility criterion in WAC 246-310-220(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.

See Table 2 below for a comparison of the three applicants' total capital expenditures and per station statistics to compare relative cost control. As shown below, DVA Elma and Kalpine's proposed developments are considerably more costly, with capital cost per station just under six times more expensive than FMC Aberdeen's requested expansion. ($\$309,262/\$52,919 = 5.84$)”

Table 2 Comparison

	FKC Aberdeen	Kalpine Dialysis	DaVita Elma
Capital Expenditures	\$423,348	\$2,747,094	\$2,747,094
# of stations	8	8	8
Capital (\$) Per Station	\$52,919	\$309,262	\$309,262
Patients-Year 3	132	46	46
Capital (\$) Per Patient – Year 3	\$3,207	\$53,785	\$53,785
Treatments – Year 3	19,008	6,423	6,423
Capital (\$) Per Treatment – Year 3	\$3	\$48	\$48

FMC Aberdeen Source: CN 17-40, Screening Response #1, p 3.

Kalpine Source: CN 17-44 Application, p. 10.

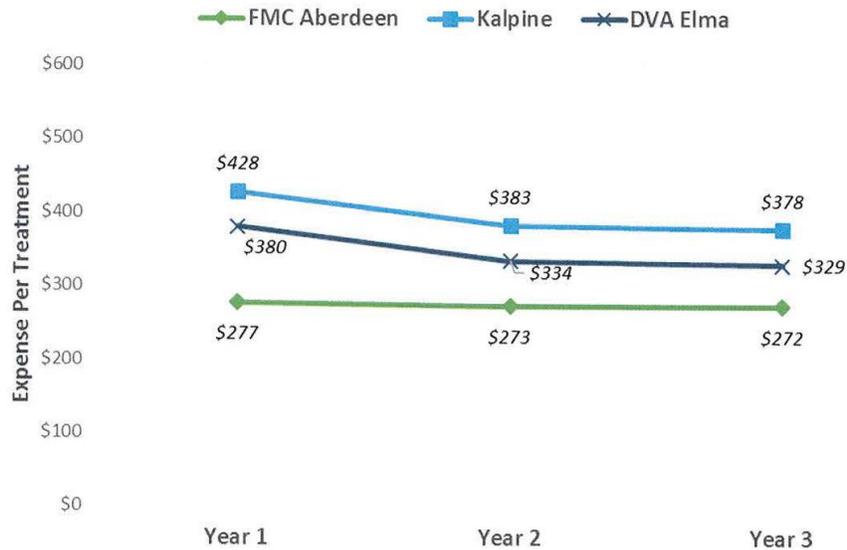
DVA Source: CN 17-46 Application, p. 9.

Operating expense per unit of measure is a second metric routinely used to evaluate and compare the relative efficiency, per unit of service, of the three applicants. Lower operating expenses per treatment demonstrates greater efficiency by FMC Aberdeen, thus, superior conformance to the guiding principles of efficiency and cost effectiveness for CON review. Figure 3 below shows the total direct expenses per treatment for [full] years 1-3 for each applicant's respective project.

Based on this evaluation, DVA Elma is more efficient than the Kalpine proposal, but much less efficient, i.e. higher average cost, than FMC Aberdeen, which is the most efficient.

- The proposed DVA Elma facility has projected average operating expenses that are 20.8% greater than FMC Aberdeen ($\$329/\$272 = 120.8\%$) in each organization's third full year of operation.
- Kalpine's projected average expenses would even be 14.8% more than the proposed DVA Elma facility in each facility's third full year of operation ($\$378/\$329 = 114.8\%$).
- Kalpine's projected expense per treatment in its third full year of operation is 38.8% more ($\$378/\$272 = 138.8\%$) than FMC Aberdeen in its third full year of operation.

FMC Aberdeen is projected to be the most efficient, i.e., able to achieve lower per unit expenses, because of its comparative advantage capturing economies of scale, which is the result of expanding existing capacity to 24 stations in the event its project is approved. It is also due to the fact that Kalpine and DVA Elma are proposing a facility that is much larger than actually needed, creating idle capacity and, by definition, a relatively less efficient operation compared to FMC. This is further detailed below. [source: FMC public comment, pp11-12]



FMC Aberdeen: CN 17-40, Screening Response #1, Revised Exhibit 138 (p 207). Includes physician compensation.

Kalpine Source: CN 17-44, Screening Response #1, Revised Appendix 9a, p. 63.

DVA Source: CN 17-46, Application, Appendix 9, p. 184.

“DVA Elma proposes an 8,000 sq. ft. facility, which is clearly too large for only 8 stations. This creates unnecessary project costs which in recent decisions, the Department has not allowed. The single line drawing provided in Appendix 16 of CN #17-46 shows expansion space for 2 additional stations beyond its current request for 8 stations, with total facility build-out capacity of 10 dialysis stations. Further, there is significantly more space identified in the single line drawing, which clearly shows the proposed facility would have a large amount of idle space. In other words, the facility is being overbuilt, which increases capital costs.

The Department has recently denied several CN applications that have included too much expansion space in the facility single line drawing. In a recent decision regarding DaVita's CN #15-06A2 requesting six stations for a new dialysis facility in the Lewis County service area, in its evaluation, where it denied the DVA request, the Department stated the following:

‘In reviewing the line drawing supplied by DaVita, the project is a 13-station dialysis facility rather than a six station facility. The department has historically approved dialysis projects containing some shelled-in space for reasonable future expansion. This space has been intended to allow for cost-effective expansions where a small number of become needed in a planning area. In this case the number of stations for expansion exceeds the needed stations by over two times. Also this expansion space is integral to the treatment space proposed for this project. The department generally views expansion space as a

separate unfinished space that could be finished in the future for expansion. This project does not seem to fit this concept. It appears from the line drawing that the expansion space would need to be finished as part of this project. This expansion space will need to be paid for by the costs and charges for dialysis treatments provided in the six stations until such time as an expansion would be approved. It does not seem cost-effective to over build a project to this extent. The department concludes that this project is overbuilt for the projected need in this dialysis planning area ... these rates are higher than necessary to support the unnecessary capital and operating costs of this over built facility.'

This determination by the department caused it to fail the DVA application on Financial Feasibility grounds, and its application was denied. In 2016, in a settlement with the department over this Lewis County denial, DVA agreed to eliminate this excess space and to build out a facility for only six stations, which was the net planning area need.

In the cases of Elma, DVA is proposing essentially the type of project build-out that was denied by the department in Lewis County in 2015-an overbuilt facility with significant idle capacity. The DVA Elma single line drawing shows that all of the additional stations would be located in the main treatment area. Its drawing shows space for two additional stations would be finished, while "shell" space would also be constructed, which appears to include additional space for two-three more stations. The space for all of these expansion stations would need to be constructed and would add to the capital costs, whether it's the two shown on the drawings or it's those two stations plus an additional two-three stations, for a total expansion of four-five stations. DVA Elma has not explained whether it planned to utilize space allocated for all of these future stations productively and cost-effectively, or if it will leave this space as idle capacity. Based on existing, available information, it appears this space will be idle, and in part, shelled space.

The over-built facility proposed by DVA Elma is a poor choice for patients in the Grays Harbor Planning Area and it raises costs. In light of the Department's recent stance on expansion space, DVA Elma's proposed project fails CN Financial Feasibility criteria and its project should be denied." [source: FMC public comment, pp13-14]

DaVita Rebuttal Comment

FMC's argument that its proposed facility will be more efficient in terms of capital expenses fails to take into account FMC's total required expenditure for the relocation and expansion. When DaVita's costs are compared against FMC's total costs, the capital and operating expenditures per station and treatment are comparable. FMC includes in its comments a chart that purportedly compares "the three applicants' total capital expenditures and per-station statistics to compare relative cost control." FMC uses this chart to argue that DaVita's capital cost per station is substantially higher than FMC's. This is incorrect. FMC includes in its chart only the capital costs for its proposed expansion; it omits the costs for the relocation, which are significant (\$6,128,595). As FMC admits on page 32 of its application, "the expansion necessitates relocation." In other words, FMC cannot add these eight stations in the planning area without incurring the total cost to relocate its existing facility to a new, larger location. When FMC's calculations are corrected to compare the total cost of FMC's project against the total cost of the DaVita project, the chart shows that the capital costs per station are comparable.

Figure 4

	<i>FMC-FKC Aberdeen</i>	<i>Kalpine Dialysis, LLC</i>
<i>Capital Expenditures</i>	\$6,551,943	\$2,474,094
<i># of Stations</i>	24	8
<i>Capital (\$) Per Station</i>	\$272,997	\$309,262

FMC also criticizes DaVita's anticipated operating costs, but this criticism is again misplaced. FMC makes much of the fact that DaVita's anticipated operating costs per treatment are slightly higher than FMC's anticipated operating costs per treatment. But in reality, both providers' projected operating expenses are within a reasonable range.

Furthermore, the size of FMC's proposed facility (24 stations compared to 8 at DaVita's proposed facility) dilutes both capital costs and operating costs, on a per-station basis, because certain expenses that any dialysis facility would need, regardless of size, are divided between more stations. Moreover, if this were given the undue weight FMC advocates, the Program's analysis would always favor the largest possible facility. Recent experience shows that this is not the case. In Pierce 5, for example, the Program approved several smaller facilities (rather than one large facility) to, among other reasons, improve geographic access. See Wash. State Dep't of Health, Evaluation Dated March 30, 2017 for Six Certificate of Need Applications, Each Proposing to add Dialysis Station Capacity to Pierce County Planning Area #5 (Mar. 30, 2017) (approving several small facilities in Pierce County planning area No. 5 to meet a 44-station need). DaVita's eight-station facility will serve patients where they live. It is the better choice.” [source: DaVita rebuttal comment, pp6-7]

Department Evaluation

FMC’s comments focus on a comparison of capital expenditures among itself, Kalpine, and DaVita. While the comments are pertinent for this sub-criterion, the difference in the costs identified by FMC in the table is not grounds for denial of DaVita’s project.

FMC also asserts that DaVita’s floor plans shows space to accommodate at least two more stations, for a facility total of ten. FMC also notes that the facility would have a ‘*large amount of idle capacity*’ that should be considered an over-build of space. DaVita’s rebuttal does not address this topic, rather it focuses on the cost comparison for the three projects.

While it is true that the department has denied projects for proposing an over-build of space, generally the over build has been double the amount of stations requested in the application. DaVita is not requesting to build space for a 16 or more station facility and then only operate 8 stations. The floor plans for DaVita’s project appears to include a reasonable amount of space for future station addition and expanded support staff. The issues raised by FMC are not grounds for denial of DaVita’s project.

The costs for establishing its 8-station facility in Elma is \$2,474,094. The costs are comparable to those reviewed in past applications for similar size facility. The department does not consider the capital expenditure to be excessive for this project.

Documentation provided in the application shows that DaVita’s Elma facility projects Medicare and Medicaid reimbursements equal 56.7% of the revenue at the dialysis center. This amount is consistent with percentages reviewed and approved in past DaVita projects.

The department notes that Medicare and Medicaid patients typically make up the largest percentage of patients served by a dialysis facility. CMS implemented an ESRD Prospective Payment System (PPS). Under the new ESRD PPS, Medicare pays dialysis facilities a bundled rate per treatment. The rate is not the same for each facility.

Each facility, within a given geographic area, may receive the same base rate. However, there are a number of adjustments both at the facility and at patient-specific level that affects the final reimbursement rate each facility will receive. What a dialysis facility receives from its commercial payers will also vary. Even if two different dialysis providers billed the same commercial payer the same amount, the actual payment to each facility will depend on the negotiated discount rate obtained by the commercial payer from each individual provider. The department does not have an adopted standard on what constitutes an unreasonable impact on charges for health services. Based on department's understanding of how dialysis patients may qualify for Medicare payments, the department concludes that the information presented by DaVita about its revenue indicates this project may not have an unreasonable impact on charges for Medicare and Medicaid, since that revenue is dependent upon cost based reimbursement. The remaining 61.2% of revenue is combined commercial and other revenues.

Based on the above information provided in the application, the department concludes that DaVita's projected costs associated with the establishment of an 8-station dialysis center in Elma would probably not have an unreasonable impact on the costs and charges for healthcare services in Grays Harbor County. **This sub-criterion is met.**

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

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

Fresenius Medical Care

FMC intends to finance the project using existing capital reserves. FMC provided a letter of financial commitment from Mark Fawcett, Senior Vice President & Treasurer at FMC. [source: Application Exhibit 7]

FMC also provided audited financial statements for fiscal years 2015 and 2016 to demonstrate availability of funding. [source: Application, Exhibit 15A]

Public Comment

None

Rebuttal Comment

None

Department Evaluation

FMC's actual costs to add eight stations to FMC Aberdeen Dialysis Center is \$241,947. FMC intends to finance the project with reserves and demonstrated the funds are available. If this project is

approved, the department would attach a condition requiring FMC to finance the project consistent with the financing description provided in the application.

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

Kalpine Dialysis, LLC

Kalpine identified a capital expenditure of \$2,474,094 to establish an 8-station facility in Elma, within Grays Harbor County. Kalpine provided the following statements related to the financing of the facility. [source: Application, p21 and Kalpine screening response, p4]

“Elma Dialysis Center will be cash financed. A letter of Operational and Financial commitment for both DaVita and the physician members is included as Appendix 6. The project will be financed by cash as follows: DaVita 79% (\$1,954,534); Seth Thaler 16% (\$395,855) and Vo Nguyen 5% (\$123,705).”

Kalpine provided financial commitment letters from DaVita, Dr. Vo Nguyen, and Dr. Seth Thaler. Kalpine also provided a copy of DaVita’s audited financial statements for years 2014, 2015, and 2016 to demonstrate sufficient reserves from DaVita to finance its portion of the project. Kalpine provided a letter from Ameritrade to demonstrate that Dr. Nguyen had sufficient funds to finance his portion of the project. Kalpine provided a letter from Morgan Stanley to demonstrate that Dr. Thayler had sufficient funds to finance his portion of the project. [source: Application, Appendix 6 and Kalpine screening response, Appendix 23]

Public Comment

None

Rebuttal Comment

None

Department Evaluation

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

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

DaVita HealthCare Partners, Inc.

DaVita identified a capital expenditure of \$2,474,094 to establish an 8-station facility. DaVita intends to fund the project using corporate reserves. DaVita provided a letter from its corporate chief operating officer for kidney care to demonstrate an operational and financial commitment to the project. [source: Application, p19 and Appendix 6]

DaVita also provided a copy of its audited financial statements for years 2014, 2015, and 2016 to demonstrate sufficient reserves to finance the project. [source: Application, Appendix 10]

Public Comment

None

Rebuttal Comment

None

Department Evaluation

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

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

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

Fresenius Medical Care

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

Kalpine Dialysis, LLC

Based on the source information reviewed, the department concludes that the Kalpine Dialysis, LLC project has not met the structure and process of care criteria in WAC 246-310-230

DaVita Healthcare Partners, Inc.

Based on the source information reviewed, the department concludes that the DaVita HealthCare Partners, Inc. project has not met the structure and process of care criteria in WAC 246-310-230

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

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

Fresenius Medical Care

FMC Aberdeen Dialysis Center is currently operating with 16 stations. FMC provided a breakdown of the additional FTEs needed for the 8 station addition. Table 22 below shows the current and projected FTEs for calendar year 2017 (current) through 2021. [source: Application p30 and FMC screening response, p4]

Table 22
FMC Aberdeen Dialysis Center Current and Projected FTEs

FTE by Type	Current Year 2017	Increase Year 2018	Increase Year 2019	Increase Year 2020	Increase Year 2021	Total Year 2021
Medical Director	Contracted Position					
Nurse Manager	1.00	0.00	0.00	0.00	0.00	1.00
Outpatient RN	5.00	(0.50)	0.50	0.50	0.50	6.00
LPN	0.00	1.00	0.00	0.00	0.00	1.00
Patient Care Tech	9.00	4.00	2.00	1.00	1.00	17.00
Equipment Tech	0.50	0.00	0.00	0.00	0.00	0.50
MSW	0.75	0.00	0.25	0.00	0.25	1.25
Dietician	0.75	0.00	0.25	0.00	0.25	1.25
Facility Administrator	1.00	0.00	0.00	0.00	0.00	1.00
Secretary	1.00	0.00	0.00	0.00	0.00	1.00
FTE Total	19.00	4.50	3.00	1.50	2.00	30.00

FMC provided the following statements related to assumptions used to project the number and type of FTEs for this station addition. [source: FMC screening response, p4]

“Staffing projections began with actual staffing figures at FKC Aberdeen Dialysis Center. The additional number and type of staffing was prepared using a 4:1 PCT (patient care technician) to patient ratio and a 12:1 RN to patient ratio.”

FMC provided the following statements related to recruitment and retention of staff for this proposed station addition at FMC Aberdeen. [source: Application, p32]

“FKC Aberdeen is an operational dialysis facility, currently staffed with qualified clinical and support personnel. Table 13 provides the number of current and proposed FTEs, by type. By virtue of our geographic location, we anticipate recruiting additional staff from Grays Harbor County as well as from neighboring counties in the region. To be effective in staff recruitment and retention, RCG offers competitive wage and benefit packages. For the above reasons, RCG believes that we will be successful in recruiting additional qualified, core staff to provide and promote quality of care at FKC Grays Harbor.”

FMC’s medical director is under contract and FMC provided a copy of the medical director contract between FMC and RVS, PLLC. RVS PLLC is a Washington professional service corporation comprised entirely of physicians.¹⁰ The agreement identifies the following five nephrologists that could provide medical director services at FMC Aberdeen.

- Julie P. Anuras, MD
- Christopher Burtner, MD
- Seth M. Thaler, MD
- Lana Kamal Bur, MD
- Vo Dan Nguyn, MD

The medical director contract includes all duties and responsibilities, compensation (which is consistent with the figures provided in the pro forma financial projections), and outlines a seven year term beginning in year 2015. The agreement is signed by all five physicians.

¹⁰ UBI #602 104 854; registration date March 13, 2001; expiration date March 31, 2018.

Public Comment

None

Rebuttal Comment

None

Department Evaluation

Information provided in the application demonstrates that FMC is a well-established provider of dialysis services. Specific to Washington State, FMC has been providing services in Washington State since approximately 1996. For this project, FMC is proposing to add 8 stations to an existing dialysis center in Aberdeen. FMC Aberdeen Dialysis Center has been operating at the same site since approximately November 2004. Based on the above information, the department concludes that FMC has the ability and expertise to recruit and retain a sufficient supply of qualified staff for this project.

The department concludes the FMC project **meets this sub-criterion.**

Kalpine Dialysis, LLC

If this project is approved, Kalpine will be operating a new 8-station dialysis center in year 2021. Table 23 below provides a breakdown of projected FTEs for years 2021 through 2023. [source: Application, p25]

**Table 23
Kalpine Elma Dialysis Center
Projected FTEs for Years 2021-2023**

FTE by Type	CY 2021 Increase	CY 2022 Increase	CY 2023 Increase	Total FTEs
Administrator	1.00	0.00	0.00	1.00
Administrative Assistant	0.33	0.04	0.05	0.42
Medical Social Worker	0.30	0.04	0.04	0.38
Dietician	0.30	0.04	0.04	0.38
RN-InCenter/PD/HHD	3.81	0.48	0.56	4.85
Biomed Tech	0.20	0.00	0.00	0.2
Other	0.45	0.06	0.06	0.57
Total FTEs	6.39	0.66	0.75	7.80

Kalpine also provided the following clarifications related to the staffing table above.

- *the medical director is under contract and not included in the table above.*
- *we assume a 1:12 nurse to patient ratio. All final staffing ratios are subject to the discretion of the facility's clinical team, as there may be occasions and instances of higher patient acuity that require additional staff. DaVita has historically and will continue to make any adjustments necessary to ensure the highest possible quality of care.*

[source: Kalpine screening response, p4]

Kalpine provided a copy of the draft medical director agreement among Kalpine Dialysis, LLC, Memorial Nephrology Associates, PLLC, and five individual physicians. Each of the five physicians is specifically identified in the draft agreement. The five physicians are listed below.

- Julie P. Anuras, MD
- Christopher Burtner, MD
- Seth M. Thaler, MD
- Lana Kamal Bur, MD
- Vo Dan Nguyn, MD

Memorial Nephrology Associates, PS is a company founded in 1973. According to their website, the group provides mainly nephrology services, including renal consultation, pre-ESRD care, dialysis and transplant follow up. Memorial Nephrology Associates, PS states it provides services at 7 area hemodialysis units. [source: Kalpine screening response, Appendix 3A and Memorial Nephrology Associates website]

Kalpine provided the following statements related to recruitment and retention of staff. [source: Kalpine screening response, pp4-5]

“DaVita, as the Contractual Manager, is responsible for the recruiting and hiring of teammates and anticipates no difficulty in fulfilling this responsibility for a number of reasons. Firstly, DaVita has a strong national brand as an employer of choice that would be attractive to job seekers. DaVita has been named by Fortune as one of the World’s Most Admired Companies for 10 years in a row and named by Training Magazine as one of the Top 125 companies offering exceptional training and leadership development. Secondly, DaVita has internal recruiting and onboarding teams that understand and have experience in the local market. Furthermore, the Elma facility can leverage resources from other DaVita facilities in the area. One of the advantages of the Elma location is its proximity to the neighboring DaVita facilities (Olympia and Tumwater) which allows us to share teammates across these facilities.”

Public Comment

None

Rebuttal Comment

None

Department Evaluation

Kalpine does not currently own or operate dialysis centers in Washington or any other state. For this reason, Kalpine intends to rely on DaVita—its majority owner—to determine appropriate staffing for a new 8-station dialysis center. Further, under the Management Agreement provided in the application, Kalpine intends to rely on DaVita’s experience and expertise to recruit appropriate staff for the new facility.

Based on the above information, the department concludes that Kalpine—with DaVita’s expertise—has the ability to recruit and retain a sufficient supply of qualified staff for this project.

The department concludes the Kalpine project **meets this sub-criterion.**

DaVita HealthCare Partners, Inc.

If this project is approved, DaVita will be operating a new 8-station dialysis center in year 2021. Table 24 below provides a breakdown of projected FTEs for years 2021 through 2023. [source: Application, p21]

Table 24
DaVita Elma Dialysis Center
Projected FTEs for Years 2021-2023

FTE by Type	CY 2021 Increase	CY 2022 Increase	CY 2023 Increase	Total FTEs
Administrator	1.00	0.00	0.00	1.00
Administrative Assistant	0.33	0.04	0.05	0.42
Medical Social Worker	0.30	0.04	0.04	0.38
Dietician	0.30	0.04	0.04	0.38
RN-InCenter/PD/HHD	3.81	0.48	0.56	4.85
Biomed Tech	0.20	0.00	0.00	0.2
Other	0.45	0.06	0.06	0.57
Total FTEs	6.39	0.66	0.75	7.80

DaVita also provided the following clarifications related to the staffing table above.

- *the medical director is under contract and not included in the table above.*
- *we assume a 1:12 nurse to patient ratio. All final staffing ratios are subject to the discretion of the facility's clinical team, as there may be occasions and instances of higher patient acuity that require additional staff. DaVita has historically and will continue to make any adjustments necessary to ensure the highest possible quality of care.*

[source: DaVita screening response, p2]

DaVita provided a copy of the draft medical director agreement among Total Renal Care (DaVita), Memorial Nephrology Associates, PLLC, and five individual physicians. Each of the five physicians is specifically identified in the draft agreement. The five physicians are listed below.

- Julie P. Anuras, MD
- Christopher Burtner, MD
- Seth M. Thaler, MD
- Lana Kamal Bur, MD
- Vo Dan Nguyn, MD

As previously stated, Memorial Nephrology Associates, PS is a company founded in 1973. According to their website, the group provides mainly nephrology services, including renal consultation, pre-ESRD care, dialysis and transplant follow up. Memorial Nephrology Associates, PS states it provides services at 7 area hemodialysis units. [source: Application, Appendix 3 and Memorial Nephrology Associates website]

DaVita provided the following statements related to recruitment and retention of staff. [source: Application, p22]

“DaVita anticipates no difficult in recruiting the necessary personnel to staff the DaVita Elma Dialysis Center. Based on DaVita’s experience in adjacent planning areas, we anticipate that staff will be drawn to the convenience of Elma just as patients will. This is one of the reasons why Elma was selected as the proposed site, as it will allow for coordination with the DaVita Olympia and DaVita Tumwater units.

Furthermore, DaVita implemented a national staffing program, STAR, that has resulted in a 10% rise in overall retention for new hires. STAR proactively recruits and hires candidates who best embody our Mission and Values, then focuses intensely on the quality of training and onboarding experience, thereby increasing the likelihood that our staff will remain consistent and deliver great

patient care. Moreover, DaVita has been repeatedly recognized as a Top Employer and a Military Friendly Employer (davita.com/about/awards) and offers a competitive wage and benefit package to employees.”

Public Comment

None

Rebuttal Comment

None

Department Evaluation

Information provided in the application demonstrates that DaVita is a well-established provider of dialysis services in Washington State and across the nation. For this project, DaVita is proposing to establish an 8-station center in Elma.

Based on the above information, the department concludes that DaVita has the ability and expertise to recruit and retain a sufficient supply of qualified staff for this project. **This sub-criterion is met.**

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

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

Fresenius Medical Care

FMC provided the following statements relating to this sub-criterion. [source: Application, p31]

“Program requirements for dialysis certification require that social services and dietary support services be included within the program. FKC Aberdeen currently provides regular social services and dietary support for all patients. Other typical ancillary and support services utilized by the facility include pharmacy, laboratory, and radiology.”

As stated in the above criterion, FMC provided a copy of the executed medical director contract between FMC and RVS, PLLC.

FMC also provided its existing Patient Transfer Agreement between FMC and Providence Health & Services – St. Peter Hospital in Olympia. The agreement outlines roles and responsibilities for each. There are no costs associated with the agreement. However, the department notes that the agreement is stated to be executed, but is not signed. The unsigned agreement qualifies as a draft agreement for this project.

Since FMC Aberdeen Dialysis Center is currently operational, FMC provided a list of vendors it uses for a variety of ancillary and support services. The list is recreated below. [source: FMC screening response, p6]

Vendor Name	Services Provided
City Wide Janitorial	Janitorial services
Grays Harbor Transit	Transit services for patients
Terminix	Pest control
Superior Builders	Building maintenance
Stericycle	Medical waste management/disposal services
Spectra	Routine laboratory tests
Grays Harbor PAML (Pacific Associates Medical Laboratory)	STAT lab tests
Cintas	Employee gowns and janitorial supplies
Clover Park Technical College	Student training programs
Local public utility companies	Water, gas, internet, electricity, etc.

Public Comment

None

Rebuttal Comment

None

Department Evaluation

During the screening of this project, the department noted that the executed Medical Director contract between FMC and RVS, PLLC includes the same nephrology group that is identified in both the Kalpine and DaVita projects. The department raised the issue because of a non-compete clause in the existing Medical Director Contract with FMC. In response to the department’s inquiry about whether the existing agreement would have to be revised because of the competing applications submitted, FMC provided the following response. [source: FMC screening response, p10]

“The signed Medical Director Agreement in Exhibit 5 of our Application, defines Restricted Territories to include those areas depicted in maps in Schedule H of the Agreement. See Section 6.01.1 Restricted Territory (page 107 of the pdf.). Schedule H includes maps of Shelton, Lacey and Chehalis.

There is also a Section entitled "Covenant Not to Compete" (Section 6.03, p. 107 of the pdf.) that prohibits RVS PLLC physicians from competing with Fresenius business activities in Restricted Territories.

The FMC Aberdeen facility is not in a Restricted Territory, thus the actions proposed by RVS PPLC physicians in the two competing applications would not be prohibited. Thus, there would not be revisions to the current Medical Director Agreement in place for FMC Aberdeen.”

In public comment, however, FMC appear to change its position and provided the following public comment on both Kalpine and DaVita’s applications. [source: FMC public comment, pp15-16 for Kalpine and DaVita]

“As the Department correctly identified in its screening question to [Kalpine and DaVita], physicians Seth Thaler and Vo Nguyen would be part owners of Kalpine and are members of Memorial Nephrology Associates, LLC, the nephrology group identified in FMC Aberdeen, Kalpine

and DVA Elma's respective medical director agreements. Moreover, as detailed in FMC Aberdeen's signed medical director agreement, Memorial Nephrology Associates is the nephrology group currently serving FMC Aberdeen, and Dr. Nguyen is the assigned Medical Director for the Grays Harbor facility.

[Kalpine and DaVita] believes Memorial Nephrology Associates is not in violation of the non-compete clause with Fresenius because the proposed [Kalpine and DaVita] facility does not fall within one of the "Restricted Territories" which [Kalpine and DaVita] identified as Schedule H in the Fresenius CON Medical Director Agreement ("MDA"). However, this is an incorrect reading of the entire "Covenant Not to Compete" clause in the Fresenius MDA. In particular, Paragraph 6.03.2 of the MDA states:

*6.03.2 Consultant and Member Physicians hereby represent, covenant and agree that they do not, and following the Commencement Date of this Agreement shall not, employ, contract, retain, engage, partner or joint venture **with any person or entity which receives a Financial Benefit from any person or entity which engages in the Business anywhere in the Restricted Territory**, and that no such person or entity holds, or during the Restricted Period shall hold, a direct or indirect ownership interest in Consultant. (emphasis added)*

What this means is that Kalpine's physician members cannot engage in any business that actively competes with Fresenius in any of the restricted territories. Conveniently, [Kalpine and DaVita] believes it has found a "loophole" that allows it to propose competing with Fresenius either through the Kalpine proposal or through the DVA proposal. In contrast to the limited interpretation by [Kalpine and DaVita], Paragraph 6.03.2 should be interpreted to mean that not only can the member physicians not actively do business in the restricted areas, but also cannot joint venture with others who are active within the restricted areas.

"When examining the maps depicting the "Restricted Territories" in Schedule H of the Fresenius MDA, it is very clear the "Chehalis Restricted Territory" map includes the town of Centralia, WA. This is important because DaVita, one of Kalpine's three owning entities, had its DVA Centralia facility CN-approved in 2016. Therefore, DaVita is an entity that will soon receive "Financial Benefit" from its DVA Centralia facility that does business within the Chehalis Restricted Territory. In other words, despite the "loopholes" that might allow the Kalpine physicians to compete with Fresenius in Grays Harbor, the Memorial Nephrology physicians cannot compete with Fresenius because DVA will very soon be operating a competing facility in Centralia; this violates Paragraph 6.03.2.

Regardless of whether [Kalpine and DaVita]'s Medical Director Agreement is determined to be a conflict or not, it still is highly unusual and reflects questionable business ethics. Even if it is determined there is no violation of Fresenius' and Memorial Nephrology Associates' non-compete clause, there still are several questionable business practices at play. The proposed [Kalpine and DaVita] project violates the spirit of the non-compete clause this nephrology group has with Fresenius. In doing so, it shows a lack of collaboration and teamwork that is instead replaced by a profit motive. WAC 246-310-230(4) states:

"(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." (emphasis added)

Regardless of whether there may technically be a conflict of interest or not, it is clear the [Kalpine and DaVita] project, if approved, would create an inappropriate relationship between existing providers and the new provider, including two physicians who have current clinical and business relationships with Fresenius in this same planning area. This conflict, alone, makes the [Kalpine and DaVita] request ill-suited, and not the best alternative among the competing applicants.”

After reviewing the executed medical director agreement between FMC and RVS, PLLC, the department concludes that FMC’s agreement does not require revisions. The non-compete clause and discussion of restricted territories focuses on any new dialysis facilities, rather than this existing facility. Further information regarding this topic is addressed in the Kalpine and DaVita discussion below.

Since FMC Aberdeen Dialysis Center has been operating in Grays Harbor since November 2004, it has the required ancillary and support agreements and relationships already in place. These agreements include an executed Medical Director Agreement and a draft Patient Transfer agreement. If this project is approved, the department would attach a condition requiring FMC to provide a copy of the signed Patient Transfer Agreement consistent with the draft agreement provided in the application.

The department concludes that FMC’s project **meets this sub-criterion.**

Kalpine Dialysis, LLC

Kalpine does not currently own or operate a dialysis center in Washington State. For its Elma Dialysis Center, Kalpine anticipates the following ancillary and support services would be provided on site: social services, nutrition, financial counseling, pharmacy access, patient and staff education, human resources, material management, administration and biomedical technical services.

Additional services are expected to be coordinated through DaVita’s corporate offices in Denver, Colorado and support offices in Federal Way and Tacoma, Washington. [source: Application, p24]

Kalpine also provided copies of various agreements to be used for operation of the dialysis center if this project is approved. Below is a summary of each agreement.

Draft Operating Agreement [source: Kalpine screening response, Appendix 25]

The draft agreement is among Kalpine Dialysis LLC, Total Renal Care, Inc. (DaVita), and Dialysis Done Right, LLC, a Washington State corporation governed by Vo Nguyen, MD and Seth Thaler, MD.¹¹ The draft Operating Agreement identifies the principal office to be “C/O DaVita, 2000 – 16th Street, Denver, Colorado 80202.” The draft agreement states that the “*Company is formed for the purpose of developing, establishing, owning or leasing, and operating one or more licensed outpatient dialysis and renal care service centers (each, a "Center" and collectively, the "Centers") to have the names and initial addresses set forth on Exhibit B and for the purpose of doing such other things as are necessary, convenient, desirable or incidental to the foregoing, and for such other purposes as may be agreed upon from time to time by a Majority of the Members.*” All dollar amounts in the draft agreement focus on the capital contributions of each of the three members.

The term of the agreement is perpetual unless the company is dissolved in accordance with the agreement. The term section further states: *Notwithstanding the above, in the event that Company*

¹¹ Dialysis Done Right, LLC UBI #604 149 745; registration date July 26, 2017; expiration date July 31, 2018.

is denied approval for a Certificate of Need pertaining to the initial Center from the Washington State Certificate of Need Program (the "CON"), the Company will be dissolved in accordance with the provisions of Section 13 of this Agreement.

Subscription Agreement [source: Kalpine screening response, Appendix 26]

This agreement was executed on July 28, 2017, among Kalpine Dialysis LLC, Total Renal Care, Inc. (DaVita), and Dialysis Done Right, LLC. This is the agreement that outlines the shares (subscription units) for Kalpine Dialysis, LLC. The agreement references the Operating Agreement (see above). The agreement includes specific language to ensure compliance with state and federal regulations. It specifically mentions "*Federal Ethics in Patient Referrals Act*," 42 U.S.C. § 1395nn, or any successor thereto (the "*Stark Law*"), and the anti-fraud and abuse statute, 42 U.S.C. §1320a-7b(b), or any successor thereto (the "*Anti-Kickback Statute*")." There are no costs associated with this agreement. The agreement includes the following language for termination:

"Company shall be dissolved and terminated if Company is denied approval for a Certificate of Need (the "CON") pertaining to the Center from the Washington State Certificate of Need Program or if TRC in its discretion determines to terminate Company's application for the CON."

Draft Dialysis Management Services Agreement [source: Kalpine screening response, Appendix 24]

This draft agreement is between Kalpine Dialysis LLC and DaVita HealthCare Partners. The draft agreement is intended to be used for management and day-to-day operations of the new Kalpine dialysis center. The draft Management Services Agreement is effective for 25 years following the effective date of the agreement (signing). The management fees in this agreement are identified as 10% of the net revenues each month, plus a development fee identified in an exhibit attached to the draft agreement. The agreement outlines roles and responsibilities for both entities. Appendix B included with this evaluation is a table showing a summary of roles and responsibilities for both Kalpine and DaVita.

Draft Medical Director Agreement [source: Kalpine screening response, Appendix 3A]

This draft agreement is among Kalpine Dialysis, LLC, Memorial Nephrology Associates, PLLC, and the following five individual physicians: Julia Anuras, MD, Seth Thaler, MD, Vo Nguyen, MD, Christopher Burtner, MD, and Lana Bur, MD. The draft agreement identifies roles and responsibilities for both Kalpine Dialysis, LLC and Memorial Nephrology Associates, PLLC. While all five physicians are named in the agreement, Christopher Burtner, MD is named as the medical director and the other four physicians are noted to be pre-approved for medical director services. The draft agreement identifies all costs associated with medical director services.

Draft Patient Transfer Agreement [source: Kalpine screening response, Appendix 12A]

Kalpine provided a copy of the draft patient transfer agreement to be used at the Elma facility. The draft agreement is between DaVita and Summit Pacific Medical Center, an acute care hospital located in Elma within Grays Harbor County. The draft agreement outlines roles and responsibilities for both entities. There are no costs associated with the agreement.

FMC Public Comment

During the review of this project, FMC provided comments focusing on the medical director agreement provided by both Kalpine and DaVita. The comments for Kalpine are stated below.

Medical Director Agreement

“As the Department correctly identified in its screening question to Kalpine, physicians Seth Thaler and Vo Nguyen would be part owners of Kalpine and are members of Memorial Nephrology Associates, LLC, the nephrology group identified in FMC Aberdeen, Kalpine and DVA Elma's respective medical director agreements. Moreover, as detailed in FMC Aberdeen's signed medical director agreement, Memorial Nephrology Associates is the nephrology group currently serving FMC Aberdeen, and Dr. Nguyen is the assigned Medical Director for the Grays Harbor facility.

Kalpine believes Memorial Nephrology Associates is not in violation of the non-compete clause with Fresenius because the proposed Kalpine facility does not fall within one of the "Restricted Territories" which Kalpine identified as Schedule H in the Fresenius CON Medical Director Agreement ("MDA"). However, this is an incorrect reading of the entire "Covenant Not to Compete" clause in the Fresenius MDA. In particular, Paragraph 6.03.2 of the MDA states:

*6.03.2 Consultant and Member Physicians hereby represent, covenant and agree that they do not, and following the Commencement Date of this Agreement shall not, employ, contract, retain, engage, partner or joint venture **with any person or entity which receives a Financial Benefit from any person or entity which engages in the Business anywhere in the Restricted Territory**, and that no such person or entity holds, or during the Restricted Period shall hold, a direct or indirect ownership interest in Consultant. (emphasis added)*

What this means is that Kalpine's physician members cannot engage in any business that actively competes with Fresenius in any of the restricted territories. Conveniently, Kalpine believes it has found a "loophole" that allows it to propose competing with Fresenius either through the Kalpine proposal or through the DVA proposal. In contrast to the limited interpretation by Kalpine, Paragraph 6.03.2 should be interpreted to mean that not only can the member physicians not actively do business in the restricted areas, but also cannot joint venture with others who are active within the restricted areas.

"When examining the maps depicting the "Restricted Territories" in Schedule H of the Fresenius MDA, it is very clear the "Chehalis Restricted Territory" map includes the town of Centralia, WA. This is important because DaVita, one of Kalpine's three owning entities, had its DVA Centralia facility CN-approved in 2016. Therefore, DaVita is an entity that will soon receive "Financial Benefit" from its DVA Centralia facility that does business within the Chehalis Restricted Territory. In other words, despite the "loopholes" that might allow the Kalpine physicians to compete with Fresenius in Grays Harbor, the Memorial Nephrology physicians cannot compete with Fresenius because DVA will very soon be operating a competing facility in Centralia; this violates Paragraph 6.03.2.

Regardless of whether Kalpine's Medical Director Agreement is determined to be a conflict or not, it still is highly unusual and reflects questionable business ethics. Even if it is determined there is no violation of Fresenius' and Memorial Nephrology Associates' non-compete clause, there still are several questionable business practices at play. The proposed Kalpine project violates the spirit of the non-compete clause this nephrology group has with Fresenius. In doing so, it shows a lack of collaboration and teamwork that is instead replaced by a profit motive. WAC 246-310-230(4) states:

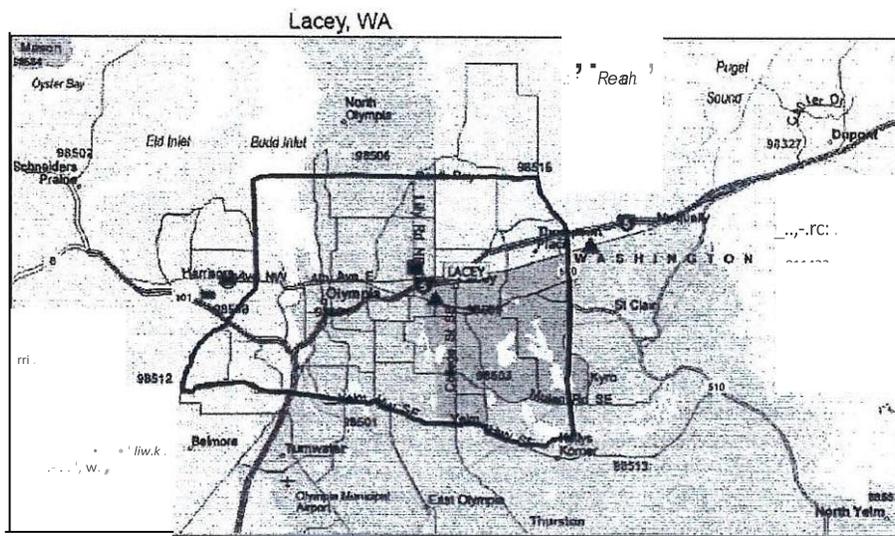
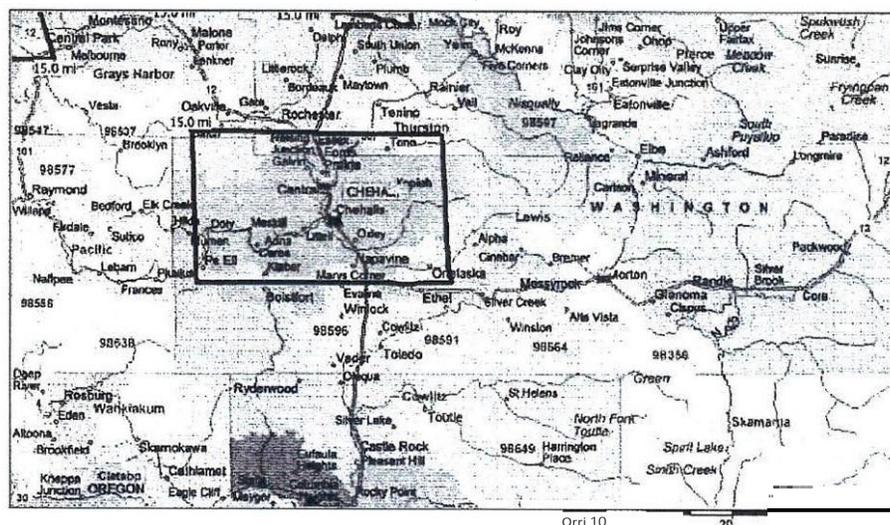
"(4) The proposed project will promote continuity in the provision of health care, not result in an unwarranted fragmentation of services, and have an appropriate relationship to the service area's existing health care system." (emphasis added)

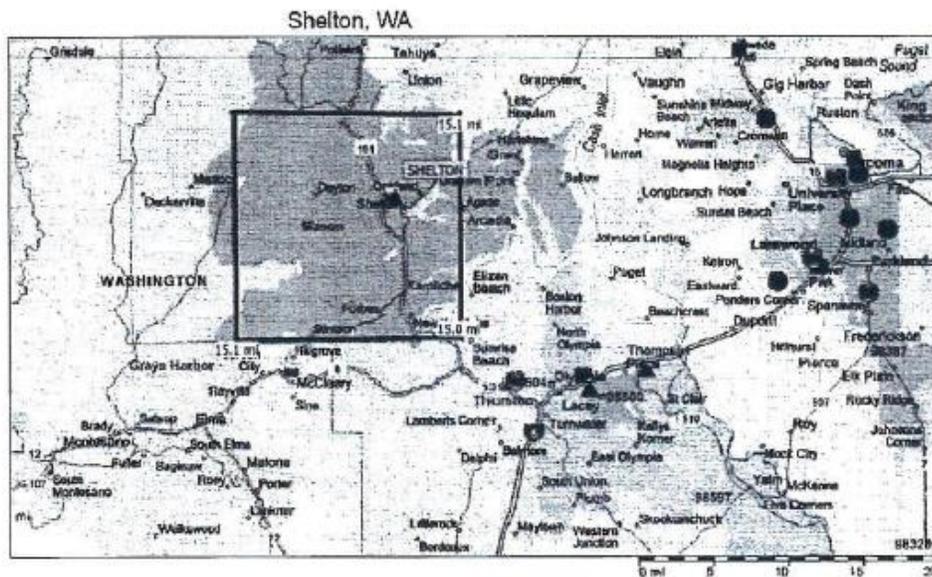
Regardless of whether there may technically be a conflict of interest or not, it is clear the Kalpine project, if approved, would create an inappropriate relationship between existing providers and the new provider, including two physicians who have current clinical and business relationships with Fresenius in this same planning area. This conflict, alone, makes the Kalpine request ill-suited, and not the best alternative among the competing applicants.” [source: FMC public comment, pp15-16]

Kalpine Rebuttal Comment

“FMC’s claim that Memorial Nephrology Associates would violate its “covenant not to compete” with FMC if it were to pursue employment with Kalpine is incorrect. First, FMC misinterprets the scope of the covenant not to compete. The covenant not to compete prohibits the members of Memorial Nephrology from working with any entity that provides outpatient dialysis services (or related hospital and laboratory services) “anywhere in the Restricted Territory.” The “Restricted Territory,” as shown below in Figure 4, is Shelton, Lacey, and Chehalis. Elma, where the Kalpine facility will be located, is not in the restricted territory.

Figure 5 **SCHEDULE H**
RESTRICTED TERRITORY MAPS
 Chehalis, WA





FMC argues that because DaVita plans to operate a dialysis facility in Chehalis, the Memorial Nephrology physicians cannot work with a DaVita-associated entity anywhere in Washington. This reading unreasonably expands the scope of the covenant not to compete in violation of Washington law. Washington public policy "requires us to carefully examine covenants not to compete, even when protection of a legitimate business interest is demonstrated, because of equally competing concerns of freedom of employment and free access of the public to professional services." Knight, Vale and Gregory v. McDaniel, 37 Wn. App. 366, 380 (1984). A covenant not to compete should be no greater in scope than is necessary to protect the business or goodwill of the employer. Wood v. May, 73 Wn.2d 307, 309-10 (1968). Similarly, a covenant not to compete is not enforceable if it injures the public by restricting access to an important service. See Perry v. Moran, 109 Wn.2d 691, 698 (1987).

It is unreasonable and unnecessary to the success of FMC's business to restrict the Memorial Nephrology physicians from partnering with a facility anywhere in Washington just because that facility is associated with a facility in a restricted area. FMC's reading of the covenant not to compete also would harm the public by restricting access to key medical providers in a rural, underserved area. The more reasonable reading of the clause (and the one that FMC initially adopted, as discussed below), is that the clause prohibits the Memorial Nephrology physicians from working for a competing dialysis facility in the restricted area. In other words, the clause would prohibit the Memorial Nephrology physicians from working at DaVita's Chehalis facility (because Chehalis is in the restricted territory), but it would not prohibit the physicians from working at the Kalpine Elma facility, which is outside of the restricted area.

Second, FMC's attempt to expand the Memorial Nephrology covenant not to compete is inconsistent with Certificate of Need policy. WAC 246-310-230(4) requires the Department to ensure that "[t]he proposed project will ... have an appropriate relationship to the service area's existing health care system." Kalpine's relationship with Memorial Nephrology is ethical, consistent with physicians' covenant not to compete with FMC, and designed to ensure that all ESRD patients in the rural Grays Harbor planning area have access to dialysis. FMC, on the other hand, is seeking to secure a

monopoly over one of the few nephrology groups in the region, thus unreasonably limiting the life-saving services that these individuals provide. FMC's position in this matter would violate Washington law on covenants not to compete, Perry, 109 Wn.2d at 698, and is inconsistent with the Department's policy of promoting access, see RCW 70.38.015(1).

Third, the Department raised this issue during screening, and the position FMC takes in its public comments is exactly opposite to the position it took in its supplemental submission. There, the Department pointed out that "[b]oth competing applicants identified the same nephrology group in their applications to establish a dialysis center in Grays Harbor County," and asked FMC to "clarify whether this factor changes the executed medical director agreement." FMC Screening Resp. at 10. FMC responded that "there would not be revisions to the current Medical Director Agreement." Id. That is because the covenant not to compete section of the MDA only "prohibits RSV PLLC physicians from competing with Fresenius business activities in" Shelton, Lacey, and Chehalis. As FMC pointed out, "[t]he FMC Aberdeen facility is not in a restricted area." Neither is the Kalpine facility. Id.

FMC cannot change its position now, after the applications were completed during screening. Doing so would be unfair to Kalpine, which should be permitted to rely upon FMC's own admissions during the application process that the physicians are free to participate in the Kalpine project, and their non-competition agreement with FMC does not affect their ability to do so.

There Is no Ethical Issue. There is nothing unethical about Memorial Nephrology planning to work with both Kalpine and FMC. In fact, it is common practice for two dialysis facilities to contract with the same medical director and/or physician group. DaVita operates approximately 900 joint venture facilities with physician groups nationwide. Many physician members of these joint ventures have medical directorships with DaVita's regional competitors. This is both appropriate and common.

And many ESRD patients would be denied convenient dialysis options if this were not the case. Particularly in areas that have only one nephrology group, that group must serve as the physician support for both facilities, even if those facilities are owned by different entities. Again, there is nothing unethical or even unusual about this practice." [source: Kalpine rebuttal comment, pp10-12]

Department Evaluation

As previously stated, during the screening of the FMC project, the department noted that the executed Medical Director contract between FMC and RVS, PLLC includes the same nephrology group that is identified in both the Kalpine and DaVita projects. The department raised the issue because of a non-compete clause in the executed Medical Director Agreement. In the FMC section of this sub-criterion, the department concluded that since FMC's agreement is executed and the non-compete clause references new facilities, FMC's agreement remains valid.

During the screening of the Kalpine project, the department asked four questions specific to the draft agreement, its non-compete clause, and the draft agreement's compliance with FMC's executed agreement. Below is the question and response exchange between the department and Kalpine.

Department Question #2:

Physicians Seth Thaler and Vo Nguyen are both associated with Memorial Nephrology Associates, PLLC. The nephrology group is identified in the medical director agreements for both Fresenius Medical Care and DaVita HealthCare Partners for their respective projects. Explain how the ownership of Kalpine Dialysis is consistent with the executed agreement in the Fresenius Medical

Care application for its Grays Harbor project under Section 9: *No Conflicts* and Section 10: *Non-Competition and Non-Solicitation*.

Kalpine Response:

“The Medical Director Agreement (“MDA”) relating to existing FMC facilities, provided as Exhibit 5 to FMC’s application, contains a “Covenant Not to Compete.” (§ 6.03.) However, these limitations apply, by their own terms, only to the “Restricted Territory.” (§6.03.1.) This is defined as “the geographic area as depicted on the maps” attached to the MDA.

(§ 6.01.7.) As can be seen on the maps, Elma, WA - the location of the proposed Kalpine Dialysis facility- is outside the Restricted Territory. (Schedule H - “Shelton, WA” map.) Therefore, this Covenant Not to Compete has no applicability to the proposed Kalpine Dialysis facility or its ownership. The draft MDA provided as Appendix 3 to Kalpine Dialysis’s application similarly contains “No Conflicts” and “Non-Competition” terms. (§§ 9 & 10.) However, the “No Conflicts” term is limited to agreements “that would be prohibited under Section 10.” (§ 9.) And, the “Non-Competition” term does not apply to “the exceptions listed in Schedule I” -which “shall be permitted under the Agreement.” (§ 10.1.6.) Therefore, exceptions listed in Schedule I would not violate either the “No Conflicts” term or the “Non-Competition” term.

The Program is correct that the draft MDA submitted with the Kalpine Dialysis application did not identify FMC’s Shelton, Lacey, Aberdeen, and Chehalis facilities in Schedule I. However, similar to the Olympia MDA arrangement DaVita has with Memorial Nephrology, if any of the FMC facilities the group already has directorships with fall within the final non-compete radius, they will be included in Schedule I of the MDA before it is signed.”

Department Question #17:

The draft agreement is between Total Renal Care (DaVita) and Memorial Nephrology Associates, PLLC. There is not a reference to Kalpine Dialysis, LLC. Please explain how this document would meet the requirements of a draft for this project.

Kalpine Response:

“Find attached a revised copy of the Draft MDA between Kalpine Dialysis, LLC and Memorial Nephrology Associates, PLLC in Appendix 3a.”

Department Question #18:

The agreement is the same nephrology group that was provided in the Fresenius Medical Care application for its Grays Harbor project. Explain how the draft agreement is compliant with Section 9: *No Conflicts* and Section 10: *Non-Competition and Non-Solicitation* of that agreement.

Kalpine Response:

“Please see answer to Question #2.”

Department Question #19:

Explain why the agreement is not considered a conflict of interest for Dr. Thayler and Dr. Nguyen who have ownership interest in Kalpine Dialysis, LLC and are governing persons of Memorial Nephrology Associates, PLLC.

Kalpine Response:

“Please see answer to Question #2.”

The response to question #2 above, coupled with FMC’s own response to the non-compete questions in the screening of its application, addresses the non-compete concerns raised by the department.

In response to the department’s questions, Kalpine submitted a revised Medical Director Agreement provided as Attachment 3A in its screening response. The draft agreement includes a ‘header’ in bold on every page. The ‘header’ is restated below.

<p style="text-align: center;"><u>DRAFT FOR DISCUSSION PURPOSES ONLY</u> DO NOT EXECUTE CONFIDENTIAL-PROPRIETARY INFORMATION PROPERTY OF DAVITA INC. AND ITS AFFILIATES (COLLECTIVELY, "DAVITA"). DAVITA RESERVES THE RIGHT TO FURTHER MODIFY THIS DOCUMENT.</p>

Based on the header above, the revised agreement provided by Kalpine does not meet the requirement to provide, at minimum a draft Medical Director Agreement specific to the project. Consistent with Certificate of Need past practices, if this project is approved, the department would attach a condition requiring Kalpine to provide an executed Medical Director Agreement consistent with the draft agreement provided in the application. However, since the draft was created for discussion purposes only; the draft includes a “Do Not Execute” statement; and DaVita reserves the right to modify the document, the draft is unreliable for Certificate of Need purposes.

Focusing on the Subscription Agreement (executed), Draft Operating Agreement, and Draft Management Services Agreement, all agreements outline the relationship between Kalpine and DaVita. If Kalpine’s project is approved, the department would include conditions requiring Kalpine to provide a copies of executed agreements consistent with the draft agreements provided in the application.

Kalpine also provided a draft Patient Transfer Agreement. During the screening of the Kalpine project, the department asked a specific question about the draft Patient Transfer Agreement provided in the application. Below is the question and response exchange between the department and Kalpine on this topic.

Department Question #30:

The draft agreement identifies a subsidiary of DaVita and an un-known hospital. There is not a reference to Kalpine Dialysis, LLC. Please explain how this document would meet the requirements of a draft for this project.

Kalpine Response:

*“Find attached a revised copy of the Draft Patient Transfer Agreement between Kalpine Dialysis, LLC and Summit Pacific Medical Center in **Appendix 12a.**”*

As noted above, Kalpine submitted a revised Patient Transfer Agreement provided as Attachment 12A in its screening response. This draft is between Summit Pacific Medical Center and Total Renal Care, Inc. (DaVita). Kalpine is not referenced in the document. Similar to the draft Medical Director Agreement discussion above, if this project is approved, the department would attach a condition

requiring Kalpine to provide an executed Patient Transfer Agreement consistent with the draft agreement provided in the application. However, since the draft does not reference the applicant—Kalpine Dialysis, LLC—the draft is unreliable for Certificate of Need purposes

Based on the information discussed above, the department concludes Kalpine’s project **does not meet this sub-criterion**.

DaVita HealthCare Partners, Inc.

DaVita provides dialysis services throughout Washington State, however, it does not operate a facility in Grays Harbor County. If this project is approved, DaVita would be operating a new center in a county where it does not currently operate. DaVita states that the following ancillary and support services would be provided on site: social services, nutrition, financial counseling, pharmacy access, patient and staff education, human resources, material management, administration and biomedical technical services.

Additional services are coordinated through DaVita’s corporate offices in Denver, Colorado and support offices in Federal Way and Tacoma, Washington; El Segundo, California; Nashville, Tennessee; Berwyn, Pennsylvania; and Deland, Florida. [source: Application, p22]

DaVita also provided copies of various agreements to be used for operation of the dialysis center if this project is approved. Below is a summary of each agreement.

Draft Medical Director Agreement [source: Application, Appendix 3]

This draft agreement is among Total Renal Care, Inc. (DaVita), Memorial Nephrology Associates, PLLC, and the following five individual physicians: Julia Anuras, MD, Seth Thaler, MD, Vo Nguyen, MD, Christopher Burtner, MD, and Lana Bur, MD. The draft agreement identifies roles and responsibilities for both DaVita and Memorial Nephrology Associates, PLLC. While all five physicians are named in the agreement, Christopher Burtner, MD is named as the medical director and the other four physicians are noted to be pre-approved for medical director services. The draft agreement identifies all costs associated with medical director services.

Draft Patient Transfer Agreement [source: Application, Appendix 12]

DaVita provided a copy of the draft patient transfer agreement to be used at the Elma facility. The draft agreement is between DaVita and an un-named hospital. The draft agreement outlines roles and responsibilities for both entities. There are no costs associated with the agreement.

FMC provided comments focusing on DaVita’s medical director agreement.

FMC Public Comment

“The DVA Elma proposal to use the same physician group that provides medical care to FMC patients is a violation of their "Covenant Not to Compete" with Fresenius. As the Department correctly identified in its screening question to DVA Elma, physicians Seth Thaler and Vo Nguyen are members of Memorial Nephrology Associates, LLC, the nephrology group identified in FMC Aberdeen, Kalpine and DVA Elma's respective medical director agreements. Moreover, as detailed in FMC Aberdeen's signed medical director agreement, Memorial Nephrology Associates is the nephrology group currently serving FMC Aberdeen, and Dr. Nguyen is the assigned Medical Director for the Grays Harbor facility. DVA Elma and Kalpine believe Memorial Nephrology Associates is not in violation of the noncompete clause with Fresenius because their proposed Elma facility does not fall within one of the "Restricted Territories" which DVA Elma and Kalpine

identified as Schedule H in the Fresenius CON Medical Director Agreement ("MDA"). However, this is an incorrect reading of the entire "Covenant Not to Compete" clause in the Fresenius MDA. In particular, Paragraph 6.03.2 of the MDA states:

*6. 03. 2 Consultant and Member Physicians hereby represent, covenant and agree that they do not, and following the Commencement Date of this Agreement shall not, employ, contract, retain, engage, partner or joint venture **with any person or entity which receives a Financial Benefit from any person or entity which engages in the Business anywhere in the Restricted Territory**, and that no such person or entity holds, or during the Restricted Period shall hold, a direct or indirect ownership interest in Consultant. (emphasis added)*

What this means is that Memorial Nephrology physicians cannot engage in any business that actively competes with Fresenius in any of the restricted territories. Conveniently, DaVita believes it has found a "loophole" that allows it to employ Memorial Nephrology physicians at its proposed Elma facility. This would mean these physicians would compete with Fresenius either through the Kalpine proposal or through the DVA proposal. In contrast to the limited interpretation by DaVita, Paragraph 6.03.2 should be interpreted to mean that not only can the member physicians not actively do business in the restricted areas, but also cannot joint venture with others who are active within the restricted areas.

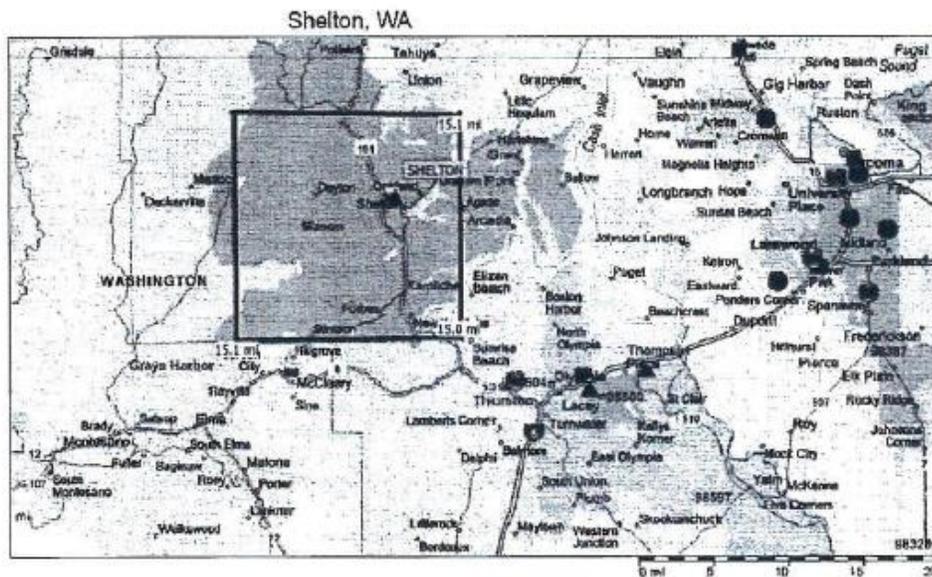
When examining the maps depicting the "Restricted Territories" in Schedule H of the Fresenius MDA, it is very clear the "Chehalis Restricted Territory" map includes the town of Centralia, WA. This is important because DaVita had its DVA Centralia facility CN-approved in 2016. Therefore, DaVita is an entity that will soon receive "Financial Benefit" from its DVA Centralia facility that does business within the Chehalis Restricted Territory. In other words, despite the "loopholes" that appear to allow the physicians to compete with Fresenius in Aberdeen, in fact, the Memorial Nephrology physicians cannot compete with Fresenius because DVA will very soon be operating a competing facility in Centralia; this violates Paragraph 6.03.2.

Regardless of whether the Physicians DVA Elma proposes to use would be in violation of their Non-Compete clause with Fresenius, it still is highly unusual and reflects questionable business ethics on the part of these physicians.

Even if it is determined there is no violation of Fresenius' and Memorial Nephrology Associates' non-compete clause, there still are several questionable business practices at play. The proposed DVA Elma project which proposes use of these same physicians violates the spirit of the non-compete clause this nephrology group has with Fresenius. In doing so, it shows a lack of collaboration and teamwork that is instead replaced by a profit motive. WAC 246-310-230(4) states:

"(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." (emphasis added)

Regardless of whether there may technically be a conflict of interest or not, it is clear either DaVita project, if approved, would create an inappropriate relationship between existing providers and the new provider, including two physicians who have current clinical and business relationships with Fresenius in this same planning area. This conflict, alone, makes the two DaVita requests ill-suited, and not the best alternative among the competing applicants. [source: FMC public comment, pp15-16]



FMC argues that because DaVita plans to operate a dialysis facility in Chehalis, the Memorial Nephrology physicians cannot work with a DaVita-associated entity anywhere in Washington. This reading unreasonably expands the scope of the covenant not to compete in violation of Washington law. Washington public policy "requires us to carefully examine covenants not to compete, even when protection of a legitimate business interest is demonstrated, because of equally competing concerns of freedom of employment and free access of the public to professional services." Knight, Vale and Gregory v. McDaniel, 37 Wn. App. 366, 380 (1984). A covenant not to compete should be no greater in scope than is necessary to protect the business or goodwill of the employer. Wood v. May, 73 Wn.2d 307, 309-10 (1968). Similarly, a covenant not to compete is not enforceable if it injures the public by restricting access to an important service. See Perry v. Moran, 109 Wn.2d 691, 698 (1987).

It is unreasonable and unnecessary to the success of FMC's business to restrict the Memorial Nephrology physicians from partnering with a facility anywhere in Washington just because that facility is associated with a facility in a restricted area. FMC's reading of the covenant not to compete also would harm the public by restricting access to key medical providers in a rural, underserved area. The more reasonable reading of the clause (and the one that FMC initially adopted, as discussed below), is that the clause prohibits the Memorial Nephrology physicians from working for a competing dialysis facility in the restricted area. In other words, the clause would prohibit the Memorial Nephrology physicians from working at DaVita's Chehalis facility (because Chehalis is in the restricted territory), but it would not prohibit the physicians from working at the DaVita Elma facility, which is outside of the restricted area.

Second, FMC's attempt to expand the Memorial Nephrology covenant not to compete is inconsistent with Certificate of Need policy. WAC 246-310-230(4) requires the Department to ensure that "[t]he proposed project will ... have an appropriate relationship to the service area's existing health care system." DaVita's relationship with Memorial Nephrology is ethical, consistent with physicians' covenant not to compete with FMC, and designed to ensure that all ESRD patients in the rural Grays Harbor planning area have access to dialysis. FMC, on the other hand, is seeking to secure a

monopoly over one of the few nephrology groups in the region, thus unreasonably limiting the life-saving services that these individuals provide. FMC's position in this matter would violate Washington law on covenants not to compete, Perry, 109 Wn.2d at 698, and is inconsistent with the Department's policy of promoting access, see RCW 70.38.015(1).

Third, the Department raised this issue during screening, and the position FMC takes in its public comments is exactly opposite to the position it took in its supplemental submission. There, the Department pointed out that "[b]oth competing applicants identified the same nephrology group in their applications to establish a dialysis center in Grays Harbor County," and asked FMC to "clarify whether this factor changes the executed medical director agreement." FMC Screening Resp. at 10. FMC responded that "there would not be revisions to the current Medical Director Agreement." Id. That is because the covenant not to compete section of the MDA only "prohibits RSV PLLC physicians from competing with Fresenius business activities in" Shelton, Lacey, and Chehalis. As FMC pointed out, "[t]he FMC Aberdeen facility is not in a restricted area." Neither is the DaVita facility. Id.

FMC cannot change its position now, after the applications were completed during screening. Doing so would be unfair to DaVita, which should be permitted to rely upon FMC's own admissions during the application process that the physicians are free to participate in the DaVita project, and their non-competition agreement with FMC does not affect their ability to do so.

There Is no Ethical Issue. There is nothing unethical about Memorial Nephrology planning to work with both DaVita and FMC. In fact, it is common practice for two dialysis facilities to contract with the same medical director and/or physician group. DaVita operates approximately 900 joint venture facilities with physician groups nationwide. Many physician members of these joint ventures have medical directorships with DaVita's regional competitors. This is both appropriate and common.

And many ESRD patients would be denied convenient dialysis options if this were not the case. Particularly in areas that have only one nephrology group, that group must serve as the physician support for both facilities, even if those facilities are owned by different entities. Again, there is nothing unethical or even unusual about this practice." [source: DaVita rebuttal comment, pp10-12]

Department Evaluation

As previously stated, during the screening of the FMC project, the department noted that the executed Medical Director contract between FMC and RVS, PLLC includes the same nephrology group that is identified in both the Kalpine and DaVita projects. The department raised the issue because of a non-compete clause in the executed Medical Director Agreement. In the FMC section of this sub-criterion, the department concluded that since FMC's agreement is executed and the non-compete clause references new facilities, FMC's agreement remains valid.

During the screening of the DaVita project, the department asked a question specific to the draft agreement, its non-compete clause, and the draft agreement's compliance with FMC's executed agreement. Below is the question and response exchange between the department and DaVita.

Department Question #8:

The draft agreement is between Total Renal Care (DaVita) and Memorial Nephrology Associates, PLLC. The agreement is the same nephrology group that was provided in the Fresenius Medical Care application for its Grays Harbor project. Explain how the draft agreement is compliant with Section 9: *No Conflicts* and Section 10: *Non-Competition and Non-Solicitation* of that agreement.

DaVita Response:

"The Medical Director Agreement ("MDA") relating to existing FMC facilities, provided as Exhibit 5 to FMC's application, contains a "Covenant Not to Compete." (§ 6.03.) However, these limitations apply, by their own terms, only to the "Restricted Territory." (§6.03.1.) This is defined as "the geographic area as depicted on the maps" attached to the MDA. (§ 6.01.7.) As can be seen on the maps, Elma, WA - the location of the proposed DaVita Dialysis facility - is outside the Restricted Territory. (Schedule H - "Shelton, WA" map.)

Therefore, this Covenant Not to Compete has no applicability to the proposed DaVita Dialysis facility or its ownership.

The draft MDA provided as Appendix 3 to DaVita Dialysis's application similarly contains "No Conflicts" and "Non-Competition" terms. (§§ 9 & 10.) However, the "No Conflicts" term is limited to agreements "that would be prohibited under Section 1 O." (§ 9.) And, the "Non-Competition" term does not apply to "the exceptions listed in Schedule 1" - which "shall be permitted under the Agreement." (§ 10.1.6.) Therefore, exceptions listed in Schedule 1 would not violate either the "No Conflicts" term or the "Non-Competition" term.

The Program is correct that the draft MDA submitted with the DaVita Dialysis application did not identify FMC's Shelton, Lacey, Aberdeen, and Chehalis facilities in Schedule 1. However, similar to the Olympia MDA arrangement DaVita has with Memorial Nephrology, if any of the FMC facilities the group already has directorships with fall within the final non-compete radius, they will be included in Schedule 1 of the MDA before it is signed."

The response to question #12 above, coupled with FMC's own response to the non-compete questions in the screening of its application, addresses the non-compete concerns raised by the department.

However, as noted in the Kalpine review above, DaVita draft Medical Director Agreement provided as Attachment 12 of the application includes the following 'header' in bold on every page. The 'header' is restated below.

<p style="text-align:center"><u>DRAFT FOR DISCUSSION PURPOSES ONLY</u> DO NOT EXECUTE CONFIDENTIAL-PROPRIETARY INFORMATION PROPERTY OF DAVITA INC. AND ITS AFFILIATES (COLLECTIVELY, "DAVITA"). DAVITA RESERVES THE RIGHT TO FURTHER MODIFY THIS DOCUMENT.</p>

Based on the header above, the document provided by DaVita does not meet the requirement to provide, at minimum a draft Medical Director Agreement specific to the project. Consistent with Certificate of Need past practices, if this project is approved, the department would attach a condition requiring DaVita to provide an executed Medical Director Agreement consistent with the draft agreement provided in the application. However, since the draft was created for discussion purposes only; the draft includes a "Do Not Execute" statement; and DaVita reserves the right to modify the document, the draft is unreliable for Certificate of Need purposes.

DaVita also provided a draft Patient Transfer Agreement between DaVita and an unidentified hospital. The document meets the minimum requirement for a draft document in a Certificate of

Need application. If this project is approved, the department would attach a condition requiring DaVita to provide an executed Patient Transfer Agreement consistent with the draft agreement provided in the application.

Based on the information discussed above, the department concludes DaVita's project **does not meet this sub-criterion**.

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

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

The department reviews two different areas when evaluating this sub-criterion. One is the conformance with Medicare and Medicaid standards and the other is conformance with state standards. To accomplish this task for these projects, the department first reviewed the quality of care compliance history for all healthcare facilities operated outside of Washington State using the 'star rating' assigned by Centers for Medicare & Medicaid Services (CMS). Then the department focused on the CMS 'star ratings' for Washington State facilities. Finally, the department focused on its own state survey data performed by the Department of Health's Investigations and Inspections Office. Below is an overview of the CMS star rating review. The department's Washington State survey data is include in each applicant's separate review under this sub-criterion.

Centers for Medicare & Medicaid Services (CMS) Star Ratings

On January 22, 2015, the Centers for Medicare & Medicaid Services (CMS) released a media statement with the following information related to its dialysis facility compare website.

"Today, the Centers for Medicare & Medicaid Services (CMS) added star ratings to the Dialysis Facility Compare (DFC) website. These ratings summarize performance data, making it easier for consumers to use the information on the website. These ratings also spotlight excellence in health care quality. In addition to posting the star ratings, CMS updated data on individual DFC quality measures to reflect the most recent data for the existing measures.

"Star ratings are simple to understand and are an excellent resource for patients, their families, and caregivers to use when talking to doctors about health care choices," said CMS Administrator Marilyn Tavenner. "CMS has taken another step in its continuous commitment to improve quality measures and transparency."

DFC joined Nursing Home Compare and Physician Compare in expanding the use of star ratings on CMS websites. The DFC rating gives a one to five-star rating based on information about the quality of care and services that a dialysis facility provides. Currently, nine DFC quality measures are being used collectively to comprise the DFC star ratings. In the future, CMS will add more measures.

In related news, CMS plans to add the Standardized Readmission Ratio (SRR) for dialysis facilities to the publicly reported quality outcome measures available on the Compare website. SRR is a measure of care coordination. SRR is not included in DFC's star rating at this time.

DFC quality measure data is either updated quarterly or annually. CMS plans to update the DFC's star rating on an annual basis beginning in October 2015."

CMS provided the following overview regarding its star rating for dialysis centers. [source: CMS website]

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

CMS assigns a one to five 'star rating' in two separate categories: best treatment practices and hospitalizations and deaths. The more stars, the better the rating. Below is a summary of the data within the two categories.

- Best Treatment Practices
This is a measure of the facility's treatment practices in the areas of anemia management; dialysis adequacy, vascular access, and mineral & bone disorder. This category reviews both adult and child dialysis patients.
- Hospitalization and Deaths
This measure takes a facility's expected total number of hospital admissions and compares it to the actual total number of hospital admissions among its Medicare dialysis patients. It also takes a facility's expected patient death ratio and compares it to the actual patient death ratio taking into consideration the patient's age, race, sex, diabetes, years on dialysis, and any co-morbidities.

The Dialysis Facility Compare website currently reports on 9 measures of quality of care for facilities. These measures are used to develop the star rating. Based on the star rating in each of the two categories, CMS then compiles an 'overall rating' for the facility. As with the separate categories: the more stars, the better the rating. The star rating is based on data collected from January 1, 2012 through December 31, 2015.¹²

The measures used in the star rating are grouped into three domains by using a statistical method known as Factor Analysis. Each domain contains measures that are most correlated. This allows CMS to weight the domains rather than individual measures in the final score, limiting the possibility of overweighting quality measures that assess similar qualities of facility care. The three domains are as follows:

- "Standardized Outcomes (SHR, SMR, and STrR)" – This first domain combines the three outcome measures for hospitalization, mortality and transfusions (SHR, SMR, and STrR).
- "Other Outcomes 1 (AV fistula, tunneled catheter)" – The arteriovenous fistula and catheter measures forms the second domain.

¹² The information or data on Dialysis Facility Compare comes from two key sources: 1) CMS Statistical Analytical Files (Medicare Claims); and 2) Consolidated Renal Operations in a Web-enabled Network (CROWN). Some ratios are calculated annually based on the information that facilities send Medicare each month; other ratios are calculated quarterly.

- "Other Outcomes 2 (Kt/V, hypercalcemia)" – The All Kt/V and hypercalcemia measures forms the third domain.

Facilities are rated as long as they have at least one measure in each of the three domains. Because the vascular access measures in the "Other Outcomes 1 (AV fistula, tunneled catheter)" domain do not apply to peritoneal dialysis patients, peritoneal dialysis-only facilities are rated based on the other two domains. They receive ratings as long as they have scores for at least one of the two domains not related to vascular access.

Fresenius Medical Care

FMC provided the following statement in response to this sub-criterion. [source: Application p32]

"Both RCG and Fresenius have proven track records in complying with applicable state and federal rules and regulations."

Public Comment

None

Rebuttal Comment

None

Department Evaluation

The department completed a review of FMC's quality and compliance with state and federal requirements below.

CMS Star Rating for Out-of-State Centers

FMC operates or provides administrative services in approximately 2,400 outpatient dialysis centers in 48 states, the District of Columbia, and Puerto Rico.¹³ For Washington State, FMC owns or operates 23 dialysis centers. The department obtained the star rating for all of the out-of-state centers.

Of the approximately 2,400 locations operated by FMC, 234 facilities had no star rating. For the remaining 2,166 facilities with a star rating, 1,739 or 80% had a rating of three or better.

CMS Star Rating for Washington State Centers

In early- and mid-year 2017, FMC purchase five operational dialysis centers from CHI Franciscan Health.¹⁴ Because of the timing of the purchase, the star rating for these facilities would reflect operations by CHI Franciscan, rather than FMC. As a result, the department reviewed the star rating for the following 19 operational dialysis centers owned and operated by FMC in full year 2017:

¹³ The only two states in which FMC does not operate are North Dakota and South Dakota.

¹⁴ The five CHI Franciscan dialysis centers are: St. Joseph Dialysis Center, Gig Harbor Dialysis Center, Franciscan East Tacoma, Franciscan South Tacoma, and Franciscan Puyallup.

**Table 25
FMC Dialysis Facilities**

Facility Name	CMS Certification Number	CMS Star Rating
FMC LEAH LAYNE DIALYSIS CENTER	502558	4
FMC COLUMBIA BASIN	502518	5
FMC COLVILLE	502557	5
FMC ABERDEEN	502531	5
PANORAMA DIALYSIS	502567	5
FMC SPOKANE KIDNEY CENTER	502527	3
FMC NORTHPOINTE DIALYSIS UNIT	502528	4
FMC CHEHALIS	502539	5
FMC THURSTON COUNTY DIALYSIS CENTER	502575	5
FMC VALLEY DIALYSIS UNIT	502535	3
PNRS SALMON CREEK	502524	4
PNRS FT VANCOUVER	502522	3
FMC MOSES LAKE DIALYSIS UNIT	502529	4
FMC LACEY	502530	5
FMC SHELTON	502548	2
QUALICENTERS - WALLA WALLA LLC	502517	5
FMC OMAK DIALYSIS CENTER	502533	4
PNRS CLARK COUNTY DIALYSIS CLINIC	502574	4

[source: Dialysis Facility Compare Dataset]

As shown above, all but one of FMC’s Washington State dialysis facilities show a three or better star rating.

Washington State Survey Data

As shown above, currently FMC owns, operates, or manages 23 facilities in 12 separate counties in Washington State. Focusing on the 18 facilities that FMC has operated in year 2017, the department has conducted and completed at least 20 surveys within the last two years. All surveys resulted in no significant non-compliance issues. [source: DOH IIO survey data]

In addition to the facilities owned and operated by FMC, the department also reviewed the compliance history for the five physicians associated with the RVS, PLLC medical group that is identified in FMC’s existing Medical Director Contract. The five physicians are:

- Julie P. Anuras, MD
- Christopher Burtner, MD
- Seth M. Thaler, MD
- Lana Kamal Bur, MD
- Vo Dan Nguyn, MD

Using data from the Medical Quality Assurance Commission, the department found that all five have no enforcement actions on their respective licenses. Further, since FMC’s Aberdeen Dialysis Center is currently operational with 16 stations, the department reviewed data from the Medical Quality Assurance Commission for each identified employee of the dialysis center. This review confirmed that all current employees have not enforcement actions on their respective licenses.

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 medical director group associated with the facility. The department concludes that FMC Aberdeen Dialysis Center has been operating in compliance with applicable state and federal licensing and certification requirements. The department also conclude there is reasonable assurance that the addition of stations to FMC Aberdeen Dialysis Center would not cause a negative effect on the facility’s compliance history. The department concludes that FMC’s project **meets this sub-criterion**.

Kalpine Dialysis, LLC

Kalpine provided the following statement in response to this sub-criterion. [source: Application p24]

“The applicant has no adverse history of license revocation or decertification in Washington State.”

Public Comment

None

Rebuttal Comment

None

Department Evaluation

Kalpine does not currently own or operate dialysis centers in Washington or any other state. For this reason, the department is unable to review a quality of care history for Kalpine. In this application, Kalpine provided a document intended to qualify for a draft Medical Director Agreement. Even though the department concluded that the document does not qualify as a draft agreement, the physician information identified in the document allows the department to review the compliance history for the five physicians associated with the medical group that is identified in the agreement.

- Julie P. Anuras, MD
- Christopher Burtner, MD
- Seth M. Thaler, MD
- Lana Kamal Bur, MD
- Vo Dan Nguyn, MD

Using data from the Medical Quality Assurance Commission, the department found that all five have no enforcement actions on their respective licenses.

Kalpine’s majority owner is DaVita. Typically, the majority owner’s quality of care history would be included in this section. However, given that DaVita also submitted an application in this concurrent review, DaVita’s quality of care history will not be repeated here.

Based on the above information, the department concludes that Kalpine did not provide the required draft documents to allow the department to determine reasonable assurance that the project will be operated in conformance with applicable state licensing requirements or whether the project will be operated in conformance with the applicable Medicare and Medicaid conditions of participation.

For the reasons stated above, the department concludes the Kalpine project **does not meet this sub-criterion**.

DaVita HealthCare Partners, Inc.

DaVita provided the following statement in response to this sub-criterion. [source: Application p23]

“The applicant has no adverse history of license revocation or decertification in Washington State.”

Public Comment

None

Rebuttal Comment

None

Department Evaluation

The department completed a review of DaVita’s quality and compliance with state and federal requirements below.

CMS Star Rating for Out-of-State Centers

DaVita reports dialysis services to CMS for 2,488 facilities in 45 states and the District of Columbia.¹⁵ Of the 2,488 facilities reporting to CMS by DaVita, 295 had no star rating. For the remaining 2,193 facilities with a star rating, 85.9%% had a rating of three or better.

CMS Star Rating for Washington State Centers

DaVita owns, operates, or manages 42 facilities in 18 separate counties. Of the 42 centers, 40 of them are currently operating. Of the 40 centers, 8 do not have the necessary amount of data to compile a star rating.¹⁶ The department reviewed the star rating for the remaining 32 centers.

**Table 26
DaVita Washington State Dialysis Facilities**

Facility Name	CMS Certification Number	CMS Star Rating
FEDERAL WAY COMMUNITY DIALYSIS CENTER	502513	4
OLYMPIA DIALYSIS CENTER	502555	5
GRAHAM DIALYSIS CENTER	502554	5
YAKIMA DIALYSIS CENTER	502541	4
MID-COLUMBIA KIDNEY CENTER	502504	4
NORTH SPOKANE RENAL CENTER	502538	3
OLYMPIC VIEW DIALYSIS CENTER	502525	3
KENT COMMUNITY DIALYSIS CENTER	502526	4
EVERETT DIALYSIS CENTER	502560	5
SPOKANE VALLEY RENAL CENTER	502537	5
TACOMA DIALYSIS CENTER	502551	3
MILL CREEK DIALYSIS CENTER	502561	5

¹⁵ The five states where DaVita does not operate are: Alaska, Delaware, Mississippi, Vermont, and Wyoming.

¹⁶ The six centers are: Battleground Dialysis Center, Belfair Dialysis Center, Cascade Dialysis Center, Echo Valley Dialysis Center, Rainier View Dialysis Center, and Tumwater Dialysis Center.

Table 26 (continued)
DaVita Washington State Dialysis Facilities

Facility Name	CMS Certification Number	CMS Star Rating
ZILLAH DIALYSIS	502571	4
CHINOOK KIDNEY CENTER	502559	5
PARKLAND DIALYSIS CENTER	502566	3
MT ADAMS KIDNEY CENTER	502514	5
WHIDBEY ISLAND DIALYSIS CENTER	502564	3
DAVITA MT BAKER KIDNEY CENTER	502501	5
BELLEVUE DIALYSIS CENTER	502542	3
DOWNTOWN SPOKANE RENAL CENTER	502547	3
LAKESWOOD COMMUNITY DIALYSIS CENTER	502519	4
PILCHUCK DIALYSIS	502577	4
EAST WENATCHEE DIALYSIS	502569	5
UNION GAP DIALYSIS CENTER	502543	5
VANCOUVER DIALYSIS CENTER	502550	3
ELLENSBURG DIALYSIS CENTER	502552	4
SEAVIEW DIALYSIS CENTER	502562	5
PUYALLUP COMMUNITY DIALYSIS CENTER	502534	3
KENNEWICK DIALYSIS	502572	4
WESTWOOD DIALYSIS CENTER	502544	4
WENATCHEE VALLEY DIALYSIS	502568	5

As shown above, all of DaVita’s Washington State dialysis facilities show a three or better star rating.

Washington State Survey Data

For Washington State, DaVita owns, operates, or manages 42 facilities in 18 separate counties. Two of the 42 are CN approved, but not yet state surveyed and operational. The department reviewed the compliance history for the 40 operational DaVita dialysis centers listed above. For the Washington State facilities, the department has conducted and completed at least 40 surveys in the most recent three years. All surveys resulted in no significant non-compliance issues. [source: DOH IIO survey data]

In this application, DaVita provided a document intended to qualify for a draft Medical Director Agreement. Even though the department concluded that the document does not qualify as a draft agreement, the physician information identified in the document allows the department to review the compliance history for the five physicians associated Memorial Nephrology Associates, the physician group that is identified in the agreement.

- Julie P. Anuras, MD
- Christopher Burtner, MD
- Seth M. Thaler, MD
- Lana Kamal Bur, MD
- Vo Dan Nguyn, MD

Using data from the Medical Quality Assurance Commission, the department found that all five have no enforcement actions on their respective licenses.

DaVita is currently operating under a Corporate Integrity Agreement (CIA) with the Office of the Inspector General of the Department of Health and Human Services that was signed on October 22, 2014. DaVita provided a copy of the signed agreement. [source: Application, Appendix 4] The department notes that the agreement focuses on DaVita's joint ventures with nephrologists to operate dialysis clinics; rather than patient care or billing practices.

DaVita's CIA has 16 specific sections under 'Term and Scope' that requires DaVita to:

- establish and maintain a Compliance Program that includes a Chief Compliance Officer and Management Compliance Committee;
- establish written standards for covered persons (as defined in the CIA);
- establish training and education for covered persons;
- ensuring compliance with anti-kickback statute;
- provide notice to joint venture partners and medical directors of specific information related to patient referrals and ownership information;
- unwind specific joint venture clinics;
- retain an independent monitor selected by OIG;
- establish compliance audits;
- establishment of a risk assessment and mitigation process;
- establish a financial recoupment process;
- cooperate with all OIG investigations;
- maintain its disclosure program;
- removal of 'ineligible persons' as defined in the CIA;
- notify the OIG of government investigation or legal proceedings;
- repayment of overpayments; and
- report all reportable events as defined in the CIA.

Appendix B of the CIA identifies the eleven separate joint ventures that must be unwound, which includes a total of 26 dialysis clinics in five different states.¹⁷ None of the joint ventures or dialysis clinics are located in Washington State.

For this specific CIA, DaVita would not be excluded from participation in Medicare, Medicaid or other Federal health care programs provided that DaVita complies with the obligations outlined in the CIA.

The department concludes that DaVita did not provide the required draft documents to allow the department to determine reasonable assurance that the project will be operated in conformance with applicable state licensing requirements or whether the project will be operated in conformance with the applicable Medicare and Medicaid conditions of participation.

The department concludes that DaVita's project **does not meet 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-

¹⁷ The five states are: California (9); Colorado (7); Florida (5); Kentucky (1); and Ohio (4).

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 statements in response to this sub-criterion. [source: Application, pp31-32]

“The proposed project promotes continuity of care as it seeks to expand FKC Aberdeen's existing dialysis care services. FKC Aberdeen is the only dialysis center in the Grays Harbor County Dialysis Planning Area and has an established relationship with the community and other health care providers in the area. Although the expansion necessitates relocation, RCG and Fresenius's experience developing and operating facilities will ensure that this is done on a timely basis to address the need for additional stations based on the dialysis forecast model described above. See Exhibit 16 for the FKC Aberdeen transfer agreement.”

Public Comment

None

Rebuttal Comment

None

Department Evaluation

FMC has been a provider of dialysis services in Washington State for many years. This project proposes a station addition to an existing facility in Grays Harbor County. FMC's project would promote continuity in the provision of healthcare services in the planning area #5 by adding needed stations.

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

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

Kalpine Dialysis, LLC

Kalpine provided the following statements in response to this sub-criterion. [source: Application, p24 & Appendix 12A]

“Kalpine Dialysis LLC is structured to promote continuity and coordination of care and drive the best possible patient outcomes. Kalpine Dialysis LLC will draw on the expertise and experience of both DaVita and the physician members in this region, and represents a commitment to creating an outstanding operation in Elma by leveraging our combined network of physicians, hospitals, access surgeons, and preventative care in the South Sound.

Additionally, Appendix 18 includes an example of DaVita's Physician, Community and Patient Services offered through DaVita's Kidney Smart Education Program. Appendix 12 includes an

example draft transfer agreement; without an operating facility an actual transfer agreement with specific terms cannot be executed.”

Public Comment

None

Rebuttal Comment

None

Department Evaluation

Kalpine is a new entity and would be a new provider in Washington State and Grays Harbor County. Though Kalpine has no history of establishing relationships with existing healthcare networks, its majority owner has a long history of meeting this sub-criterion. For this application, Kalpine was unable to meet the sub-criterion under WAC 246-310-230(2) and (3).

Consistent with Kalpine’s failure to meet the sub-criterion under WAC 246-310-230(2) and (3), Kalpine cannot meet this sub-criterion. Kalpine has not sufficiently documented that they will be able to establish the required transfer agreement with a local hospital. **Kalpine does not meet this sub-criterion.**

DaVita HealthCare Partners, Inc.

DaVita provided the following statements in response to this sub-criterion. [source: Application, p22 & Appendices 12, 17, & 18]

“Appendix 17 provides a summary of quality and continuity of care indicators used in DaVita's quality improvement program. The DaVita Continuous Quality Improvement (CQI) program incorporates all areas of the dialysis program. The program monitors and evaluates all activities related to clinical outcomes, operations management, and process flow. Dialysis-specific statistical tools (developed by DaVita) are used for measurement, analysis, communication, and feedback. Continuing employee and patient education are integral parts of this program. Appendix 17 includes an example of DaVita Quality Index (DQI) data. Appendix 18 includes an example of DaVita's Physician, Community and Patient Services offered through DaVita's Kidney Smart Education Program. Appendix 12 includes a copy of the affiliation letter between St. Clare Hospital and Lakewood Dialysis. DaVita has been honored as one of the World's Most Admired Companies® by FORTUNE® magazine since 2006, confirming its excellence in working effectively with the communities it serves. (davita.com/aboutUawards)”

Public Comment

None

Rebuttal Comment

None

Department Evaluation

DaVita has been a provider of dialysis services in Washington State for many years. Though DaVita has a history of establishing relationships with existing healthcare networks, this application for an 8-station facility in Grays Harbor did not meet the sub-criterion under WAC 246-310-230(2).

Consistent with DaVita’s failure to meet the sub-criterion under WAC 246-310-230(2), DaVita cannot meet this sub-criterion. DaVita has not sufficiently documented that they will be able to

establish the required transfer agreement with a local hospital. **DaVita does not meet this sub-criterion.**

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

Fresenius Medical Care

FMC provided the following statements in response to this sub-criterion. [source: Application, pp31-32]

“The applicant has no history with respect to the actions noted in Certificate of Need regulation 248-19-390 (5)(a) now codified at WAC 246-310-240 (5) (a).”

Public Comment

None

Rebuttal Comment

None

Department Evaluation

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

Kalpine Dialysis, LLC

Kalpine provided the following statements in response to this sub-criterion. [source: Application, pp24-25]

“The applicant has no adverse history of license revocation or decertification in Washington State. Elma Dialysis Center will provide comprehensive in-center and home dialysis services. Kalpine Dialysis LLC’s proposal represents an excellent combination of operational expertise and clinical oversight. The Managing entity, DaVita, has the highest percent of 4 and 5 Star rated centers in the country, as measured by CMS, and the physician members operate as part of a nephrology practice that is deeply committed to Grays Harbor and the surrounding patient population. In addition, the Department of Health surveys dialysis centers to ensure compliance with federal and state laws.”

Public Comment

None

Rebuttal Comment

None

Department Evaluation

This sub-criterion is addressed in sub-section (3) above and **is not met.**

DaVita HealthCare Partners, Inc.

DaVita provided the following statements in response to this sub-criterion. [source: Application, pp23]

“The applicant has no adverse history of license revocation or decertification in Washington State.”

Public Comment

None

Rebuttal Comment

None

Department Evaluation

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

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

Fresenius Medical Care

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

Kalpine Dialysis, LLC

Based on the source information reviewed, the department concludes that the Kalpine Dialysis Center project has not met the cost containment criteria in WAC 246-310-240.

DaVita Healthcare Partners, Inc.

Based on the source information reviewed, the department concludes that the DaVita HealthCare Partners, Inc. project has not met the cost containment criteria in WAC 246-310-240.

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

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

If there are multiple applications, the department's assessment is to apply any service or facility superiority criteria contained throughout WAC 246-310 related to the specific project type in Step three. The superiority criteria are objective measures used to compare competing projects and make the determination between two or more approvable projects which is the best alternative. If WAC 246-310 does not contain any service or facility type superiority criteria as directed by WAC 246-310-200(2) (a)(i), then the department would use WAC 246-310-240(2)(a)(ii) and (b) for criteria to make the assessment of the competing proposals. If there are no known recognized standards as identified in WAC 246-310-200(2)(a)(ii) and (b), then using its experience and expertise, the department would assess the competing projects and determine which project should be approved.

Step One

Fresenius Medical Care

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

Kalpine Dialysis, LLC

For this project, Kalpine did not meet the applicable review criteria under WAC 246-310-220 and 230. Therefore, Kalpine's project will not be evaluated further under Step Two or Three or the remainder of this sub-criterion.

DaVita HealthCare Partners, Inc.

For this project, DaVita did not meet the applicable review criteria under WAC 246-310-220 and 230. Therefore, DaVita's project will not be evaluated further under Step Two or Three or the remainder of this sub-criterion.

Step Two

Fresenius Medical Care

For this sub-criterion, FMC provided discussion related to the following two options. [source: Application, pp33-35; FMC screening response, 6-8]

- 1) Do nothing
- 2) Establish a new 8-station center at a different site than Aberdeen

A summary of FMC's discussion of the advantages and disadvantages for each option is below.

Do Nothing

- Would do nothing to improve access.
- Outmigration would increase. Planning Area residents will need to out-migrate to receive care, and do so in increasing numbers without added capacity. As such, patient care will be fragmented, which harms access and quality of care.
- Capital and operating costs would be least under this option, since there would be none.
- Suffers from significant disadvantages by not promoting access and continuity of care.
- Forces patients to continue to out-migrate, which is inefficient and costly for planning area residents.

Establish a new 8-station center at a different site than Aberdeen

- Purely in terms of access, this option provides the same advantages as [the submitted project].
- There are no disadvantages from an access perspective.
- As discussed above, the current site must be relocated irrespective of this request for an additional eight stations. If the current site were not relocated, there could arise access problems in the future. Thus, the option to consider is whether to relocate the existing stations and build a different facility for the additional stations.
- Adds additional dialysis stations to the Planning Area, as warranted by the department's dialysis forecast model.
- Relative to option one, this option would fragment care and unnecessarily spread organizational resources that otherwise could be used for quality improvement and care coordination purposes.

- As stated above, this option would not be considered, since the current FMC site suffers from flood plain issues and space constraints. This option presumes the current site remain operational, which is not feasible.
- There are current flood plain issues and space constraints at the current facility location, thus, a new site is needed to operate the existing stations irrespective of the request for additional stations. The question is whether to build a single site for all current and requested stations or to build out two sites-one for current stations and another, for the additional requested stations. In this regard, the build-out of a single site is much more cost-effective and efficient, which is the application submitted.

Public Comment

None

Rebuttal Comment

None

Step Three

This step is applicable only when two or more projects can be approved. Since FMC's application is the only application that met all previous applicable review criteria, this step does not apply.

Department Evaluation of Steps One and Two for FMC

FMC provided a comprehensive discussion of the two alternatives considered before submitting this application. FMC rejected the 'do nothing' alternative because the numeric methodology shows need for stations in the planning area. Further, the 'do nothing' alternative is not effective for FMC's current Aberdeen site because of the potential flooding issues.

Given that the numeric methodology is based on the historical number of patients dialyzing in the planning area, the methodology also demonstrates patient growth in the planning area. FMC appropriately rejected the 'do nothing' alternative.

FMC also rejected the alternative of adding 8 stations to the planning area, but not at the current Aberdeen site. This alternative assumes no flood plain and space constraint issues at the current site, which is not the case. This option also requires FMC to operate two facilities in Grays Harbor County, which FMC does not consider to be cost effective or practical for coordination. FMC appropriately rejected this alternative.

Also, information provided in the application demonstrates that superior alternatives, in terms of cost, efficiency, or effectiveness, are not available or practicable for the patients in Grays Harbor County planning area. An additional eight stations in the county would result in patients having more flexibility scheduling for dialysis.

The estimated capital expenditure associated with the 8-station addition is \$2,173,750; FMC's portion of the cost is \$241,947. These costs include FMC's portion of the building construction, fixed and moveable equipment, and architect / engineering fees.

Given that the only other option to this project is to do nothing and taking into account the projected need for additional stations in the planning area, the department concludes that the project submitted by FMC is the best available alternative for the community. **This sub-criterion is met.**

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

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

Fresenius Medical Care

“The construction proposed for the relocated site 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.

Of the proposed site's approximate 11,500 square feet, 1,280 square feet is for the expansion portion of the project and 10,220 is expected for the relocation portion of the existing 16 stations. Further, the estimated capital expenditure associated with this project is \$423,348 toward the expansion portion of project and \$6, 128,585 for the relocation.”

[source: Application, pp35-36]

Public Comment

None

Rebuttal Comment

None

Department Evaluation

FMC proposes to relocate its existing 16-station dialysis center and add 8 new stations. The process to obtain approval for a relocation under WAC 246-310-289(3) is submission of an exemption application with the appropriate review fee. FMC’s project currently under review is the 8-station addition and all costs and equipment related to the station addition. The costs for the relocation are not evaluated again in this project. As previously stated in this evaluation, the amount identified for the station addition portion 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.

Fresenius Medical Care

“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. Further, it is important to understand the basis for FKC reimbursement, given this Department question, which raises the issue of capital expenditures and their potential effect on costs and charges for health services.

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 FKC.

In the case of private sector payers, FKC 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").

FKC does not negotiate any of its contracts at the facility-level, thus, the capital costs associated with the proposed FKC Aberdeen expansion would have no impact on payer negotiations or levels of reimbursement. In this regard, facility-level activities, such as number of FTEs, operating expenses or capital expenditures have no effect on negotiated rates, since such negotiations do not consider facility-level operations. As such, the proposed FKC relocation and expansion would have no effect on rates FKC would receive in the Grays Harbor Planning Area.” [source: Application pp27-28]

Public Comment

None

Rebuttal Comment

None

Department Evaluation

FMC’s project involves construction. This sub-criterion was evaluated under WAC 246-310-220(2), under which the department substantiated all costs identified for the station addition. With the need for additional stations in the Grays Harbor planning area and the assumptions related to the costs and charges discussed under the Financial Feasibility section of this evaluation, the department does not anticipate an unreasonable impact on the costs and charges to the public as a result of addition stations in the planning area. The department concludes that FMC **meets this sub-criterion.**

- (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

“The construction proposed for 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. Of the proposed site’s approximate 11,500 square feet, 1,280 square feet is for the expansion portion of the project and 10,220 is expected for the relocation portion of the existing 16 stations. Further, the estimated capital expenditure associated with this project is \$423,348 toward the expansion portion of project and \$6, 128,585 for the relocation.” [source: Application pp37-38]

Public Comment

None

Rebuttal Comment

None

Department Evaluation

FMC’s project could have the potential to improve delivery of dialysis services to the residents of Grays Harbor County planning area with the addition of dialysis stations in the planning area. **This sub-criterion is met.**

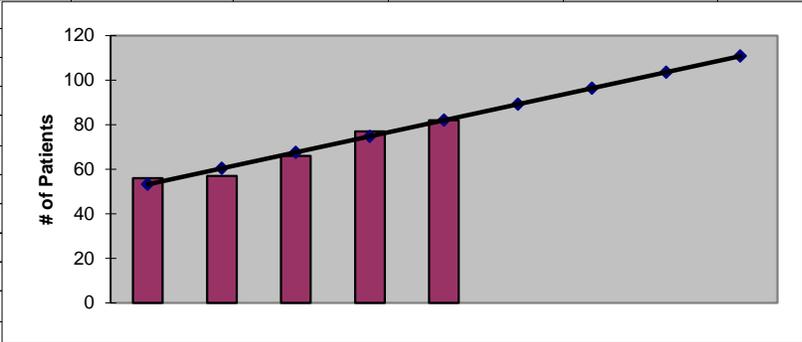
APPENDIX A



2017
Grays Harbor County
ESRD Need Projection Methodology

Planning Area		6 Year Utilization Data - Resident Incenter Patients					
Grays Harbor	2011	2012	2013	2014	2015	2016	
Grays Harbor County	63	56	57	66	77	82	
TOTALS	63	56	57	66	77	82	
246-310-284(4)(a)	Rate of Change		-11.11%	1.79%	15.79%	16.67%	6.49%
	6% Growth or Greater?		FALSE	FALSE	TRUE	TRUE	TRUE
	Regression Method:	Linear					
246-310-284(4)(c)			Year 1	Year 2	Year 3	Year 4	
			2017	2018	2019	2020	
Projected Resident Incenter Patients	from 246-310-284(4)(b)		89.20	96.40	103.60	110.80	
Station Need for Patients	Divide Resident Incenter Patients by 4.8		18.5833	20.0833	21.5833	23.0833	
	Rounded to next whole number		19	21	22	24	
246-310-284(4)(d)	subtract (4)(c) from approved stations						
Existing CN Approved Stations			16	16	16	16	
Results of (4)(c) above		-	19	21	22	24	
Net Station Need			-3	-5	-6	-8	
Negative number indicates need for stations							
Planning Area Facilities							
Name of Center	# of Stations						
FMC Aberdeen	16						
Total	16						
Source: Northwest Renal Network data 2011-2016							
Most recent year-end data: 2016 posted 02/07/2017							

x	y	Linear
2012	56	53
2013	57	60
2014	66	68
2015	77	75
2016	82	82
2017		89.200
2018		96.400
2019		103.600
2020		110.800



SUMMARY OUTPUT

<i>Regression Statistics</i>	
Multiple R	0.975112161
R Square	0.950843727
Adjusted R Square	0.934458303
Standard Error	2.988868236
Observations	5

ANOVA					
	<i>df</i>	<i>SS</i>	<i>MS</i>	<i>F</i>	<i>Significance F</i>
Regression	1	518.4	518.4	58.02985075	0.004695552
Residual	3	26.8	8.933333333		
Total	4	545.2			

	<i>Coefficients</i>	<i>Standard Error</i>	<i>t Stat</i>	<i>P-value</i>	<i>Lower 95%</i>	<i>Upper 95%</i>	<i>Lower 95.0%</i>	<i>Upper 95.0%</i>
Intercept	-14433.2	1903.559004	-7.582218346	0.004759198	-20491.17432	-8375.22568	-20491.17432	-8375.22568
X Variable 1	7.2	0.945163125	7.617732651	0.004695552	4.192069104	10.2079309	4.192069104	10.2079309

RESIDUAL OUTPUT

<i>Observation</i>	<i>Predicted Y</i>	<i>Residuals</i>
1	68.4	-2.4
2	65.3	3.7
3	62.2	0.8
4	59.1	-3.1
5	56	1

APPENDIX B

APPENDIX B

Kalpine Dialysis, LLC	DaVita HealthCare Partners
<p>Kalpine retains the power, duties and ultimate responsibilities vested in Owner as the owner of all or any part of the Business, and, during the Term of this Agreement, Owner is and will remain the responsible licensee of such applicable part of the Business and, as such, shall be fully liable and legally accountable at all times to all patients, governmental agencies, and others for patient care, and for all other clinical aspects of the operation and maintenance of the Business.</p>	<p>Supervise, manage, and operate, including without limitation, all dialysis services and related services such as hemodialysis, peritoneal dialysis of any type, staff assisted hemodialysis, dialysis related laboratory and pharmacy services, the provision of home dialysis services and supplies, the administration of dialysis-related pharmaceuticals (including without limitation EPO, Aranesp, iron supplements, vitamin D supplements, or other products related to the treatment of anemia and secondary hyperparathyroidism) to ESRD patients (collectively, "Dialysis Services").</p>
<p>Kalpine shall select the Medical Director. All compensation and other amounts payable to the Medical Director will be charged as an expense to Owner.</p>	<p>An affiliate of Contractual Manager shall recruit, employ, engage, lease, hire, train, promote, direct, supervise and terminate the employment or lease of such non-physician personnel (or arrange for the same through an employee leasing arrangement or as independent contractors) as such Affiliate determines is appropriate for the operation of the Center (collectively, the "Non-Physician Personnel"), including without limitation an administrator for the Center. Contractual Manager's Affiliate shall determine the eligibility requirements and the salary, wage, bonus, and other compensation levels, the personnel policies and employee benefits, and shall develop performance standards for, the Non-Physician Personnel. Such Affiliate shall use its reasonable discretion when making such determinations. Contractual Manager shall consult with Members of Owner in connection with and prior to the recruitment, engagement or replacement of any administrator at the Center.</p>
<p>Owner shall maintain, and at Owner's expense, at all times during the Term of this Agreement Workers' Compensation coverage in accordance with statutory requirements for Owner's employees who provide services under this Agreement, Commercial Property damage insurance written on full replacement value basis and for Owner's assets, Professional and General Liability insurance covering Owner's employees who perform any work, duties, or obligations in connection with this Agreements against claims for bodily injury or death and property damage, which insurance shall provide coverage on a claims-made or occurrence basis with a per occurrence limit of not less than One Million Dollars (\$1,000,000) per occurrence and Three Million Dollars (\$3,000,000) per annual aggregate and which limits may be satisfied by any combination of primary and excess or umbrella policies.</p>	<p>Affiliate of Contractual Manager will be the employer of the Non-Physician Personnel. All salaries, wages, bonuses, benefits, taxes and all other compensation and costs or other payments attributable to the Non-Physician Personnel shall be paid for by the designated Affiliate of Contractual Manager as the employer of said Non-Physician Personnel. Owner shall reimburse the designated Affiliate of Contractual Manager that employs the Non-Physician Personnel each month for any and all personnel costs related to the operation of the Center. At no time shall Owner be deemed to be the employer of any Non-Physician Personnel. Without limiting the generality of the foregoing, the costs attributable to the Non-Physician Personnel shall include but not be limited to the employer's contribution of FICA, unemployment compensation, and other employment taxes, retirement and profit sharing plan contributions, group life, accident, and health insurance premiums, disability, and other employee benefits, as well as the costs of obtaining appropriate malpractice and/or errors and omissions insurance, in each case to the extent determined by Contractual Manager or an Affiliate.</p>

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	<p>Staffing schedules for the Center will be determined by an Affiliate of Contractual Manager. Certain of the Non-Physician Personnel, as chosen by Contractual Manager or an' Affiliate in its reasonable discretion from time to time, shall attend continuing education and other employee programs offered by Contractual Manager or its Affiliates, including but not limited to programs at DaVita University and the DaVita Academy, national meetings, staff rallies and other programs for personnel affiliated with Contractual Manager, and all costs and expenses related thereto, including but not limited to, travel, room and board, and tuition, shall be included as an operating cost of the Center.</p>
	<p>Contractual Manager shall operate and manage the Centers in a manner consistent with the operation of its other wholly-owned dialysis facilities. Contractual Manager shall establish all operational policies and procedures reasonably necessary for establishing the appropriate standards of patient care at the Center. Said policies and procedures shall include, but shall not be limited to, those policies and procedures necessary to comply with the Medicare conditions for coverage of ESRD services, 42 CFR Section 405.2100 et seq., and applicable state laws relating to the operation of dialysis centers. Contractual Manager shall maintain and update, as reasonably required, quality control programs for the Center, including written procedures for handling patient complaints. Said procedures shall be designed to meet the legal requirements of state and federal statutes and regulations applicable to the Center.</p>
	<p>Contractual Manager, on Owner's behalf, shall select and purchase, lease, license or otherwise acquire or arrange for the use of, all assets necessary to operate the Business, including, without limitation, real property, medical, computer and other equipment, motor vehicles, software, supplies, drugs, inventory, utilities and other materials and items, in such quantities and at such times as Contractual Manager shall determine to be adequate or appropriate to operate the Business. Contractual Manager may acquire or lease or license any of such assets in its own name or in the name of any of its Affiliates or in the name of Owner. Contractual Manager may also arrange for improvements to be made to the Center, on Owner's behalf, if Contractual Manager determines such improvements to be reasonably necessary to maintain or upgrade quality, to replace obsolete or run-down equipment or to comply with any applicable laws, rules, regulations, or guidelines of any governmental or quasi-governmental or licensing authority or agency. All of the costs and expenses related or incident to Contractual Manager's obligations under this Section 2(c) shall be the responsibility of and shall be for the account of Owner, regardless of whether Contractual Manager provides such assets or procures such assets on Owner's behalf. If Contractual Manager purchases (whether in its own name or in the name of Owner) pharmaceuticals, supplies or other assets on behalf of Owner, Owner shall be responsible for the payment (either directly to the vendor, or to Contractual Manager if purchased by it on behalf of Owner) of the invoice price for such assets without mark-up or additional costs imposed by Contractual Manager, and Owner shall be entitled to its pro-rata share of any company-wide rebates received by Contractual Manager in connection with such purchases. Contractual Manager makes no representation or warranty, express or implied, as to the condition of any assets purchased or otherwise acquired by it on behalf of Owner from any person or entity that is not an Affiliate of Contractual Manager, and Contractual Manager shall not be liable for any defects in any of such items.</p>

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	<p>Contractual Manager shall at the sole cost of Owner, provide the Business with computer hardware (including but not limited to any and all necessary wiring) and software comparable to that installed at other dialysis and renal care centers managed by Contractual Manager or its Affiliates as of the date hereof. Contractual Manager may determine from time to time that said hardware and software requires upgrading or replacement, the cost of which shall be the responsibility of and paid for by Owner. All computer software, including such upgrades, shall remain the property of Contractual Manager during and following the Term of this Agreement and shall be returned to Contractual Manager upon termination hereof. Owner is hereby granted a non-exclusive right to use said software during the Term of this Agreement. The computer hardware, including any upgrades, provided to Owner may be retained by Owner following termination of this Agreement.</p>
	<p>Contractual Manager shall make or install, or cause to be installed, at Owner's expense and in the name of Owner, any proper repairs, replacements, additions, and improvements in and to the Center and the furnishings and equipment thereof as Contractual Manager, in its reasonable judgment, shall deem necessary in order to keep and maintain the same in good repair, working order and condition, and outfitted and equipped for the proper operation thereof in accordance with industry standards and comparable to those prevailing in other similar facilities, and all applicable state or local rules, regulations, or ordinances.</p>
	<p>Contractual Manager shall perform bookkeeping and accounting procedures for the Business, and shall maintain financial records for the Business in accordance with reasonable industry standards. Contractual Manager shall prepare and provide to Owner with respect to the Business reasonably detailed operating reports (including balance sheets, cash flow analyses and number of treatments) on a monthly basis within forty-five (45) days from the last day of each calendar month and on an annual basis within ninety (90) days from the last day of each calendar year. Financial data set forth in the operating reports shall be reported on an accrual basis. Contractual Manager shall not be responsible for preparing operating reports or records relating to any operations other than the Business. Contractual Manager may, in its discretion, maintain any or all of the books and records relating to the Business at the Center or at any other location, provided that Owner shall have access to such books and records as set forth below in Section 3(a). Contractual Manager shall, on Owner's behalf and at Owner's expense, prepare and file, or cause to be prepared and filed by qualified professionals, in each case for signature by Owner, all necessary local, state and federal income tax returns and all necessary business tax returns, including but not limited to sales, use and personal property tax returns relating to the Business. All amounts payable with respect to any of such taxes shall be the responsibility of and shall be for the account of Owner. Owner shall assist Contractual Manager or Contractual Manager's tax preparation consultant, at Contractual Manager's request, with the preparation of said returns.</p>
	<p>Contractual Manager shall perform billing and collection functions on behalf of Owner with respect to the operation of the Business, including with respect to private pay patients and reimbursement from third party payors. All out-of-pocket costs and expenses relating to the billing and collection services, including without limitation, any fees or expenses payable to collection agencies, shall be for the account of Owner. Contractual Manager shall provide assistance to Owner in the preparation (for Owner's signature) and filing of all costs reports, exception requests and other reports and data necessary for obtaining appropriate reimbursement for the items and services provided by the Business under the Medicare and applicable Medicaid programs and any other third party.</p>

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	<p>Contractual Manager shall maintain on behalf of Owner, and at Owner's expense, at all times during the Term of this Agreement Workers' Compensation coverage in accordance with statutory requirements for Contractual Manager's employees who provide services under this Agreement. Commercial Property damage insurance written based on full replacement value and for Contractual Manager's assets, Professional and General Liability covering Contractual Manager's employees who perform any work or duties in connection with this Agreement against claims for bodily injury or death and property damage; which insurance shall provide coverage on a claims-made basis with a per occurrence limit of not less than One Million Dollars (\$1,000,000) per occurrence and Three Million Dollars (\$3,000,000) per annual aggregate and which limits may be satisfied by any combination of self insurance or umbrella policies. Contractual Manager may carry any insurance required by this Agreement under a blanket policy. All premiums, deductibles, and retentions shall be the responsibility of and for the account of Owner.</p>
	<p>Contractual Manager may enter into, or modify, supplement, amend, or terminate, or grant waivers or releases of obligations under, such contracts, leases, licenses, instruments and other agreements ("Contracts"), in the name of and at the expense of Owner, as may be deemed necessary or advisable for the furnishing of all professional, consulting, and staffing services, concessions, drugs, supplies, utilities, equipment or other property maintenance, insurance and other products, goods, and services as may be necessary or appropriate from time to time for the maintenance and operation of the Business, or as may otherwise be necessary or appropriate to carry out Contractual Manager's obligations under this Agreement, including without limitation, transplant agreements, and affiliation agreements. Contractual Manager is hereby expressly authorized, as Owner's agent, to execute and deliver any of such Contracts in the name of and on behalf of Owner, and presentation of a copy of this Agreement shall constitute conclusive evidence of such agency; provided, however, that Contractual Manager is authorized to enter into and maintain in its own name any national and regional Contracts in which the Center may participate, as well as such other Contracts for the Center which, in the judgment of Contractual Manager, are to be entered into in Contractual Manager's name. ...Contractual Manager is expressly authorized to contract, in the name and on behalf of Owner, for the provision by Contractual Manager or its Affiliates of any services to be provided to the Business. Notwithstanding the foregoing, without the prior written approval of Owner, Contractual Manager may not, in the name or on behalf of Owner, enter into any leases of real property, any loan agreements, or any material Contract that does not relate to the operation or maintenance of the Business; provided, however, Contractual Manager may, in the name and on behalf of Owner, modify, supplement, amend, or terminate, or grant waivers or releases of obligations under, any of such Contracts if the same will not have a material adverse effect on Owner or the Business.</p>
	<p>Contractual Manager shall apply for and use its reasonable efforts to obtain and maintain in the name and at the expense of Owner, all licenses, permits, and Medicare and applicable Medicaid provider numbers required or appropriate in connection with the operation of the Business.</p>
	<p>Contractual Manager shall use its reasonable efforts to take such action as shall be reasonably necessary to ensure that the Center and the management thereof by Contractual Manager complies with all federal, state and local laws, regulations and ordinances applicable to the Center or the Business or the management thereof by Contractual Manager.</p>