STATE OF WASHINGTON

DEPARTMENT OF HEALTH

Olympia, Washington 98504

June 21, 2022

Jenna Gilbreath, Director, Special Projects
DaVita Inc. North Star Division
e-mail: jenna.gilbreath@davita.com

RE: Certificate of Need Application #22-12 DaVita Kennewick Dialysis Center

Dear Ms. Gilbreath:

The review of the Certificate of Need application submitted by DaVita, Inc. proposing to add three dialysis stations to the existing 11-station Kennewick Dialysis Center in Kennewick, within Benton County, has been completed. The three beds include two new dialysis stations and conversion of the existing exempt isolation station to a non-exempt isolation station. At project completion, Kennewick Dialysis Center would operate a total of 13 dialysis stations, which includes 12 general-use dialysis stations and one non-exempt isolation station. Attached is a written evaluation of the application.

For the reasons stated in this evaluation, the project is consistent with applicable criteria of the Certificate of Need Program, provided that DaVita, Inc. agrees to the following in its entirety.

Project Description:

This certificate approves the addition of three dialysis stations to DaVita's 20-station Kennewick Dialysis Center, for a total of 13 dialysis stations, including one non-exempt isolation station. DaVita's Kennewick Dialysis Center will remain at its current location in Kennewick and continue to provide the following services: in-center hemodialysis, home hemodialysis, a non-exempt isolation station, dialysis for patients visiting Benton County, and shifts beginning after 5:00 pm. A breakdown of the dialysis stations after project completion is shown below

Station Type	CMS Certified Stations	Station Counted for Station Use and Methodology
General Use In-Center Stations	12	12
Permanent Bed Station	0	0
Non-Exempt Isolation Station	1	1
Exempt Isolation Station	0	0
Total Stations	**13**	**13**

Conditions:

1. Approval of the project description as stated above. DaVita 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. DaVita shall finance this project using existing capital reserves, as described in the application.
3. DaVita agrees that after conversion of the current exempt isolation station to a non-exempt isolation station, Kennewick Dialysis Center is not eligible to add another exempt isolation station under WAC 246-310-809.

Approved Costs:
The approved capital expenditure for this three-station addition is $448,428, which includes construction, costs for fixed and moveable equipment, associated fees, and sales tax. All costs are to be paid by DaVita Inc. from its existing corporate reserves.

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

If any of the above provisions are rejected, this 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 this e-mail address: FSLCON@doh.wa.gov.

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

Sincerely,

Eric Hernandez, Program Manager
Certificate of Need
Office of Community Health Systems

Attachment

2022 CYCLE TWO NON-SPECIAL CIRCUMSTANCE EVALUATIONS DATED JUNE 21, 2022, FOR TWO CERTIFICATE OF NEED APPLICATIONS SUBMITTED BY DAVITA, INC. PROPOSING TO ADD DIALYSIS STATIONS TO EXISTING DIALYSIS CENTERS. THE FACILITIES ARE:

- **DAVITA CHINOOK KIDNEY CENTER**
- **DAVITA KENNEWICK DIALYSIS CENTER**

APPLICANT DESCRIPTION

DaVita, Inc.

DaVita is a national provider of dialysis services operating in 46 states and the District of Columbia.[1] In Washington State, DaVita is approved to own and operate several dialysis centers.[2] [source: Certificate of Need Program files and Application, p4-7]

DaVita, Inc. submitted this application under its subsidiary of Total Renal Care, Inc. For Certificate of Need purposes, DaVita, Inc. is the applicant and will be referenced in this evaluation as "DaVita."

PROJECT DESCRIPTIONS

DaVita Chinook Kidney Center

This project focuses on DaVita's Chinook Kidney Center which will be referenced in this evaluation as "Chinook." The dialysis center is located at 1351 Aaron Drive, Building C1, in Richland [99352], within Benton County. Currently, Chinook has a total of 18 general use dialysis stations, plus one permanent bed station, and one exempt isolation station, for a facility total of 20 dialysis stations. A breakdown of the current number of stations is shown in the table below. [source: Application, p10]

Station Type	CMS Certified Stations	Station Counted for Station Use and Methodology
General Use In-Center Stations	18	18
Permanent Bed Station	1	1
Exempt Isolation Station	1	0
Total Stations	**20**	**19**

This application proposes to add one dialysis station, resulting in a facility total of 21 dialysis stations, which includes a permanent bed station and one exempt isolation station. The dialysis center would continue to provide the following services. [source: Application, p10]

- In-center hemodialysis for patients who dialyze in the chronic setting,
- Hemodialysis for patients requiring isolation,
- Hemodialysis for patients requiring a permanent bed, and
- Hemodialysis for patients requiring treatment shifts that begin after 5:00 PM,

Additional services provided include:

- Treatment for visiting hemodialysis patients from other areas outside Benton County, and
- Community education for patients recently diagnosed with Chronic Kidney Disease (CKD).

[1] DaVita operates in 46 states and the District of Columbia. The four states where DaVita does not have facilities are: Alaska, Delaware, Vermont, and Wyoming.

[2] The department acknowledges that DaVita has a number of approved projects and pending applications with the department. As the corresponding decisions are released, these numbers fluctuate.

DaVita's estimated capital expenditure for this one-station addition project is $27,248, which includes costs for fixed and moveable equipment, associated fees, and sales tax. Construction is not needed to add the additional station. All costs will be paid by DaVita from its reserves. [source: Application, p20]

Within the application and screening materials, DaVita determined this evaluation would be released in June 2022. Using that timeline, DaVita estimated the additional station would be operational by the end of December 2022. [source: January 28, 2022, Screening Responses, p2] Under this timeline, full calendar year one is 2023, and full calendar year three is 2025.

DaVita Kennewick Dialysis Center

This project focuses on DaVita's Kennewick Dialysis Center which will be referenced in this evaluation as "Kennewick." The dialysis center is located at 3208 West 19th Avenue, Suite 101, in Kennewick [99337], within Benton County. Currently, Kennewick has a total of 10 general use dialysis stations, plus one exempt isolation station, for a facility total of 11 dialysis stations. A breakdown of the current number of stations is shown in the table below. [source: Application, p10]

Station Type	CMS Certified Stations	Station Counted for Station Use and Methodology
General Use In-Center Stations	10	10
Permanent Bed Station	0	0
Exempt Isolation Station	1	0
Total Stations	**11**	**10**

This application proposes to add two dialysis stations and convert the current exempt isolation station to a non-exempt isolation station for a net addition of three stations, resulting in a facility total of 13 dialysis stations with no permanent bed station or exempt isolation station. After conversion of the exempt isolation station granted under WAC 246-310-809, Kennewick Dialysis Center would not be eligible to add another exempt isolation station under that section. The dialysis center would continue to provide the following services. [source: Application, p8 and p10]

- In-center hemodialysis for patients who dialyze in the chronic setting,
- Hemodialysis for patients requiring isolation,
- Hemodialysis for patients requiring treatment shifts that begin after 5:00 PM,

Additional services provided include:

- Treatment for visiting hemodialysis patients from other areas outside Benton County, and
- Community education for patients recently diagnosed with Chronic Kidney Disease (CKD).

DaVita's estimated capital expenditure for this three-station addition project is $448,428, which includes construction, costs for fixed and moveable equipment, associated fees, and sales tax. All costs will be paid by DaVita from its reserves. [source: Application, p20]

Within the application and screening materials, DaVita determined this evaluation would be released in June 2022. Using that timeline, DaVita estimated the three additional stations would be operational by the end of October 2023. [source: Application, p9] Under this timeline, partial year one is 2023, full calendar year one is 2024, and full calendar year three is 2026.

APPLICABILITY OF CERTIFICATE OF NEED LAW

Both applications propose to add dialysis stations to existing dialysis centers. These applications are subject to review as an increase in the number of dialysis stations in a kidney disease center under provisions of RCW 70.38.105(4)(h) and WAC 246-310-020(1)(e).

EVALUATION CRITERIA

WAC 246-310-200(1)(a)-(d) identifies the four determinations that the department must make for each application. WAC 246-310-200(2) provides additional direction on how the department is to make its determination.

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).

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

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

WAC 246-310-803

WAC 246-310-803 requires an applicant to submit specific data elements to the Certificate of Need Program. For the 2021 concurrent review cycle, the data must be received before February 15, 2021. The applicant submitted data elements timely.

TYPE OF REVIEW

As directed under WAC 246-310-806, the department accepted these applications under the Kidney Disease Treatment Facilities-Nonspecial Circumstances Concurrent Review Cycle #2 for calendar year 2021. Below is the chronologic summary of the application review cycle. The dates are identical for both applications.

APPLICATION CHRONOLOGY

Action	DaVita, Inc. Both Projects
Letters of Intent Submitted	November 1, 2021
Applications Submitted	December 1, 2021
Department's Pre-review Activities including • DOH First Screening Letter • Applicant's First Screening Responses Received	 December 30, 2021 January 28, 2022
Beginning of Review	February 7, 2022

Action	DaVita, Inc. Both Projects
End of Public Comment • No public comments received • No public hearing requested or conducted	March 9, 2022
Rebuttal Comments Deadline	April 6, 2022
Department's Anticipated Decision Date	June 22, 2022
Department's Actual Decision Date	June 21, 2022

AFFECTED PERSONS

Affected persons are defined under WAC 246-310-010(2). In order to qualify as an affected person, someone must first qualify as an "interested person," defined under WAC 246-310-010(34). For these projects, no one sought affected person status.

PUBLIC COMMENT AND REBUTTAL

During the review of these projects, the department received no comments, therefore the sub-criteria within this evaluation do not contain references to public comment or rebuttal.

SOURCE INFORMATION REVIEWED

- DaVita, Inc.'s Two Certificate of Need applications both received December 1, 2021
- DaVita, Inc.'s Two screening responses both received January 28, 2022
- DaVita's Chinook Kidney Center Certificate of Need facility file
- DaVita's Kennewick Dialysis Center Certificate of Need facility file
- Historical kidney dialysis utilization data from Comagine Health ESRD Network 16 (formerly Northwest Renal Network)
- Department of Health's ESRD Need Projection Methodology for the Benton County ESRD planning area posted to its website in March of 2021
- Licensing data provided by the Medical Quality Assurance Commission, Nursing Quality Assurance Commission, and Health Systems Quality Assurance Office of Customer Service
- DaVita, Inc.'s website at https://www.davita.com/
- Comagine Health ESRD Network 16 website at https://comagine.org/esrd
- Centers for Medicare and Medicaid Services website at https://www.medicare.gov/care-compare

CONCLUSIONS

DaVita Chinook Kidney Center

For the reasons stated in this evaluation, the application submitted by DaVita proposing to add one dialysis station to DaVita Chinook Kidney Center located in the Benton County ESRD Planning Area is consistent with applicable criteria of the Certificate of Need Program, provided that the applicant agrees to the following in its entirety.

Project Description:

This certificate approves the addition of one dialysis station to DaVita's 20-station Chinook Kidney Center, for a total of 21 dialysis stations, which includes a permanent bed station and one exempt isolation station. DaVita's Chinook Kidney Center will remain at its current location in Richland and continue to provide the following services: in-center hemodialysis, a permanent bed station, an isolation dialysis station, dialysis for patients visiting Benton County, and shifts beginning after 5:00 pm. A breakdown of the dialysis stations after project completion is shown below

Station Type	CMS Certified Stations	Station Counted for Station Use and Methodology
General Use In-Center Stations	19	19
Permanent Bed Station	1	1
Exempt Isolation Station	1	0
Total Stations	**21**	**20**

Conditions:

1. Approval of the project description as stated above. DaVita 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. DaVita shall finance this project using existing capital reserves, as described in the application.

Approved Costs:

The approved capital expenditure for this one-station addition is $27,248, which includes costs for fixed and moveable equipment, associated fees, and sales tax. All costs are to be paid by DaVita Inc. from its existing corporate reserves.

DaVita Kennewick Dialysis Center

For the reasons stated in this evaluation, the application submitted by DaVita proposing to add three dialysis stations to DaVita Kennewick Center located in the Benton County ESRD Planning Area is consistent with applicable criteria of the Certificate of Need Program, provided that the applicant agrees to the following in its entirety.

Project Description:

This certificate approves the addition of three dialysis stations to DaVita's 20-station Kennewick Dialysis Center, for a total of 13 dialysis stations, including one non-exempt isolation station. DaVita's Kennewick Dialysis Center will remain at its current location in Kennewick and continue to provide the following services: in-center hemodialysis, a non-exempt isolation station, dialysis for patients visiting Benton County, and shifts beginning after 5:00 pm. A breakdown of the dialysis stations after project completion is shown below

Station Type	CMS Certified Stations	Station Counted for Station Use and Methodology
General Use In-Center Stations	12	12
Permanent Bed Station	0	0
Non-Exempt Isolation Station	1	1
Exempt Isolation Station	0	0
Total Stations	**13**	**13**

Conditions:

1. Approval of the project description as stated above. DaVita 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. DaVita shall finance this project using existing capital reserves, as described in the application.
3. DaVita agrees that after conversion of the current exempt isolation station to a non-exempt isolation station, Kennewick Dialysis Center is not eligible to add another exempt isolation station under WAC 246-310-809.

Approved Costs:
The approved capital expenditure for this three-station addition is $448,428, which includes construction, costs for fixed and moveable equipment, associated fees, and sales tax. All costs are to be paid by DaVita Inc. from its existing corporate reserves.

CRITERIA DETERMINATIONS
A. Need (WAC 246-310-210)

DaVita Chinook Kidney Center

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

DaVita Kennewick Dialysis Center

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

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

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

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

WAC 246-310-812 contains the methodology for projecting numeric need for dialysis stations within a planning area. This methodology projects the need for kidney dialysis treatment stations through a regression analysis of the historical number of dialysis patients residing in the planning area using verified utilization information obtained from the Comagine Health ESRD Network 16, formerly Northwest Renal Network.[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 246-310-812(4)(a)] This is derived by calculating the annual growth rate in the planning area using the year-end number of resident incenter patients for each of the previous six consecutive years, concluding with the base year.[4]

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.

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

[4] WAC 246-310-800(2) 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 2020.

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' Comagine Health ESRD Network 16 data, again concluding with the base year. [WAC 246-310-812(4)(b) and (c)]

WAC 246-310-812(5) identifies that for all planning areas except Adams, Columbia, Douglas, Ferry, Garfield, Jefferson, Kittitas, Klickitat, Lincoln, Okanogan, Pacific, Pend Oreille, San Juan, Skamania, Stevens, and Wahkiakum counties, the number of projected patients is divided by 4.8 to determine the number of stations needed in the planning area. For the specific counties listed above, the number of projected patients is divided by 3.2 to determine needed stations. Additionally, the number of stations projected as needed in the target year is rounded up to the nearest whole number.

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

Department Evaluation for Both Applications

DaVita proposes to add one station to Chinook and add a net of three stations to Kennewick by adding two stations and converting the exempt isolation station to a non-exempt isolation station. DaVita relied on the numeric methodology posted to the department's website for the planning area which calculates need for four stations in projection year 2025. [source: Application pp14-15]

Department Evaluation of the Numeric Methodology for the Benton County ESRD Planning Area

The department annually calculates the numeric methodology for each of the 57 ESRD planning areas in Washington State and posts each of the results to its website. The department's year 2021 numeric methodology was posted in March 2021. Based on the calculation of the annual growth rate in the planning area, the department used the linear regression to determine numeric need. The number of projected patients was divided by 4.8 to determine the number of stations needed in the Benton County planning area. Following is a summary of the department's numeric methodology.

Department's Table 1
Benton County Planning Area
Numeric Methodology Summary

4.8 in-center patients per station		
2025 Projected # of stations	Minus Current # of stations	2025 Net Need or (Surplus)
50	46	4

DaVita operates two of the three facilities operating in the planning area. DaVita Chinook Kidney Center is approved for 19 stations, DaVita Kennewick Dialysis Center is approved for 10 stations, and Fresenius Medical Care's Columbia Basin Dialysis Center is approved for 17 stations. As shown in the table above, once the 46 existing stations are subtracted from the projected need, the result is a net need of four stations in projection year 2025. DaVita is requesting the addition of one station to Chinook and three stations to Kennewick. The department's methodology is included in this evaluation as Appendix A. The department concludes both of DaVita's applications **meet the numeric methodology standard**.

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

WAC 246-310-812(5)

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

(a) All stations for a facility have been in operation for at least three years; or

(b) Certificate of need approved stations for a facility have not become operational within the timeline as represented in the approved application.

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

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

DaVita, Inc.

There are three dialysis centers operating in the planning area. DaVita provided the following table and statement related to the utilization at all three facilities. [source: Chinook Application, p14; Kennewick Application, p14]

Applicant's Table

Table 5	Quarterly Utilization of Existing Stations				Eligibility Criteria		
			NWRN 6/30/2021		Standard Met?	Standard Met?	Standard Met?
Existing Dialysis Facilities in Benton County	Provider	Approved Stations	Patients	Patients Per Station	4.5 Patients Per Station	Operating 3+ years?	Missed Operational Timeline?
DVA CHINOOK 502559	DVA	19	79	**4.16**	No →	Yes	-
FMC COL. BASIN 502518	FMC	17	61	**3.59**	No →	No →	Yes
DVA KENNEWICK 502572	DVA	10	45	**4.50**	Yes	-	-

"Table 5 shows that DVA Chinook and FMC Columbia Basin do not meet the utilization standards for this planning area. Pursuant to WAC 246-310-812(5) "when a planning area has one or more facilities not meeting the in-center patients per station standard, the department will consider the 4.5 in-center patients per station standard met for those facilities when:" continuing to subsection 246-310-812(5)(a) & (b) "all stations for a facility have been in operation for at least three years; or Certificate of need approved stations for a facility have not become operational within the timeline as represented in the approved application."

"DVA Chinook meets the criteria outlined in 246-310-812(5)(a) as all stations have been in operation for greater than three years. FMC confirms that the FMC Columbia Basin facility expansion is "Not Yet Complete" in their CN 21-76 Screening Response dated September 30, 2021. Therefore, FMC

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

Columbia Basin meets the criteria outlined in 246-310-812(5)(b) as the latest approved stations did not become operational within the timeline represented on their application nor by the proposed 1st treatment date of 6/2/2021 outlined in the approved timeline modification request approved on November 20, 2020."

Department Evaluation of Both Applications

WAC 246-310-812(5) states that the "*data used to make this calculation must be from the most recent quarterly modality report from the Northwest Renal Network as of the letter of intent submission date.*" The date of the letter of intent is November 1, 2021, for this review. The data available as of November 1, 2021, is second quarter June 30, 2021, data that was available on August 10, 2021.

As previously stated, there are three facilities operating, or approved to operate, in the Benton County planning area. Documentation provided in the June 30, 2021, report is consistent with the facility utilization presented by DaVita in their Table 5, above. The department notes that FMC Columbia Basin performed its first treatment in its expansion on December 6, 2021, missing it's projected first treatment date of June 2, 2021, by over six months.

Based on the information above, the department concludes that the planning area meets the utilization standards in WAC 246-310-812(5). **This sub-criterion is met for both projects.**

(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 aged 65 and over. 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 not sufficient to enable them to pay for the care or to pay deductibles or coinsurance amounts required by a third-party payer.[6] The policy should also include the process one must use to access charity care at the facility.

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

Chinook Kidney Center and Kennewick Dialysis Center

DaVita provided the following information for this sub-criterion. [source: Chinook Application, p17; Kennewick Application, p17]

"DaVita's history of providing dialysis services at numerous locations throughout Washington State shows that all persons, including the underserved groups identified in WAC 246-310-210(2), have adequate access to DaVita's facilities, as required by the regulation. We have provided as Appendix 14 copies of the applicable admission, patient financial evaluation, and patient involuntary transfer policies."

DaVita also provided the following policies and procedures for both facilities. [source: Chinook and Kennewick Applications, Appendix 14]

- Accepting End State Renal Disease Patients for Treatment
- Patient Behavior Agreements, 30-Day Discharge, Involuntary Discharge or Involuntary Transfer
- Patient Financial Evaluation Policy (Charity Care Policy)
- Patient's Rights Policy

Medicare and Medicaid Programs

Both Chinook and Kennewick are currently Medicare and Medicaid certified. As directed in WAC 246-310-815, DaVita based its payer mix each facility's current payor mix.

Chinook Kidney Center

For Chinook, DaVita provided a table showing the current percentages of revenues by payer and revenues by patient. The information is summarized below. [source: Chinook Application, p13 and p21]

Medicare Provider Number: 502559
Medicaid Provider Number: 1578701272

Applicant's Table

Table 11 DaVita Chinook Kidney Center Historical & Projected Payer Mix	Percentage by Revenue	Percentage by Patient
Medicare	52.18%	73.29%
Medicaid	12.52%	14.21%
Commercial, Other Government, and Other	35.31%	12.50%
Total	100.00%	100.00%

Kennewick Dialysis Center

For Kennewick, DaVita provided a table showing the current percentages of revenues by payer and revenues by patient. The information is summarized below. [source: Kennewick Application, p13 and p21]

Medicare Provider Number: 502572
Medicaid Provider Number: 1790068542

Applicant's Table

Table 11 DaVita Kennewick Dialysis Historical & Projected Payer Mix	Percentage by Revenue	Percentage by Patient
Medicare	53.53%	68.29%
Medicaid	18.22%	17.62%
Commercial, Other Government, and Other	28.26%	14.09%
Total	100.00%	100.00%

Department Evaluation of Both Applications

DaVita has been providing dialysis services to the residents of Washington State for many years. DaVita provided a policy titled "Accepting End Stage Renal Disease Patients for Treatment" which provides the assurance that DaVita would provide treatment to without regard to "*race, color, national origin, gender, sexual orientation, age, religion, or disability…*" provided that the patient's care can be managed in an outpatient facility. [source: Chinook Application, Appendix 14; Kennewick Application, Appendix 14]

All DaVita dialysis centers are Medicare and Medicaid certified. Documentation provided in the application demonstrates that each dialysis center would continue both Medicare and Medicaid certifications once stations are added. To further demonstrate this intention DaVita provided its historical and projected revenues for both facilities. [source: Chinook Application, p13 and p21; Applicant's October 11, 2021, Chinook screening responses, p2; Kennewick Application, p13 and pp21-22]

DaVita also provided a policy titled "Patient Financial Evaluation Policy" which provides the necessary information and process a patient would use to obtain charity care at each dialysis center. DaVita further demonstrated its intent to provide charity care for patients by including a "Charitable Care" line item as a deduction from revenue within the pro forma income statement. [source: January 28, 2022, screening response for both facilities, Appendix 9]

DaVita provided copies of the necessary policies used at all DaVita dialysis centers, which includes Chinook and Kennewick dialysis centers. These policies reflect DaVita's commitment to provide adequate access to all residents of the service area. The policies are consistent with those reviewed and approved by the department in the past. Given that DaVita currently operates both facilities and uses these policies and procedures at these centers, the policies provided in the applications are executed policies. The department concludes DaVita's proposals **meet this sub-criterion**.

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

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

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

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

(4) The project will not have an adverse effect on health professional schools and training programs. The assessment of the conformance of a project with this criterion shall include consideration of:
(a) The effect of the means proposed for the delivery of health services on the clinical needs of health professional training programs in the area in which the services are to be provided.
(b) If proposed health services are to be available in a limited number of facilities, the extent to which the health professions schools serving the area will have access to the services for training purposes.

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

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

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

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

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

(1) The immediate and long-range capital and operating costs of the project can be met.
WAC 246-310-815 outlines the financial feasibility review requirements for dialysis projects. For these two projects, DaVita must demonstrate compliance with the following sub-sections of WAC 246-310-815(1).

WAC 246-310-815(1)
(1) The kidney dialysis facility must demonstrate positive net income by the third full year of operation.
(a) The calculation of net income is subtraction of all operating and non-operating expenses, including appropriate allocated and overhead expenses, amortization and depreciation of capital expenditures from total revenue generated by the kidney dialysis facility.
(b) Existing facilities. Revenue and expense projections for existing facilities must be based on that facility's current payer mix and current expenses.
(c) New facilities.
(i) Revenue projections must be based on the net revenue per treatment of the applicant's three closest dialysis facilities.
(ii) Known expenses must be used in the pro forma income statement. Known expenses may include, but are not limited to, rent, medical director agreement, and other types of contracted services.
(iii) All other expenses not known must be based on the applicant's three closest dialysis facilities.

(iv) If an applicant has no experience operating kidney dialysis facilities, the department will use its experience in determining the reasonableness of the pro forma financial statements provided in the application.

(v) If an applicant has one or two kidney dialysis facilities, revenue projections and unknown expenses must be based on the applicant's operational facilities

Given that these two projects propose the addition of stations to existing dialysis centers, sub-sections (1)(a) and (b) above apply to each project.

Chinook Kidney Center

As previously stated, DaVita estimated the dialysis center would be operational by the end of December 2022. [source: January 28, 2022, screening responses, p2] Under this timeline, full calendar year one is 2023, and full calendar year three is 2025.

At project completion, Chinook would be operating with total of 21 dialysis stations, which includes one permanent bed station and one exempt isolation station. DaVita provided the assumptions used to project in-center treatments and patients. The assumptions are restated below. [source: January 28, 2022, screening response, Appendix 9]

- *First Full Year: 2023, based on a first patient date in December 2022 at the expanded facility.*
- *Total Stations: CON Approved stations. One CON-exempt isolation station is also included in driving relevant category calculations (bio-med FTE, overall facility depreciation).*
- *Total Chronic Capacity: 6 shift capacity of CON-approved stations is assumed to be 100% utilization.*
- *Patient Census Projections: Census projections are based on a 5-year projection of planning area patients using a regression of 5 years historical data and DaVita's own experience and expertise. This is the same trend line (based on the Department's methodology as applied through 2025), but extended out through the projection period to project planning area census throughout. DaVita uses projected planning area census, existing planning area capacity, and additional market and experiential knowledge to project new facility census.*

Using the assumptions stated above, DaVita projected the number of in-center dialyses and patients for Chinook for years 2023 through 2025. The projections are summarized in the table below. [source: January 28,2022, screening response, p3 and Appendix 9]

Applicant's Table

	Partial 2022 Jan-Nov	Partial 2022 Dec	Full Year 2023	Full Year 2024	Full Year 2025
Total Stations (end of the year - excludes CON-exempt iso station)	19	20	20	20	20
Total Shifts	6	6	6	6	6
Total Chronic Capacity (end of period)	114	120	120	120	120
Total Chronic Patients (end of the period)	83	83	87	91	94
% of Capacity	*72.8%*	*69.2%*	*72.5%*	*75.8%*	*78.3%*
Average Annual Chronic Patients (avg of beginning & end of period)	81.0	83.0	85.0	89.0	92.5
Total Chronic Treatments	11,004	1,025	12,597	13,190	13,709
Total Home Patients (end of the period)	0	0	0	0	0
Average Annual Home Patients (avg of beginning & end of period)	0.0	0.0	0.0	0.0	0.0
Total Home Treatments	0	0	0	0	0
Total Patients (avg of beginning & end of period)	81.0	83.0	85.0	89.0	92.5
Total Treatments	11,004	1,025	12,597	13,190	13,709

DaVita, Inc. provided assumptions for its projected financial statements, which are restated below. [source: January 28, 2022, screening response, Appendix 9]

- *Charity Care: estimated at 1.3% of gross revenue, consistent with DaVita's historical experience.*
- *Total Treatments: Total Treatment Volume is assumed to be based on average yearly census, a 5% missed treatment rate consistent with DaVita's own experience and expertise, and three treatments weekly for 52 weeks per year.*
- *Revenue per treatment: No inflation is applied to revenue per treatment, which is based on the last full year of operation for the facility and its payer mix.*
- *General expenses: Based on cost per treatment for the last full calendar year (2020) for the facility by category. This excludes lease expenses (noted below), depreciation expense (based on projected capital expenditures and existing depreciation), medical director expense (noted below), and labor costs (noted below).*
- *Cost inflation: DaVita does not assume inflation in any expense category except where otherwise noted – no current contract cost increases are known except where otherwise noted, and thus are not included.*
- *Medical Director Expense: based on contracted, known expenses in latest medical director agreement that runs through the extent of the three-year projection window.*
- *Lease Expense: base rent for the projection period is directly pulled from page 1 of the third amendment to the lease contract. Tax and CAM are based on the last full calendar year (2020) for this facility, calculated at $60,813 per year.*
- *Labor Assumptions: Based on safe, fair, and efficient staffing ratios for projected census and required staff type. Benefits, taxes, and non-base pay are assumed at a rate of 41.81% of base salaries and wages based on 2020 data for the facility. No inflation is assumed.*

DaVita, Inc. also provided a copy of the lease for the current site, including the base rent and associated additional expenses. [source: Application, Appendix 15]

Based on the assumptions and clarifications above, DaVita, Inc. provided both historical and projected revenue, expenses, and net income for historical years 2018-2021 and projected years 2022 through 2025, summarized below. [source: Application, Appendix 8; January 28, 2022, screening response, Appendix 9]

Department's Tables 2
Chinook Kidney Center
Historical and Current Revenue and Expense Summary

	CY 2019 Historical	**CY 2020 Historical**	**CY 2021 Current**
Total Number of Stations	20	20	20
Net Revenue	$3,496,130	$4,859,040	$4,737,564
Total Expenses	$3,173,371	$3,465,535	$3,382,612
Net Profit / Loss	**$322,759**	**$1,393,505**	**$1,354,952**

Chinook Kidney Center
Projected Revenue and Expense Summary for Years 2022 - 2025

	CY 2022 Expansion Year	CY 2023 Full Year 1	CY 2024 Full Year 2	CY 2025 Full Year 3
Total Number of Stations	20/21	21	21	21
Net Revenue	$4,993,926	$5,229,778	$5,475,886	$5,691,230
Total Expenses	$3,479,534	$3,613,856	$3,745,776	$3,861,839
Net Profit / Loss	**$1,514,392**	**$1,615,922**	**$1,730,110**	**$1,829,391**

The "Net Revenue" line item is gross dialysis revenue, minus deductions for bad debt and charity care.

The "Total Expenses" line item includes all expenses related to the projected operation of Chinook. The expenses include all costs identified in the assumptions outlined above. All Medical Director costs and both lease costs are explained in the assumptions above.

Department Evaluation
WAC 246-310-815(1)(b) requires an applicant to base its revenue projections for existing facilities on the current payer mix and base its expense projections on current expenses. Chinook Kidney Center is currently operating with 20 dialysis stations, including its one permanent bed station and one isolation station. DaVita based its projected utilization of Chinook on its current utilization, plus one additional station. DaVita projects revenues will cover expenses at Chinook through the third full year of the proposed project. DaVita's approach for this project meets the requirements.

DaVita provided a copy of the executed lease agreement for the current site to demonstrate site control and documented the lease costs in its financial projections.

DaVita also provided a copy of the Medical Director Agreement with Wassim Khawandi, MD, that was executed on June 20, 2017, and amended on December 3, 2020, and includes automatic annual renewals. The agreement names Wassim Khawandi, MD, as the medical director for Chinook. The costs identified in the Medical Director Agreement are substantiated in the revised revenue and expense statement submitted in screening.

Based on the above information provided by the applicant, the department concludes that DaVita's projected revenue and expense statements for Chinook are reasonable. **This sub-criterion is met.**

Kennewick Dialysis Center
As previously stated, DaVita estimated the dialysis center would be operational by the end of October 2023. [source: Application, p9; January 28, 2022, screening response, p2] Under this timeline, partial year one is 2023, full calendar year one is 2024, and full calendar year three is 2026.

At project completion, Kennewick would be operating with total of 13 dialysis stations, which includes one non-exempt isolation station. DaVita provided the assumptions used to project in-center treatments and patients. The assumptions are restated below. [source: January 28, 2022, screening response, Appendix 9]

- *First Full Year: 2024, based on a first patient date in October 2023 at the expanded facility.*
- *Total Stations: CON Approved stations. One CON-exempt isolation station is also included in driving relevant category calculations (bio-med FTE, overall facility depreciation).*

- *Total Chronic Capacity: 6 shift capacity of CON-approved stations is assumed to be 100% utilization.*
- *Patient Census Projections: Census projections are based on a 5-year projection of planning area patients using a regression of 5 years historical data and DaVita's own experience and expertise. This is the same trend line (based on the Department's methodology as applied through 2025), but extended out through the projection period to project planning area census throughout. DaVita uses projected planning area census, existing planning area capacity, and additional market and experiential knowledge to project new facility census.*

Using the assumptions stated above, DaVita projected the number of in-center dialyses and patients for Kennewick Dialysis Center for years 2022 through 2026. The projections are summarized in the table below. [source: January 28,2022, screening response, Appendix 9]

Applicant's Table

	Forecast 2022	Partial 2023 Jan-Sep	Partial 2023 Oct-Dec	Full Year 2024	Full Year 2025	Full Year 2026
Total Stations (end of the year - excludes CON-exempt iso station)	10	10	13	13	13	13
Total Shifts	6	6	6	6	6	6
Total Chronic Capacity (end of period)	60	60	78	78	78	78
Total Chronic Patients (end of the period)	49	51	51	54	57	60
% of Capacity	*81.7%*	*85.0%*	*65.4%*	*69.2%*	*73.1%*	*76.9%*
Average Annual Chronic Patients (avg of beginning & end of period)	47.5	50.0	51.0	52.5	55.5	58.5
Total Chronic Treatments	7,040	5,558	1,890	7,781	8,225	8,670
Total Home Patients (end of the period)	0	0	0	0	0	0
Average Annual Home Patients (avg of beginning & end of period)	0.0	0.0	0.0	0.0	0.0	0.0
Total Home Treatments	0	0	0	0	0	0
Total Patients (avg of beginning & end of period)	47.5	50.0	51.0	52.5	55.5	58.5
Total Treatments	7,040	5,558	1,890	7,781	8,225	8,670

DaVita, Inc. provided assumptions for its projected financial statements, which are restated below. [source: January 28, 2022, screening response, Appendix 9]

- *Charity Care: estimated at 1.3% of gross revenue, consistent with DaVita's historical experience.*
- *Total Treatments: Total Treatment Volume is assumed to be based on average yearly census, a 5% missed treatment rate consistent with DaVita's own experience and expertise, and three treatments weekly for 52 weeks per year.*
- *Revenue per treatment: No inflation is applied to revenue per treatment, which is based on the last full year of operation for the facility and its payer mix.*
- *General expenses: Based on cost per treatment for the last full calendar year (2020) for the facility by category. This excludes lease expenses (noted below), depreciation expense (based on projected capital expenditures and existing depreciation), medical director expense (noted below), and labor costs (noted below).*
  This also excludes Repairs & Maintenance expense category which is based on year to date cost per treatment for 2021 for the facility due to the unusually high repairs & maintenance cost that this facility experienced in 2020.
- *Cost inflation: DaVita does not assume inflation in any expense category except where otherwise noted – no current contract cost increases are known except where otherwise noted, and thus are not included.*
- *Medical Director Expense: based on contracted, known expenses in latest medical director agreement that runs through the extent of the three-year projection window.*

- *Lease Expense: base rent for the projection period is based off of sections 2 & 3 of the lease contract which commenced on December 1, 2011 at a rate of $12,591 per month with a CPI-based rent adjustmed [sic]averaging 1.7% over the last 10 years. It is assumed that rent will continue to increase at the rate of 1.7% each year. Given that this lease expires on 12/1/2023, it is assumed that the monthly rent continues to increase at a 1.7% rate each lease year through 2026. Tax and CAM are based on the last full calendar year (2020) for this facility, estimated at $13,947 per year.*
- *Labor Assumptions: Based on safe, fair, and efficient staffing ratios for projected census and required staff type. Benefits, taxes, and non-base pay are assumed at a rate of 46.66% of base salaries and wages based on 2020 data for the facility. No inflation is assumed.*

DaVita, Inc. also provided a copy of the lease for the current site to document site control. The lease includes the base rent and associated additional expenses and documented the lease costs in its financial projections. The lease between Total Renal Care (aka DaVita) and EDG-DV Kennewick , LLC, was executed on December 1, 2011, for a term of 12 years and expires on November 30, 2023, with the option for two additional five-year renewal terms. The lease contains the method by which the lease amount will be calculated on renewal and DaVita provided its estimate of those lease amounts in its screening responses. [source: Application, Appendix 15]

Based on the assumptions and clarifications above, DaVita, Inc. provided both historical and projected revenue, expenses, and net income for historical years 2018-2021 and projected years 2022 through 2026, summarized below. [source: Application, Appendix 8; January 28, 2022, screening response, Appendix 9]

Department's Tables 3
Kennewick Dialysis Center
Historical and Current Revenue and Expense Summary

	CY 2019 Historical	CY 2020 Historical	CY 2021 Current	CY 2022 Projected
Total Number of Stations	10	10	10	10
Net Revenue	$2,714,284	$2,634,297	$2,412,021	$2,727,881
Total Expenses	$2,113,418	$2,416,643	$2,082,438	$2,256,531
Net Profit / Loss	**$600,866**	**$217,654**	**$329,583**	**$471,350**

Kennewick Dialysis Center
Projected Revenue and Expense Summary for Years 2022 - 2025

	CY 2023 Expansion Year	CY 2024 Full Year 1	CY 2025 Full Year 2	CY 2026 Full Year 3
Total Number of Stations	13	13	13	13
Net Revenue	$2,885,812	$3,015,026	$3,187,314	$3,359,601
Total Expenses	$2,367,662	$2,481,333	$2,591,533	$2,721,646
Net Profit / Loss	**$518,150**	**$533,693**	**$595,781**	**$637,955**

The "Net Revenue" line item is gross dialysis revenue, minus deductions for bad debt and charity care.

The "Total Expenses" line item includes all expenses related to the projected operation of Kennewick. The expenses include all costs identified in the assumptions outlined above. All Medical Director costs and both lease costs are explained in the assumptions above.

Department Evaluation
WAC 246-310-815(1)(b) requires an applicant to base its revenue projections on the current payer mix and base its expense projections on current expenses. Kennewick is currently operating with 11 dialysis stations, including its one exempt isolation station. DaVita based its projected utilization of Kennewick on its current utilization, plus three additional stations[7]. DaVita projects revenues will cover expenses at Kennewick through the third full year of the proposed project. DaVita's approach for this project meets the requirements.

DaVita provided a copy of the executed lease agreement for the current site to demonstrate site control and documented the lease costs, duration, and renewal terms in its financial projections. The lease contains the method by which the lease amount will be calculated on renewal and DaVita provided its estimate of those lease amounts in its screening responses. With the renewal terms, DaVita has demonstrated site control at least five years after project completion.

DaVita also provided a copy of the Medical Director Agreement with Puneet Tandon, MD, that was executed on November 21, 2013, for an initial term of 10 years and includes automatic annual renewals. The agreement names Puneet Tandon, MD, as the medical director for Kennewick. The costs identified in the Medical Director Agreement are substantiated in the revised revenue and expense statement submitted in screening.

Based on the above information provided by the applicant, the department concludes that DaVita's projected revenue and expense statements for Kennewick are reasonable. **This sub-criterion is met.**

(2) *The costs of the project, including any construction costs, will probably not result in an unreasonable impact on the costs and charges for health services.*
WAC 246-310-815 outlines the financial feasibility review requirements for dialysis projects. For this project, the applicant must demonstrate compliance with the following sub-sections of WAC 246-310-815(2). Using its experience and expertise the department compared the proposed project's costs with those previously considered by the department.

WAC 246-310-815(2)
An applicant proposing to construct finished treatment floor area square footage that exceeds the maximum treatment floor area square footage defined in WAC 246-310-800(11) will be determined to have an unreasonable impact on costs and charges and the application will be denied. This does not preclude an applicant from constructing shelled space.

Chinook Kidney Center
The estimated capital expenditure necessary for the construction of Chinook Kidney Center is $27,249. DaVita, Inc. provided its capital cost breakdown shown below. [source: Application, p20]

[7] Includes the conversion of the currently-exempt isolation station to non-exempt status

Department's Table 4
Chinook Kidney Center Estimated Capital Costs

Item	Total	% of Total
Building Construction	$0	0.0%
Fixed Equipment (not in construction)	$815	3.0%
Moveable Equipment	$25,008	91.8%
Architect / Engineering Fees	$1.358	5.0%
Supervision/Inspection/Permits	$68	0.02%
Total Estimated Capital Costs	**$27,249**	**100.0%**

DaVita clarified that Washington State sales tax is included with the costs above at a rate of 8.6% for all costs, with the exception of dialysis stations.[8] [source: Application, p20]

Specific to the project's impact on costs and charges for health services, DaVita provided the following statements. [source: Application, p21]
"The DaVita Chinook Kidney Center Detailed Projected Operating Statement (Pro Forma) covering the first three full years in operation is included in Appendix 9. As required per WAC 246-310-815(1)(b), that pro forma is based on DaVita Chinook Kidney Center's current payor mix and current expenses. All major pro forma assumptions are also outlined in Appendix 9.

The proposed facility expansion will operate at utilization levels consistent with required utilization levels after three years. 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, and will actually increase patient access in the planning area.

WAC 246-310-815(2) requires that applicants limit the costs of facility projects by creating a test of reasonableness in the construction of finished treatment floor area square footage. The treatment floor area must not exceed the maximum treatment floor area square footage defined in WAC 246-310-800(11). As outlined in response to question twelve under the Project Description, DaVita does not propose to construct treatment floor space in excess of the maximum treatment floor area square footage, and thus, under the WAC 246-310-815(2) test, this project does not have an unreasonable impact on costs and charges.

"Additionally, as noted in response to question eight, 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."

Focusing on WAC 246-310-815(2), DaVita provided a table comparing the square footage of Chinook Kidney Center with an additional station and the maximum allowable square footage defined by WAC 246-310-800(11). [source: Application, pp11-12]

Department Evaluation
The costs for adding the additional station to Chinook is $27,249. The costs are almost exclusively limited to the additional moveable equipment necessary for the station addition and are comparable to those reviewed in past applications for similar size projects. The department does not consider the capital expenditure to be excessive for this project.

[8] Dialysis stations are not taxed by Washington State.

Documentation provided in the application shows that Chinook Kidney Center's current Medicare and Medicaid reimbursements equals 64.7% of the revenue at the dialysis center. This amount is reasonable and 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 35.3% of net revenue is commercial, other government, and other.

To demonstrate compliance with WAC 246-310-800(11), DaVita provided a table showing Chinook's allowable maximum treatment floor area square footage for a 21-station facility, with space for two future stations is 6,213. DaVita's project will use 3,480 square feet. DaVita's project does not exceed the allowable maximum treatment floor area square footage.

Based on the above information provided by the applicant, the department concludes that DaVita's projected costs associated with addition of one station to Chinook would probably not have an unreasonable impact on the costs and charges for healthcare services in the Benton County planning area. **This sub-criterion is met.**

Kennewick Dialysis Center

The estimated capital expenditure necessary for the construction of Kennewick Dialysis Center is $448,428. DaVita, Inc. provided its capital cost breakdown shown below. [source: Application, p20]

Department's Table 5
Kennewick Dialysis Center Estimated Capital Costs

Item	Total	% of Total
Building Construction	$326,353	72.8%
Fixed Equipment (not in construction)	$10,371	2.3%
Moveable Equipment	$70,164	15.6%
Architect / Engineering Fees	$20,308	4.5%
Supervision/Inspection/Permits	$21,231	4.7%
Total Estimated Capital Costs	**$448,428**	**100.0%**

DaVita clarified that Washington State sales tax is included with the costs above at a rate of 8.6% for all costs, with the exception of dialysis stations.[9] [source: Application, p20]

Specific to the project's impact on costs and charges for health services, DaVita provided the following statements. [source: Application, p21]
"The DaVita Kennewick Dialysis Detailed Projected Operating Statement (Pro Forma) covering the first three full years in operation is included in Appendix 9. As required per WAC 246-310-815(1)(b), that pro forma is based on DaVita Kennewick Dialysis's current payor mix and current expenses. All major pro forma assumptions are also outlined in Appendix 9.

The proposed facility expansion will operate at utilization levels consistent with required utilization levels after three years. 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, and will actually increase patient access in the planning area.

WAC 246-310-815(2) requires that applicants limit the costs of facility projects by creating a test of reasonableness in the construction of finished treatment floor area square footage. The treatment floor area must not exceed the maximum treatment floor area square footage defined in WAC 246-310-800(11). As outlined in response to question twelve under the Project Description, DaVita does not propose to construct treatment floor space in excess of the maximum treatment floor area square footage, and thus, under the WAC 246-310-815(2) test, this project does not have an unreasonable impact on costs and charges.

"Additionally, as noted in response to question eight, 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.."

Focusing on WAC 246-310-815(2), DaVita provided a table comparing the square footage of Kennewick with the additional stations and the maximum allowable square footage defined by WAC 246-310-800(11). [source: Application, pp11-12]

Department Evaluation

The costs for adding the additional stations to Kennewick is $448,428. The costs include construction, the additional fixed and moveable equipment necessary for the station addition, and associated fees and are comparable to those reviewed in past applications for similar size projects. The department does not consider the capital expenditure to be excessive for this project.

Documentation provided in the application shows that Kennewick's current Medicare and Medicaid reimbursements equals 71.75% of the revenue at the dialysis center. This amount is reasonable and 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.

[9] Dialysis stations are not taxed by Washington State.

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 28.26% of net revenue is commercial, other government, and other.

To demonstrate compliance with WAC 246-310-800(11), DaVita provided a table showing Kennewick's allowable maximum treatment floor area square footage for a 13-station facility, with no space reserved for future stations is 3,500. DaVita's project will use 2,389 square feet. DaVita's project does not exceed the allowable maximum treatment floor area square footage.

Based on the above information provided by the applicant, the department concludes that DaVita's projected costs associated with addition of two stations and conversion of the exempt isolation station to non-exempt status at Kennewick would probably not have an unreasonable impact on the costs and charges for healthcare services in the Benton County planning area. **This sub-criterion is met.**

(3) <u>The project can be appropriately financed.</u>

Chapter 246-310 WAC 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.

<u>Chinook Kidney Center and Kennewick Dialysis Center</u>

DaVita identified a capital expenditure of $27,249 to add one station to Chinook and $448,427 to add two new stations to Kennewick. The project would be funded using corporate reserves. DaVita provided a letter from its Chief Operating Officer, Michael Staffieri, to demonstrate an operational and financial commitment to the project. [source: Chinook Application, p20 and Appendix 6; Kennewick Application, p20 and Appendix 6]

DaVita, Inc. also provided a copy of its audited financial statements for years 2018, 2019, and 2020 to demonstrate sufficient reserves to finance the project. [source: Chinook and Kennewick Applications, Appendix 10]

<u>Department Evaluation of Both Applications</u>

DaVita intends to finance each project with its reserves and demonstrated the funds are available. If either 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 that these projects **meet this sub-criterion**.

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

DaVita Chinook Kidney Center

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

DaVita Kennewick Dialysis Center

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

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

Chapter 246-310 WAC 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.

Chinook Kidney Center

If this project is approved, DaVita, Inc. expects the additional stations would be operational by the end of December 2022. The first full calendar year of operation with the additional station is 2023 and full calendar year three is 2025. The table below provides a breakdown of projected FTEs for years 20212022 through 2025. [source: January 28, 2022, screening response, p3]

Department's Table 6
Chinook Kidney Center
Historical, Current, and Projected FTEs

FTE by Type	CY 2021	CY 2022 Increase	CY 2023 Increase	CY 2024 Increase	CY 2025 Increase	Total
Administrator	1.00	0.00	0.00	0.00	0.00	1.00
Administrative Assistant	0.76	0.24	0.00	0.00	0.00	1.00
Medical Social Worker	0.67	0.08	0.00	0.00	0.00	0.75
Dietician	0.62	0.13	0.00	0.00	0.00	0.75
Registered Nurses	3.72	0.29	0.09	0.20	0.47	4.47
Patient Care Technician	8.69	0.45	0.23	0.22	0.45	10.04
BioMed Technician	0.44	0.09	0.00	0.00	0.00	0.53
Other	1.50	0.00	0.00	0.00	0.00	1.50
Total FTEs	**17.40**	**1.28**	**1.56**	**1.41**	**0.69**	**5.8**

The medical director is under contract and not included in the table above. [source: Appendix 10]

DaVita, Inc. provided the following statements related to its current and proposed staffing of the dialysis center and its recruitment and retention efforts and experience. [source: Application, p23]

"DaVita projects FTEs based on staffing ratios for patients per shift, combined with clinical expertise. Standard ratios are noted in Table 13. Overall census estimates are based on the assumptions describing the pro forma in Appendix 9. The "Other" category includes, among other miscellaneous categories, patient education and inventory management roles, as well as training hours.

"FY18-FY20 are actual historical hours, divided by 2080 hours per year to convert to FTE. These are averages throughout the year and will certainly fluctuate during a given year. FY21 forecast is extrapolated based on FY21 Q3 data. Biomed hours relate directly to the number of stations at a facility so they are relatively stable even as census goes up slightly between FY18-FY25."

DaVita also provided the following statements when asked about recruitment under current market conditions. [source: January 28, 2022, screening responses, p5]
"DaVita shares the Program's concern regarding the challenging labor environment across Washington State. To address this, DaVita added an incremental recruiter to our recruiting team, who is dedicated to recruitment in this geography. DaVita has also implemented internal referral bonuses for key team members, such as registered nurses. Additionally, DaVita has greatly increased its commitment to international nurse recruitment and sponsorship. Nurses sponsored from abroad have already begun working for DaVita and are serving patients in this geography.

"The region also has a nurse float pool, in which the nurses are not assigned to one clinic but instead float to where the staffing need is. In the event that Chinook Kidney Center faces unforeseen barriers to staff recruitment that would impact the ability to perform timely patient care at the expanded facility, DaVita would send float nurse support to the clinic to ensure timely care."

Department Evaluation
Information provided in the application demonstrates that DaVita is a well-established provider of dialysis services in Washington State and in Benton County. Chinook has been operational at the current site since approximately November 2009. [source: Chinook Kidney Center facility file]

In year 2021, the facility was operating with approximately 17.40 FTEs. For this project, DaVita is proposing to add one additional station and anticipates a net increase of 2.64 FTEs by the end of year 2025, full year three.

Given that the one-station increase requires additional FTEs, DaVita intends to rely on its recruitment and retention effort that have been proven successful in the past. This approach by DaVita is both reasonable and prudent.

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.

Kennewick Dialysis Center
If this project is approved, DaVita, Inc. expects the additional stations would be operational by the end of October 2023. The first full calendar year of operation with the additional station is 2024 and full calendar year three is 2026. The table below provides a breakdown of projected FTEs for projection years 2021 through 2026. [source: Kennewick Application, p23]

Department's Table 7
Kennewick Dialysis Center
Historical, Current, and Projected FTEs

FTE by Type	CY 2021	CY 2022 Increase	CY 2023 Increase	CY 2024 Increase	CY 2025 Increase	CY 2026 Increase	Total
Administrator	0.73	0.02	0.00	0.00	0.00	0.00	0.75
Administrative Assistant	0.44	0.06	0.00	0.00	0.00	0.00	0.50
Medical Social Worker	0.35	0.05	0.03	0.01	0.02	0.03	0.49
Dietician	0.35	0.05	0.03	0.01	0.02	0.03	0.49
Registered Nurses	2.18	0.29	0.18	0.08	0.15	0.16	3.04
Patient Care Technician	4.05	0.53	0.34	0.15	0.29	0.29	5.65
BioMed Technician	0.28	0.00	0.05	0.00	0.00	0.00	0.33
Other	0.53	(0.03)	0.00	0.00	0.00	0.23	0.73
Total FTEs	**8.91**	**0.97**	**0.63**	**0.25**	**0.48**	**0.74**	**11.98**

The medical director is under contract and not included in the table above. [source: Appendix 10]

DaVita, Inc. provided the following statements related to its current and proposed staffing of the dialysis center and its recruitment and retention efforts and experience. [source: Application, p23]
"DaVita projects FTEs based on staffing ratios for patients per shift, combined with clinical expertise. Standard ratios are noted in Table 13. Overall census estimates are based on the assumptions describing the pro forma in Appendix 9. The "Other" category includes, among other miscellaneous categories, patient education and inventory management roles, as well as training hours.

"FY18-FY20 are actual historical hours, divided by 2080 hours per year to convert to FTE. These are averages throughout the year and will certainly fluctuate during a given year. FY21 forecast is extrapolated based on FY21 Q3 data. Biomed hours relate directly to the number of stations at a facility so they are relatively stable even as census goes up slightly between FY18-FY25."

DaVita also provided the following statements when asked about recruitment under current market conditions. [source: January 28, 2022, screening responses, p4]
"DaVita shares the Program's concern regarding the challenging labor environment across Washington State. To address this, DaVita added an incremental recruiter to our recruiting team, who is dedicated to recruitment in this geography. DaVita has also implemented internal referral bonuses for key team members, such as registered nurses. Additionally, DaVita has greatly increased its commitment to international nurse recruitment and sponsorship. Nurses sponsored from abroad have already begun working for DaVita and are serving patients in this geography.

"The region also has a nurse float pool, in which the nurses are not assigned to one clinic but instead float to where the staffing need is. In the event that Kennewick Dialysis faces unforeseen barriers to staff recruitment that would impact the ability to perform timely patient care at the expanded facility, DaVita would send float nurse support to the clinic to ensure timely care."

Department Evaluation
Information provided in the application demonstrates that DaVita is a well-established provider of dialysis services in Washington State and in Benton County. Kennewick Dialysis Center has been operational at the current site since January 2017. [source: Kennewick Dialysis Center facility file]

In year 2021, the facility was operating with approximately 8.91 FTEs. For this project, DaVita is proposing to add two additional stations and convert the existing exempt isolation station to a non-exempt isolation station and anticipates a net increase of 3.07 FTEs by the end of year 2026, full year three.

Given that the station increase requires additional FTEs, DaVita intends to rely on its recruitment and retention effort that have been proven successful in the past. This approach by DaVita is both reasonable and prudent.

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.

Chapter 246-310 WAC 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.

Chinook Kidney Center
DaVita provides dialysis services throughout Washington State, including its Chinook and Kennewick dialysis centers in the Benton County planning area. If this project is approved, Chinook Kidney Center will add a net of one in-center dialysis station to Benton County. DaVita provided the following statements regarding services that would be provided on site and those provided off site. [source: Application, p25]

"Ancillary services such as social services, nutrition services, financial counseling, pharmacy access, patient education, staff education, information services, material management, administration and biomedical technical services are provided on site. Additional services are coordinated through DaVita's main office in Denver, Colorado, and support offices in Federal Way and Tacoma, Washington, and elsewhere. These ancillary and support services provided centrally include the Guest Services Program that provides assistance in locating other dialysis facilities for patients wishing to travel or relocate. In addition, DaVita offers centralized revenue cycle, management services, quality improvement services, biomedical equipment maintenance and a number of other high-value off-site programs."

DaVita provided the following listing of vendors with which it has ancillary and support relationships for Chinook Kidney Center. [source: Application, Appendix 11]

Applicant's Table

Agreement	Vendor
Extensive Facility Maintenance	CBRE
Patient Transfer	Trios, Kadlec,
Janitorial	Quality Cleaning
Waste Disposal	Waste Management
Medical Waste Disposal	Stericycle
Information Management	Iron Mountain
Mutual Emergency Backup Dialysis	Kennewick Kidney Center Mid-Columbia Kidney Center
Emergency PD Support	Mid-Columbia Kidney Center
Laboratory Services	DaVita Laboratory Services
Stat Laboratory Services	Good Shepard in Hermiston
Stat Laboratory Services	Good Shepard in Hermiston
Home Training Supplies	NA
DME Supplies	Norco Medical
Student Training	Charter SIPS
Student Training	Charter SIPS
Renal Network	Northwest Renal Network (Network 16)
Transplant Agreements	Virginia Mason, University of Washington, Swedish Sacred Heart
Pest Control	Terminix

Additionally, DaVita provided a table in the application identifying the entities with which it currently has working relationships for Chinook and the type of relationship. [source: Application, pp25-26]

Applicant's Table

Table 14 **Healthcare Facility Relationships**	**Type of Relationship**
Canyon Lakes Restorative	Nursing Home Dialysis Transfer Agreement
Kadlec Medical Center	Patient Transfer
Local Physician Groups	Attending and Rounding

"No existing working relationships are expected to change as a result of this project, although area hospitals and nursing homes may expect enhanced access for their ESRD patients upon project completion."

DaVita provided executed Patient Transfer Agreements between itself and both Trios and Kadlec Medical Center. Both were executed in 2014 and identify the roles and responsibilities of each entity. [source: Application, Appendix 12]

DaVita also provided a copy of the current Medical Director Agreement with Wassim Khawandi, MD, that was executed on June 20, 2017, and amended on December 3, 2020, and includes automatic annual renewals. The agreement names Wassim Khawandi, MD, as the medical director for Chinook. The costs identified in the Medical Director Agreement are substantiated in the revenue and expense statement submitted in screening.

The Medical Director Agreement identifies roles and responsibilities for both DaVita and the medical director. The agreement identifies the annual and monthly compensation. [source: Application, Appendix 3]

Department Evaluation

Chinook Kidney Center has been operating Benton County since its establishment in 2009. All ancillary and support services have been established for the dialysis center. DaVita states that no additional agreements or further revisions to existing agreements are necessary for this project.

Within the application, DaVita provided a copy of both the executed Patient Transfer Agreements with Kadlec Medical Center and Trios, as well as current Medical Director Agreement with Wassim Khawandi, MD.

DaVita also provided a listing of all current ancillary and support services specific to Chinook. DaVita does not anticipate any changes to these agreements.

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

Kennewick Dialysis Center

DaVita provides dialysis services throughout Washington State, including its Chinook and Kennewick dialysis centers in the Benton County planning area. If this project is approved, Kennewick Dialysis Center will add a net of one in-center dialysis station to Benton County. DaVita provided the following statements regarding services that would be provided on site and those provided off site. [source: Application, p25]

"Ancillary services such as social services, nutrition services, financial counseling, pharmacy access, patient education, staff education, information services, material management, administration and biomedical technical services are provided on site. Additional services are coordinated through DaVita's main office in Denver, Colorado, and support offices in Federal Way and Tacoma, Washington, and elsewhere. These ancillary and support services provided centrally include the Guest Services Program that provides assistance in locating other dialysis facilities for patients wishing to travel or relocate. In addition, DaVita offers centralized revenue cycle, management services, quality improvement services, biomedical equipment maintenance and a number of other high-value off-site programs."

DaVita provided the following listing of vendors with which it has ancillary and support relationships for Kennewick. [source: Application, Appendix 11]

Applicant's Table

Agreement	Vendor
Extensive Facility Maintenance	CBRE
Patient Transfer	Trios Medical Center
Janitorial	Quality Cleaning
Waste Disposal	Waste Management
Medical Waste Disposal	Stericycle
Information Management	Iron Mountain
Mutual Emergency Backup Dialysis	Mid Columbia Kidney Center Chinook Kidney Center
Emergency PD Support	Mid Columbia Kidney Center
Laboratory Services	DaVita Laboratory Services
Stat Laboratory Services	Good Shepherd Medical Center
Stat Laboratory Services	Good Shepherd Medical Center
Home Training Supplies	NA
DME Supplies	Norco Medical
Student Training	Charter College
Student Training	Charter College
Renal Network	Northwest Renal Network (Network 16)
Transplant Agreements	Virginia Mason, University of Washington, Swedish, Sacred Heart
Pest Control	Terminix

Additionally, DaVita provided a table in the application identifying the entities with which it currently has working relationships for Kennewick and the type of relationship. [source: Application, pp25-26]

Applicant's Table

Table 14 **Healthcare Facility Relationships**	**Type of Relationship**
Gary Olels **Kennewick Life Care**	Nursing Home Dialysis Transfer Agreement
Kadlec Medical Center	Patient Transfer
Local Physician Groups	Attending and Rounding

"No existing working relationships are expected to change as a result of this project, although area hospitals and nursing homes may expect enhanced access for their ESRD patients upon project completion."

DaVita provided executed Patient Transfer Agreements between itself and both Trios and Kadlec Medical Center. Both were executed in 2014 and identify the roles and responsibilities of each entity. [source: Application, Appendix 12]

DaVita also provided a copy of the current Medical Director Agreement with Puneet Tandon, MD, that was executed on November 21, 2013, and amended on November 19, 2018. The agreement was for an initial term of ten years and includes automatic annual renewals. The agreement names Puneet Tandon, MD, as the medical director for Kennewick. The costs identified in the Medical Director Agreement are substantiated in the revenue and expense statement submitted in screening.

The Medical Director Agreement identifies roles and responsibilities for both DaVita and the medical director. The agreement identifies the annual and monthly compensation. [source: Application, Appendix 3]

Department Evaluation

Kennewick Dialysis Center has been operating Benton County since its establishment in 2013. All ancillary and support services have been established for the dialysis center. DaVita states that no additional agreements or further revisions to existing agreements are necessary for this project.

Within the application, DaVita provided a copy of both the executed Patient Transfer Agreements with Kadlec Medical Center and Trios, as well as current Medical Director Agreement with Puneet Tandon, MD.

DaVita also provided a listing of all current ancillary and support services specific to Kennewick Dialysis Center. DaVita does not anticipate any changes to these agreements.

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

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

Chapter 246-310 WAC 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.

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

DaVita, Inc.

DaVita, Inc. provided the following statements in response to this sub-criterion. [source: Chinook Application, p26; Kennewick Application, p26]

"DaVita and the United States Department of Health and Human Services, Office of Inspector General entered into a Corporate Integrity Agreement ("CIA") to promote compliance with the statutes, regulations, and written directives of Medicare, Medicaid, and all other Federal health care programs and, in particular, included the appointment of an Independent Monitor to prospectively review DaVita's arrangements with nephrologists and other health care providers for compliance with the

Anti-Kickback Statute (collectively, "Federal Health Care Programs and Laws"). That Independent Monitor completed the prospective review process in the fall of 2017. Each arrangement is now reviewed by the Risk Rating team to ensure that it is compliant with these Federal Health Care Programs and Laws.

Department Evaluation

The department reviews three different areas when evaluating this sub-criterion. One is a review of the Centers for Medicare and Medicaid Services (CMS) "Terminated Provider Counts Report" covering years 2019 through 2021. The department uses this report to identify dialysis facilities that were involuntarily terminated from participation in Medicare reimbursement.

The department also reviews a dialysis provider's conformance with Medicare and Medicaid standards, with a focus on Washington State facilities. The department uses the CMS 'Survey Activity Report' to identify Washington State facilities with a history of condition level findings. For CMS surveys, there are two levels of deficiencies: standard and condition.[10]

- Standard Level
  A deficiency is at the Standard level when there is noncompliance with any single requirement (or several requirements) within a particular standard that is not of such character as to substantially limit a facility's capacity to furnish adequate care, or which would not jeopardize or adversely affect the health or safety of patients if the deficient practice recurred.

- Condition Level
  Deficiency at the Condition level may be due to noncompliance with requirements in a single standard that, collectively, represent a severe or critical health or safety breach, or it may be the result of noncompliance with several standards within the condition. Even a seemingly small breach in critical actions, or at critical times, can kill or severely injure a patient, and such breaches would represent a serious or severe health or safety threat.

The department also reviews the CMS 'star ratings' for Washington State facilities. CMS provides the following overview regarding its star rating for dialysis centers.
"The star rating shows how well a dialysis center delivers care compared to the national average, based on Medicare data. Each dialysis center receives a rating between 1 and 5 stars, with 3 stars representing the national average. A five-star rating means a center has quality of care that is considered 'much above average' compared to other dialysis facilities. A one or two-star rating means that measured health outcomes for that center were below average. The star rating is part of Medicare's work to make data on the quality of patient care easier to understand and use. Patient survey results aren't included in the star rating." [source: CMS website]

Below is a summary of the three areas reviewed for DaVita.

Terminated Provider Counts Report

Focusing on years 2019 through 2021 and all DaVita dialysis centers operational in 46 states and the District of Columbia, none were involuntarily terminated from participation in Medicare reimbursement.

[10] Definitions of standard and condition level surveys: https://www.compass-clinical.com/deciphering-tjc-condition-level-findings/

It is noted that DaVita provided information regarding a Corporate Integrity Agreement that was complete in year 2017; decertification of a dialysis center in Tennessee in 2007; and decertification of a dialysis center in Texas in 2008. None of these three past events explained by DaVita are within the specific 'three full calendar year look back' typically used by the department for this review criteria.

Conformance with Medicare and Medicaid Standards
Focusing on years 2019 through current, of DaVita's 48 Washington State dialysis centers, 40 were surveyed at least once. Of the 40 surveyed facilities, two centers had condition level findings. [source: CMS Quality, Certification, and Oversight Reports]

Redondo Heights Dialysis Center
- During an October 2021 standard survey, surveyors found no standard or condition level deficiencies.
- During a March 2020 standard survey, surveyors cited the facility for three condition level findings in the areas of: patient responsibilities of the medical director, medical records, and governance. The citations required plans of correction and a follow-up visit in February 2021.
- The facility was not surveyed in year 2019.

Kent Dialysis Center
- During a December 2021 standard survey, surveyors found no standard or condition level deficiencies.
- During a January 2021 complaint survey, surveyors cited the facility for two condition level findings in the areas of: compliance with Federal, State, and Local laws and personnel qualifications. The citations required plans of correction and a follow-up visit in March 2021.
- The facility was not surveyed in years 2019 or 2020.

CMS Star Rating for Washington State Centers
As of the writing of this evaluation, DaVita operates a total of 48 dialysis centers in Washington State, and of those 41 have a CMS star rating, the remaining seven facilities not being operational long enough to compile a CMS star rating. The average star rating for the 41 facilities is 4.4. [source: CMS Dialysis Facility – Listing by Facility Report, last updated September 17, 2020]

Chinook Kidney Center
DaVita provided an executed Medical Director Agreement with Wassim Khawandi, MD, as the medical director for the Chinook Kidney Center. [source: Application, Appendix 3] Using data from the Medical Quality Assurance Commission, the department found that Dr. Khawandi is compliant with state licensure and have no enforcement actions on their licenses.

DaVita provided a listing of credentialed staff for Chinook, which includes: one certified dietician, 16 certified hemodialysis technicians, one social worker, and eight registered nurses. Using data from the DOH Office of Customer Service, the department found that the credentialed staff are in full compliance with no limits on their licenses.

In review of this sub-criterion, the department considered the total compliance history of the dialysis facilities owned and operated by DaVita. The department also considered the compliance history of all physicians to be associated with the new facility. Based on the information reviewed, the department concludes that DaVita has been operating in compliance with applicable state and federal licensing and certification requirements. The department also concludes there is reasonable assurance that the new

dialysis center would also operate in compliance with state and federal requirements. The department concludes that **this sub-criterion is met.**

Kennewick Dialysis Center

DaVita provided an executed Medical Director Agreement with Puneet Tandon, MD, as the medical director for the Kennewick Dialysis Center. [source: Application, Appendix 3] Using data from the Medical Quality Assurance Commission, the department found that Dr. Tandon is compliant with state licensure and have no enforcement actions on their licenses.

DaVita provided a listing of credentialed staff for Kennewick, which includes: one certified dietician, nine certified hemodialysis technicians, one social worker, and two registered nurses. Using data from the DOH Office of Customer Service, the department found that the credentialed staff are in full compliance with no limits on their licenses.

In review of this sub-criterion, the department considered the total compliance history of the dialysis facilities owned and operated by DaVita. The department also considered the compliance history of all physicians to be associated with the new facility. Based on the information reviewed, the department concludes that DaVita has been operating in compliance with applicable state and federal licensing and certification requirements. The department also concludes there is reasonable assurance that the new dialysis center would also operate in compliance with state and federal requirements. The department concludes that **this sub-criterion is met.**

(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.

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

Chinook Kidney Center and Kennewick Dialysis Center

DaVita provided the following statements in response to this sub-criterion. The statements in the two applications are identical save for the facility name in the first paragraph.. [source: Chinook Application, p27, Kennewick Application, p27]

"Appendix 18 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 18 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 a draft transfer agreement between DaVita Kennewick Dialysis and an area care hospital partner. 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/about/awards).

"From the perspective of a dialysis patient with multiple relevant healthcare providers, such as a primary care provider, nephrologist, home care caregivers or skilled nursing or assisted living caregivers, and perhaps (unfortunately) a recently-visited hospital. DaVita is committed to the wellbeing of its patients, and for patients with a diagnosis as complex as end-stage renal disease, that wellbeing by necessity requires communication and coordination with multiple caregivers, such as those above. DaVita uses an interdisciplinary team consisting of the facility social worker, dietician, clinical nurse manager, medical director, and the patient's nephrologist to facilitate communication and coordination through the healthcare system. If a comorbidity is identified that impacts the patient's health, the patient's nephrologist or medical director would reach out to the patient's primary care physician for consult. DaVita would also ensure any change in the care plan from the patient's nephrologist is executed in consultation with the facility medical director. DaVita collaborates with home or assisted living and skilled nursing caregivers on a daily basis, including in cases such as the patient's above, reviewing transportation, dialysis medication needs, access care, as well as taking in any dialysis-related concerns those patients may have and reviewing them in consultation with the interdisciplinary team. When a hospital is unfortunately required to intervene in a patient's care, DaVita facilitates rapid discharges back to chronic dialysis, coordination of medical records into the patient's chart, and coordination with the patient's nephrologist for any care plan changes. Additionally, all DaVita dialysis centers enter into hospital and nursing home transfer agreements, and participate in community emergency preparedness drills to ensure maximum coordination in the healthcare arena. Dialysis is one of the healthcare modalities that, due to its regular cadence and length, is one of patients' most consistent touchpoints with the healthcare system, and DaVita is committed to working with its patients to use these points to coordinate and communicate among the patient's healthcare providers across the healthcare system."

Department Evaluation of Both Projects

DaVita has been a provider of dialysis services in Washington State for many years. DaVita also has a history of establishing relationships with existing healthcare networks in the state, including the Benton County planning area. Additionally, DaVita's projects would promote continuity in the provision of healthcare services in the planning area by increasing the number of stations at Chinook Kidney Center by at one station and the number of stations at Kennewick Dialysis Center by three stations – the same amount projected by the department's numeric need methodology for year 2025.

DaVita provided sufficient rationale 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 these projects **meet this sub-criterion**.

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

Department Evaluation of Both Projects

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

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

Chinook Kidney Center

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, Inc. project has met the cost containment criteria in WAC 246-310-240.

Kennewick Dialysis Center

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, Inc. project has met the cost containment criteria in WAC 246-310-240.

(1) Superior alternatives, in terms of cost, efficiency, or effectiveness, are not available or practicable.

To determine if a proposed project is the best alternative, the department takes a multi-step approach. Step one determines if the application has met the other criteria of WAC 246-310-210 thru 230. If it has failed to meet one or more of these criteria, then the project is determined not to be the best alternative and would fail this sub-criterion.

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

If there are multiple applications, the department's assessment is to apply any service or facility superiority criteria contained throughout WAC 246-310 related to the specific project type in Step three. The department completes step three under WAC 246-310-827.

Step One

For both projects, DaVita met the applicable review criteria under WAC 246-310-210, 220, and 230. Therefore, the department moves to step two for each project.

Step Two/Step Three

Chinook Kidney Center

For this sub-criterion, DaVita discussed the three options below. [source: Application p27]

*"**Alternative 1: Do nothing. That is, do not apply for additional stations in the Benton County planning area.** Benton County is growing in ESRD population, with a three-year annualized in-center ESRD census growth rate of more than 2.7% and demonstrated need for four (4) stations. With strong demand for access to DaVita's services but no application, patients will be forced to dialyze at less convenient times, locations, or even out of the planning area entirely. This alternative was rejected.*

__Alternative 2: Apply for one (1) station in the Benton County planning area.__ As summarized above, Benton County shows substantial need for dialysis services. DaVita has demonstrated its ability to rapidly offer high-quality dialysis services to patients in the Benton County planning area and the proposed expansion at DaVita Chinook would provide the planning area with more convenient chair times and additional capacity in a cost effective manner. __This alternative was selected__.

__Alternative 3: Apply for four (4) stations in the Benton County planning area.__ This is not a financially viable option. Furthermore, there is greater patient demand at DaVita's Kennewick facility which has

room for a small expansion in the existing clinic. Expanding DaVita Chinook Kidney Center by four (4) stations would preclude DaVita Kennewick from expanding and providing additional capacity in a location that would best serve patient needs within the planning area. This alternative was rejected."

Kennewick Dialysis Center

For this sub-criterion, DaVita discussed the three options below. [source: Application p28]

Alternative 1: Do nothing. That is, do not apply for additional stations in the Benton County planning area*. Benton County is growing in ESRD population, with a three-year annualized in-center ESRD census growth rate of more than 2.7% and demonstrated need for four (4) stations. With strong demand for access to DaVita's services but no application, patients will be forced to dialyze at less convenient times, locations, or even out of the planning area entirely. This alternative was rejected.*

Alternative 2: Apply for two (2) stations and convert the exempt isolation station to non-exempt in the Benton County planning area*. As summarized above, Benton County shows substantial need for dialysis services. DaVita has demonstrated its ability to rapidly offer high-quality dialysis services to patients in the Benton County planning area and the proposed expansion at DaVita Kennewick would provide the planning area with more convenient chair times and additional capacity.* ***This alternative was selected.***

Alternative 3: Apply for four (4) stations in the Benton County planning area. *DaVita Kennewick Dialysis would require a significant amount of construction and capital expenditure to add four stations within the existing clinic's footprint. There are much more cost effective ways to add four stations in the planning area. This alternative was rejected*

Department Evaluation of Both Projects

DaVita provided an appropriate discussion of why adding dialysis capacity to its two facilities in the planning area instead of either doing nothing or establishing a new four-station dialysis center in the area is the superior option.

Once DaVita determined that adding stations to the planning area was the best alternative for the residents, DaVita concluded that distributing the additional stations between its two existing facilities would allow for timely and cost-effective completion of the projects

DaVita submitted these two applications consistent with WAC 246-310-812(8)(b) as required.[11] The sum of the additional stations requested is equal to the four stations projected as needed in 2025 for Benton County. Because there is sufficient projected need to approve both otherwise approvable projects, the department need not conduct a superiority analysis to determine which project should be approved over the other. The department is satisfied that the applicant appropriately chose to submit these two applications for station additions in order to allow continued access to the needed services and to meet the projected need in the planning area.

The department concludes that the projects submitted by DaVita are the best available alternatives for the Benton County planning area. **This sub-criterion is met.**

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[11] WAC 246-310-812(8)(b) states: *"If a provider, including any affiliates, submits multiple applications in for projected need in a planning area, the department will use the following process: …(b) the sum of the stations required in the applicants cannot exceed the projected need at the time of the applications in the planning area."*

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

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

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

Department Evaluation

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

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

Chinook Kidney Center

DaVita provided the following response for this sub-criterion. [source: Application, p29]

"DaVita Chinook Kidney Center will meet all current energy conservation standards required. Furthermore, DaVita design standards, reflected in the single-line drawing, are planned to promote energy efficiency, create efficient workflows, clean sightlines and a safe and welcoming environment for patients."

Kennewick Dialysis Center

DaVita provided the following response for this sub-criterion. [source: Application, p29]

"DaVita Kennewick Dialysis Center will meet all current energy conservation standards required. Furthermore, DaVita design standards, reflected in the single-line drawing, are planned to promote energy efficiency, create efficient workflows, clean sightlines and a safe and welcoming environment for patients."

Department Evaluation of Both Projects

DaVita's Chinook project requires additional equipment to add one station, but no construction; the Kennewick project requires both equipment and construction to add three stations. DaVita provided information within each application to demonstrate that each project will meet all required codes and regulations. Further, the additional stations have the potential to improve delivery of dialysis services to the residents of the Benton County planning area. **This sub-criterion is met for both projects.**

APPENDIX A

2021
Benton County
ESRD Need Projection Methodology

	Planning Area	6 Year Utilization Data - Resident Incenter Patients					
	Benton	2015	2016	2017	2018	2019	2020
	Benton County	154	155	168	189	201	182
	TOTALS	154	155	168	189	201	182
246-310-812(4)(a)	Rate of Change		0.65%	8.39%	12.50%	6.35%	-9.45%
	6% Growth or Greater?		FALSE	TRUE	TRUE	TRUE	FALSE
	Regression Method:	Linear					
246-310-812(4)(c)			Year 1	Year 2	Year 3	Year 4	**Year 5**
			2021	2022	2023	2024	**2025**
Projected Resident Incenter Patients	from 246-310-812(4)(b)		205.10	213.80	222.50	231.20	**239.90**
Station Need for Patients	**Divide Resident Incenter by 4.8**		42.73	44.54	46.35	48.17	**49.98**
	Rounded to next whole number		**43**	**45**	**47**	**49**	**50**
246-310-812(4)(d)	subtract (4)(c) from approved stations						
Existing CN Approved Stations		Total	46	46	46	46	**46**
Results of (4)(c) above			43	45	47	49	**50**
Net Station Need			3	1	-1	-3	**-4**
Negative number indicates need for stations							

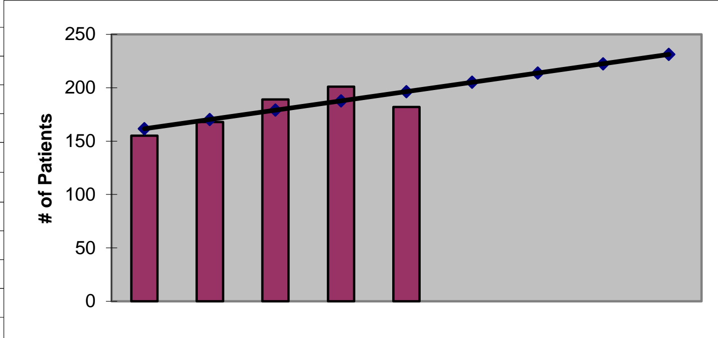
Planning Area Facilities

Name of Center	# of Stations
FMC Columbia Basin	17
DaVita Kennewick	10
DaVita Chinook	19
Total	46

Source: Northwest Renal Network / Comagine ESRD Network 16 data 2015-2020
Most recent year-end data: 2020 posted 02/19/2021

2021
Benton County
ESRD Need Projection Methodology

x	y	Linear
2016	155	**162**
2017	168	**170**
2018	189	**179**
2019	201	**188**
2020	182	**196**
2021		**205.10**
2022		**213.80**
2023		**222.50**
2024		**231.20**
2025		**239.90**



SUMMARY OUTPUT

Regression Statistics	
Multiple R	0.765992289
R Square	0.586744186
Adjusted R Square	0.448992248
Standard Error	13.33041635
Observations	5

ANOVA

	df	*SS*	*MS*	*F*	*Significance F*
Regression	1	756.9	756.9	4.259425999	0.131013087
Residual	3	533.1	177.7		
Total	4	1290			

	Coefficients	*Standard Error*	*t Stat*	*P-value*	*Lower 95%*	*Upper 95%*	*ower 95.0%*	*pper 95.0%*
Intercept	-17377.6	8506.775712	-2.04279513	0.133686682	-44449.95694	9694.756936	-44450	9694.76
X Variable 1	8.7	4.215447782	2.063837687	0.131013087	-4.715436218	22.11543622	-4.71544	22.1154