



STATE OF WASHINGTON
DEPARTMENT OF HEALTH
Olympia, Washington 98504

February 12, 2021

Jennie Funk – Divisional Vice President
DaVita Inc. North Star Division
e-mail: jennie.funk@davita.com

RE: Certificate of Need Application #21-20 DaVita Inc. Vancouver Dialysis Project

Dear Ms. Funk:

We have completed review of the Certificate of Need application submitted by DaVita, Inc. proposing to add two dialysis stations to Vancouver Dialysis Center under the special circumstance provisions of Washington Administrative Code 246-310-818. Enclosed is a written evaluation of the application.

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

Project Description:

This certificate approves the addition of two dialysis stations to the 13-station Vancouver Dialysis Center, for a facility total of 15 dialysis stations. Vancouver Dialysis Center will remain at its current location in Vancouver and continue to provide the following services: in-center hemodialysis, home hemodialysis, home peritoneal dialysis, hemodialysis for visitors, an isolation dialysis station, and shifts beginning after 5:00 pm.

Station Type	CMS Certified Stations	Station Counted for Station Use and Methodology
General Use In-Center Stations	14	14
Permanent Bed Station	0	0
Exempt Isolation Station	1	0
Isolation Station	0	0
Total Stations	15	14

As required under Washington Administrative Code 246-310-818(10) which states, “*Station(s) approved under this section must be operational within six months of approval, otherwise the approval is revoked.*”

Conditions:

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

Approved Costs:

The approved capital expenditure for this two-station addition is \$413,450. This amount represents the costs for moveable equipment. All costs will be paid by DaVita.

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

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

Send your written response to the Certificate of Need Program at 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

Enclosure

2020 CYCLE TWO SPECIAL CIRCUMSTANCE EVALUATION DATED FEBRUARY 12, 2021, FOR THE CERTIFICATE OF NEED APPLICATION SUBMITTED BY DAVITA, INC. PROPOSING TO ADD TWO DIALYSIS STATIONS TO VANCOUVER DIALYSIS CENTER LOCATED IN THE CLARK COUNTY ESRD PLANNING AREA.

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, p5-9]

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 DESCRIPTION

This project focuses on DaVita’s Vancouver Dialysis Center which will be referenced in this evaluation as “Vancouver Dialysis Center.” The dialysis center is located at 9120 Northeast Vancouver Mall Drive, #160 in Vancouver [98662] in the Clark County ESRD planning area. Currently, Vancouver Dialysis Center has a total of 12 general use dialysis stations, plus one exempt isolation station, for a facility total of 13 dialysis stations. A breakdown of the current number of stations is shown in the table below. [source: Application, p2 and CN #1668 effective January 1, 2018]

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

This application proposes to add two dialysis stations to Vancouver Dialysis Center resulting in a facility total of 15 dialysis stations, which includes the one exempt isolation station. Vancouver Dialysis Center would remain at its current location in Vancouver and continue to provide the following services. [source: Application, p11 and December 15, 2020, screening response, p2]

- Hemodialysis patients who dialyze in the chronic setting,
- Hemodialysis patients requiring isolation,
- Hemodialysis patients requiring treatment shifts that begin after 5:00 PM,
- Continuous Ambulatory Peritoneal Dialysis (CAPD) patients, and
- Continuous Cycle Peritoneal Dialysis (CCPD) patients.

Additional services provided include:

- Training and support for patients for peritoneal dialysis,
- Treatment for visiting hemodialysis patients from other areas outside Clark 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 two-station addition project is project is \$413,450, which includes costs for construction, fixed equipment, moveable equipment, and associated fees and sales tax. All costs would be paid by DaVita’s reserves. [source: Application, p22 and p25]

Within the application, DaVita determined this evaluation would be released in mid-February 2021. Using that timeline, DaVita estimated the additional stations would be operational in August 2021. [source: Application, p11] Under this timeline, partial calendar year one is 2021, full calendar year one is 2022, and full calendar year three is 2024.

APPLICABILITY OF CERTIFICATE OF NEED LAW

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

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. For kidney dialysis applications submitted under WAC 246-310-818 ‘Special Circumstance One- or Two-Station Expansion,’ the following review criteria do not apply and will not be discussed in this evaluation.

WAC 246-310-809	One-time exempt isolation station reconciliation
WAC 246-310-812	Kidney disease treatment facilities—Methodology
WAC 246-310-821	Kidney disease treatment facilities—Standards for planning areas without an existing facility
WAC 246-310-830	Kidney disease treatment facilities—Relocation of facilities
WAC 246-310-833	One-time state border kidney dialysis facility station relocation

WAC 246-310-803

WAC 246-310-803 requires an applicant to submit specific data elements to the Certificate of Need Program. For the 2020 concurrent review cycle, the data must be received before February 16, 2020. The applicant submitted data elements timely.

TYPE OF REVIEW

As directed under WAC 246-310-806, the department accepted this application under the Kidney Disease Treatment Centers-Special Circumstances Concurrent Review Cycle #2 for calendar year 2020. Even though applications submitted under WAC 246-310-806 are reviewed under a concurrent review cycle, the applications are not reviewed competitively. Below is the chronologic summary of the application’s review.

APPLICATION CHRONOLOGY

Action	DaVita, Inc.
Letter of Intent Submitted	October 1, 2020
Application Submitted	November 2, 2020
Department's Pre-review Activities including <ul style="list-style-type: none">• DOH First Screening Letter• Applicant's First Screening Responses Received	November 16, 2020 December 15, 2020
Beginning of Review	December 22, 2020
End of Public Comment <ul style="list-style-type: none">• Public comments accepted through the end of public comment• No public hearing requested or conducted	January 21, 2021
Rebuttal Comments Deadline	January 28, 2021
Department's Anticipated Decision Date	February 12, 2021
Department's Actual Decision Date	February 12, 2021

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 this project, no entitles sought or received affected person status.

PUBLIC COMMENT AND REBUTTAL

There was no public comment submitted for this application; as a result, the applicant was precluded from providing rebuttal comments. This fact is stated here and will not be restated throughout this evaluation.

SOURCE INFORMATION REVIEWED

- DaVita Inc.'s Certificate of Need application received November 2, 2020
- DaVita Inc.'s first screening response received December 15, 2020
- Historical kidney dialysis utilization data from Comagine Health ESRD Network 16 (Northwest Renal Network)
- Department of Health's ESRD Need Projection Methodology for the Clark County ESRD planning area posted to its website in March of 2020
- 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://nwrn.org/>
- Centers for Medicare and Medicaid Services website at <https://www.medicare.gov/care-compare>

CONCLUSION

For the reasons stated in this evaluation, the application submitted by DaVita, Inc. proposing to add two dialysis stations to Vancouver Dialysis Center located in the Clark 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 two dialysis stations to the 13-station Vancouver Dialysis Center, for a facility total of 15 dialysis stations. Vancouver Dialysis Center will remain at its current location in Vancouver and continue to provide the following services: in-center hemodialysis, home hemodialysis, home peritoneal dialysis, hemodialysis for visitors, an isolation dialysis station, and shifts beginning after 5:00 pm.

Station Type	CMS Certified Stations	Station Counted for Station Use and Methodology
General Use In-Center Stations	14	14
Permanent Bed Station	0	0
Exempt Isolation Station	1	0
Isolation Station	0	0
Total Stations	15	14

As required under Washington Administrative Code 246-310-818(10) which states, “Station(s) approved under this section must be operational within six months of approval, otherwise the approval is revoked.”

Conditions:

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

Approved Costs:

The approved capital expenditure for this two-station addition is \$413,450. This amount represents the costs for moveable equipment. All costs will be paid by DaVita.

CRITERIA DETERMINATIONS

A. Need (WAC 246-310-210)

Based on the source information reviewed and agreement to the conditions identified in the conclusion section of this evaluation, the department concludes that 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 246-310-818

WAC 246-310-818(1) - (13) outline the review requirements for dialysis projects submitted under the special circumstance review criteria. For this project, DaVita must demonstrate compliance with the following sub-sections of WAC 246-310-818.

WAC 246-310-818(1) The department will approve one or two additional special circumstance stations for an existing kidney dialysis facility (facility) if it meets the following criteria, regardless of whether the need methodology in WAC 246-310-812 projects a need for additional stations in the planning area:

- (a) For 4.8 planning areas, the facility has operated at or above an average of 5.0 patients per station for the most recent six consecutive month period preceding the letter of intent submission date for which data is available. Data used to determine patients per station must be obtained from the Northwest Renal Network; or
- (c) The facility can accommodate one or two additional stations within its existing building, which may include shelled space. If renovation is needed to accommodate the additional station(s), renovation must be within the existing building.

DaVita, Inc.

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

- Six months of utilization data beginning in April 2020 through September 2020 provided by Comagine Health ESRD Network 16; and
- Single line drawings showing the current and projected stations and support areas of the dialysis center as well as where the new stations would be located.
- The following statement regarding permanent bed station space in the line drawings:
“DaVita Vancouver does not serve patients requiring a permanent bed station. The square footage table and single line drawings are accurate.”

[source: Application, Appendix 17 and December 15, 2020, screening response, p2 and Appendix 22]

Department Evaluation

For this project, the six months preceding the letter of intent submission period for the Year 2020 Special Circumstance Concurrent Review Cycle #2 for the Clark County ESRD planning area is April 2020 through September 2020.

Within its application, DaVita submitted data obtained from Comagine Health ESRD Network 16 for those specific six months, showing each month individually. Using this data, DaVita demonstrated compliance with this sub-criterion.

The single line drawing shows the two additional stations will be set up in existing space within the facility. Based on the information reviewed the department concludes the **sub-criterion is met**.

WAC 246-310-818(5) For 4.8 planning areas, a facility is ineligible for a special circumstance one-or two-station expansion if the owner or affiliate has approved certificate of need stations in the planning area that have operated below an average of 4.5 patients per station for the most recent six consecutive month period preceding the letter of intent submission date. Data used to calculate patients per station must be obtained from the Northwest Renal Network.

DaVita, Inc.

To demonstrate compliance with this sub-criterion, DaVita provided data from Comagine Health ESRD Network 16 showing the six-months historical utilization for several of DaVita Inc.’s dialysis centers. [source: December 15, 2020, screening response, Appendix 22]

Department Evaluation

For this project, the six months preceding the letter of intent submission period for the Year 2020 Special Circumstance Concurrent Review Cycle #2 for the Clark County ESRD planning area is April 2020 through September 2020.

There are currently six dialysis centers approved to operate in the Clark County ESRD planning area. Two are operated by DaVita, and the remaining four facilities are operated by Fresenius Medical Care (three centers) and Puget Sound Kidney Centers (one center). The utilization of the Fresenius

Medical Care and Puget Sound Kidney Centers facilities are not relevant to this sub-criterion for this DaVita project.

DaVita provided the data for its two Clark County dialysis centers. Using this data, the department calculated the historical six-month utilization of the two DaVita facilities operating in Clark County. The calculations are shown in the tables below. [source: NWRN data – April through September 2020]

Department’s Tables 1

Battle Ground Dialysis Center – Number of Stations = 12

Number of Stations	Number of Patients	Utilization
April 2020	52	5.20
May 2020	51	5.10
June 2020	54	5.40
July 2020	55	5.50
August 2020	55	5.50
September 2020	58	5.80

Vancouver Dialysis Center – Number of Stations = 10

Number of Stations	Number of Patients	Utilization
April 2020	77	6.42
May 2020	76	6.33
June 2020	75	6.25
July 2020	77	6.42
August 2020	82	6.83
September 2020	85	7.08

As shown in Tables 1 above, both of DaVita’s Clark County facilities were operating above the 4.5 patients per station utilization standard for the six months preceding the letter of intent period for this review cycle. **This sub-criterion is met.**

WAC 246-310-818(7) For 4.8 planning areas, a special circumstance one- or two-station expansion will not be approved if, with the requested new station(s), the applicant's kidney dialysis facility would fall below a calculated 4.5 patients per station. Data used to make this calculation is the average patients per station from subsection (1)(a) of this section.

DaVita, Inc.

To demonstrate compliance with this sub-criterion, DaVita provided the following statements and table. [source: Application, p17]

“The table below provides projected utilization summaries through completion of the third full year of operation (2024). In-center patient volume is based on a 5-year projection of Clark County patients using a regression of 5 years historical data and DaVita’s own experience. In-center treatments are based on an assumption of 3 treatments per week per patient for 52 weeks with a 5% allowance for missed treatments, except for 2020, which is annualized from 3rd quarter actual figures. Facility-specific growth rates and home patient volume and growth rates are based on a 5-year projection of Clark County patients using a regression of 5 years historical data, facility growth rates, planning area growth rates, historical home/in-center proportions, and DaVita’s experience. The expansion year anticipates expansion in August 2021.

The 2024 utilization rate, in the third full year of operation, exceeds 80% of 6-shift utilization of 5 general stations using a 6-shift utilization standard of 4.8 patients per station. Note that utilization is unusually high, as Vancouver already runs a 4th shift late at night due to need for its services.”

Applicant’s Table

Table 13

	Expansion Year	Projection Year	Projection Year	Projection Year
DaVita Vancouver Dialysis Center Projected Utilization	2021	2022	2023	2024
Total in-center stations (excluding CON exempt ISO)	14	14	14	14
Total in-center patients (average)	81	84	86.5	87.5
Total in-center treatments	12,004	12,449	12,819	12,968
Total home patients (average)	18	18	19	19
Total home treatments	2,684	2,716	2,748	2,781

Department Evaluation

For this project, the six months preceding the letter of intent submission period for the Special Circumstance Concurrent Review Cycle #2 for the Clark County ESRD planning area is April 2020 through September 2020. DaVita’s data provided above is projected utilization of the facility, rather than the six months preceding the letter of intent submission period data as required by rule. However, within the screening responses, DaVita submitted data obtained from Comagine Health ESRD Network 16 for those specific six months, showing each month individually.

Using these six months data preceding the letter of intent submission period, the department calculated the utilization of Vancouver Dialysis Center with 14 incenter stations (not including the exempt isolation station). The calculations show that the dialysis center’s utilization six-month average is 5.62. These calculations meet the required minimum average of 4.5 patents per station.

This sub-criterion is met.

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

DaVita, Inc.

To demonstrate compliance with this sub-criterion, DaVita provided the following table and statements showing the projected timeline for operation of the two additional stations. [source: Application, pp10-11]

“The table below outlines the anticipated dates of approval, design completion, construction commencement and completion, and preparation for survey based on an approval date, assuming all variables operate according to historical trends. DaVita continues to refine and streamline the facility development process.”

Applicant's Table

Table 1

DaVita Vancouver Dialysis Center

Anticipated Dates of Commencement & Completion of Project

Event	Anticipated Date
<i>Project Approval</i>	<i>February 12, 2021</i>
Design Complete	February 2021
Construction Commenced	N/A
Construction Completed	N/A
Facility Prepared for Survey	August 2021

Department Evaluation

The timeline identified in DaVita's application projects the two new dialysis station would be operational at Vancouver Dialysis Center within six months of approval. DaVita identified a timeline for completion of this project based on a mid-February 2021 evaluation release date. Given that WAC 246-310-818(10) requires the additional station to be operational within six months of approval, **this sub-criterion is met.**

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

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

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

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

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

A facility's charity care policy should show a willingness of a provider to provide services to patients who have exhausted any third-party sources, including Medicare and Medicaid, and whose income is equal to or below 200% of the federal poverty standards, adjusted for family size or is otherwise not sufficient to enable them to pay for the care or to pay deductibles or coinsurance amounts required by a third-party payer.³ With the passage of the Affordable Care Act (ACA), the amount of charity

³ WAC 246-453-010(4).

care is expected to decrease, but not disappear. The policy should also include the process one must use to access charity care at the facility.

DaVita, Inc.

DaVita provided the following information for this sub-criterion. [source: Application, p20]

“DaVita’s history of providing dialysis services at numerous locations throughout Washington State provides evidence that all ESRD patients have access to DaVita’s facilities, including members of the under-served groups referenced in WAC 246-310-210(2). Appendix 14 includes a copy of the admission, patient financial evaluation, and patient involuntary transfer policies which document that access will not be denied at DaVita Vancouver Dialysis Center due to indigence, racial or ethnic identity, gender or handicapped status. The pro forma shows that funds have been budgeted to provide charity care.”

DaVita also provided the following policies and procedures for this facility. [source: Application, 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)

Medicare and Medicaid Programs

Vancouver Dialysis Center is currently Medicare and Medicaid certified. DaVita provided the facility’s Medicare and Medicaid provider numbers and included tables showing the historical and projected percentages of revenue by payer, and revenue by patient for Vancouver Dialysis Center. The information is summarized below. [source: Application, p14 and p24]

Medicare Provider Number: 502550
 Medicaid Provider Number: 3991056

Applicant’s Tables

Table 15 DaVita Vancouver Dialysis Center Historical Average Payor Mix	Percentage by Revenue	Percentage by Patient
Medicare Fee-For-Service	24.71%	40.46%
Medicaid Fee-For-Service	1.08%	2.32%
Commercial, HMO, Other Government, and Other	74.21%	57.21%
Total	100.00%	100.00%

Table 14 DaVita Vancouver Dialysis Center Projected Payor Mix	Percentage by Revenue	Percentage by Patient
Medicare Fee-For-Service	26.04%	41.99%
Medicaid Fee-For-Service	1.53%	3.10%
Commercial, HMO, Other Government, and Other	72.43%	54.91%
Total	100.00%	100.00%

Department Evaluation

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: Application, Appendix 14]

All DaVita dialysis centers are Medicare and Medicaid certified. Documentation provided in the application demonstrates that Vancouver Dialysis Center would continue both Medicare and Medicaid certifications. DaVita provided its current and projected revenues for Vancouver Dialysis Center. [source: Application, p24]

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 Vancouver 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: December 15, 2020, screening response, Appendix 9A]

DaVita provided copies of the necessary policies used at all DaVita dialysis centers, which includes Vancouver Dialysis Center. 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 Vancouver Dialysis Center and uses these policies and procedures at this center, the policies provided in the application are executed policies. The department concludes DaVita’s proposal **meets this sub-criterion.**

- (3) The applicant has substantiated any of the following special needs and circumstances the proposed project is to serve.
 - (a) The special needs and circumstances of entities such as medical and other health professions schools, multidisciplinary clinics and specialty centers providing a substantial portion of their services or resources, or both, to individuals not residing in the health service areas in which the entities are located or in adjacent health service areas.
 - (b) The special needs and circumstances of biomedical and behavioral research projects designed to meet a national need and for which local conditions offer special advantages.
 - (c) The special needs and circumstances of osteopathic hospitals and non-allopathic services.
- (4) The project will not have an adverse effect on health professional schools and training programs. The assessment of the conformance of a project with this criterion shall include consideration of:
 - (a) The effect of the means proposed for the delivery of health services on the clinical needs of health professional training programs in the area in which the services are to be provided.
 - (b) If proposed health services are to be available in a limited number of facilities, the extent to which the health professions schools serving the area will have access to the services for training purposes.
- (5) The project is needed to meet the special needs and circumstances of enrolled members or reasonably anticipated new members of a health maintenance organization or proposed health maintenance organization and the services proposed are not available from nonhealth maintenance organization providers or other health maintenance organizations in a reasonable and cost-effective manner consistent with the basic method of operation of the health maintenance organization or proposed health maintenance organization.

Department Evaluation

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

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

Based on the source information reviewed and agreement to the conditions identified in the conclusion section of this evaluation, the department concludes that 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 this project, the applicant must demonstrate compliance with the following sub-sections of WAC 246-310-815(1). Using its experience and expertise the department evaluates if the applicant's pro forma income statements reasonably project the proposed project is meeting its immediate and long-range capital and operating costs by the end of the third complete year of operation.

WAC 246-310-815(1)

(1) The kidney dialysis facility must demonstrate positive net income by the third full year of operation.

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

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

DaVita, Inc.

As previously stated, DaVita projects that the two additional stations would be operational at Vancouver Dialysis Center by the end of August 2021 based on a February 2021 evaluation release date. [source: Application, p11] Under this timeline, calendar year one of this project is 2021; full year one is 2022 and year three is 2024.

Once the additional stations are added, Vancouver Dialysis Center would be operating with total of 15 dialysis stations, which includes the one exempt isolation station. DaVita provided the assumptions used to project in-center treatments and patients. The assumptions are restated below. [source: December 15, 2020, screening response, Appendix 9R]

- *“First Full Year: 2022, based on a first patient date in August 2021 for the expansion.*
- *Total Stations: CON Approved stations. One CON-exempt isolation station is also included in driving relevant category calculations (bio-med FTE, overall existing facility depreciation).*
- *Total 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 2024. 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 number of in-center dialyses and patients for Vancouver Dialysis Center for years 2021 through 2024. The projections are summarized in the table below. [source: Application, p19]

Applicant’s Table

Table 13

	Expansion Year	Projection Year	Projection Year	Projection Year
DaVita Vancouver Dialysis Center Projected Utilization	2021	2022	2023	2024
Total in-center stations (excluding CON exempt ISO)	14	14	14	14
Total in-center patients (average)	81	84	86.5	87.5
Total in-center treatments	12,004	12,449	12,819	12,968
Total home patients (average)	18	18	19	19
Total home treatments	2,684	2,716	2,748	2,781

DaVita provided the following assumptions for its projected financial statements, which are restated below. [source: December 15, 2020, screening response, Appendix 9R]

- *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, 2019, and its payer mix.*
- *General expenses: Based on cost per treatment for the last full calendar year (2019) 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 – no current contract cost increases are known, and thus none are included, except for the lease, noted below.*

- *Medical Director Expense: based on contracted, known expenses in latest medical director agreements that run through the extent of the three-year projection window.*
- *Lease Expense: base rent is directly pulled from the lease contract for each calendar year – market rent adjustment as codified in the lease terms is set at 0%, due to no defined inflation rate beyond the existing term. DaVita has site control with a unilateral renewal option at FMV. Tax & CAM are calculated based on actual 2019 tax and CAM per square foot of \$4.50 per square foot, with no inflation.*
- *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 53% of base salaries and wages based on 2019 facility data.*
- *Bad Debt: 3.5% of gross revenue, based on DaVita’s experience & expertise.”*

DaVita also provided the following clarification regarding changes reflected in the pro forma revenue and expense statement when compared to the historical statement with year 2020 included. [source: December 15, 2020, screening response, p5]

“In addition to clarification of projected patient care hours, DaVita also notes that 2020 annualized salary and benefit figures are expected to be elevated compared to prior years, as well as future years (on a per FTE basis), substantively so. This is due to the measures that DaVita has taken to care for its teammates during these unprecedented times, including, but not limited to, paying double time as opposed to overtime during Q2 2020 in all facilities, the Village Lives award (a weekly monetary award to all manager and below teammates during Q2 to help offset the unprecedented economic turmoil in teammates’ lives brought by COVID), additional childcare benefit expenses, and other expenses. These expenses are not expected to occur in future years, and are not included in the projection (as the projection is based on full-year 2019 data).

Note that another category is also expected to show an anomalous 2020: medical supplies. As the COVID-19 pandemic has continued to grip the United States, personal protective equipment (“PPE”) prices have escalated, for everything from gloves, to masks, to protective gowns, in many cases, substantially so. While DaVita has seen no supply chain disruptions that impact teammate safety or patient care (DaVita has a robust purchasing and procurement process, that, among other things, yielded a substantial supply of masks even in the early days of the pandemic, when availability was extraordinarily limited), the costs incurred are substantially escalated from prior years. This is expected to revert back to 2019 baseline costs as pandemic conditions recede with the advent of widespread vaccination in 2021.”

DaVita provided the following clarification regarding the historical and projected amounts for bad debt at Vancouver Dialysis Center. [source: December 15, 2020, screening response, p5]

“2020 figures reflect DaVita’s actual write-off experiences through most of the year, whereas 2021 figures reflect projections based on DaVita’s experience with average bad debt levels overall, which is why bad debt decreases from 2020 to 2021.

Actual bad debt can vary significantly year-to-year due to individual patient payer sources and ability to collect. One particular year at one center is not necessarily indicative of what to expect moving forward, as individual patients are transplanted, transfer out, or expire, or their insurance coverage changes.

Thus, for our projections in Appendix 9, however, we relied on a standard internal methodology, which assumes that a consistent percentage of total revenue (3.5%) will be written off for future

years. This is consistent with DaVita's overall experience. DaVita is more confident that the 3.5% projection will be consistently accurate throughout the projection period than for any one historical year, which may (and do) oscillate widely year-to-year for a given facility."

DaVita provided the following clarification regarding the lease costs for the site. [source: December 15, 2020, screening response, pp6-8]

"After submission of this application, on November 24, 2020, DaVita exercised one of its two 5-year renewal options. An executed copy of the renewal (the Vancouver lease's 6th Amendment) is attached as an addendum to Appendix 15. The sixth amendment extends the lease term through May 31, 2026, and does change the lease costs that DaVita now anticipates, as DaVita has negotiated favorable terms upon exercising its renewal right. The projected lease cost has therefore changed, and that is reflected in the new Appendix 9, attached to this application.

DaVita Vancouver currently leases 10,197 square feet at 9120 NE Vancouver Mall Drive Ste 160, Vancouver, WA, 98662. This information is found on page 1 of the Sixth Amendment, attached, as well as in the original application.

The Fourth Amendment contains information about the base rent cost per year for the original footprint of the clinic, of 6,983 square feet. The rent per square foot in the last year is \$27.01 per square foot and extends through May 31, 2021. This information is found on page 849 of the original application.

The Fifth Amendment to the Original Lease added 3,214 square feet to the initial footprint, which added additional space for home dialysis services. The rent per square foot for the expansion space in the last year is \$22.95 per square foot and extends through May 31, 2021. This information is found on page 860 of the original application.

The initial operating expenses were \$4.50 per square foot per year. This information is found on page 824 of the original application.

Future rent adjustments for the center's full 10,197 square feet are explicitly laid out in the Sixth Amendment attached to the screening reply. Rent per square foot will inflate by 2.5% per year starting on June 1 of each new year.

Operating expenses (taxes, CAM charges, and insurance premiums) are based on actual expenses incurred by the lessor. DaVita Vancouver pays its pro rata share of these operating expenses. These expenses were initially \$4.50 per square foot and are assumed to remain at this level through the projection period. This information is found on page 824 of the original application.

Given the complexity of the lease costs due to multiple amendments and additions to the original square footage of the center, a few tables are shown below to help clarify historical and future anticipated lease costs:

MONTHLY RENT COSTS – HISTORICAL – FROM 4TH AND 5TH AMENDMENTS:

		Monthly rent	
From	To	Original space	Expansion space
1/1/2017	5/31/2017	\$ 13,966.00	
6/1/2017	5/31/2018	\$ 14,384.98	
6/1/2018	5/31/2019	\$ 14,816.53	\$ 5,793.23
6/1/2019	5/30/2020	\$ 15,261.03	\$ 5,967.03
6/1/2020	5/31/2021	\$ 15,718.86	\$ 6,146.77

ANNUAL RENT COSTS (NOT LEASE COST, AS DOES NOT INCLUDE OPERATING EXPENSES) – HISTORICAL – FROM 4TH AND 5TH AMENDMENTS:

	Total annual rent
2017	\$ 170,524.86
2018	\$ 216,193.22
2019	\$ 251,645.22
2020	\$ 259,199.71

Please note that the actual lease costs reflected in the Historical Income Statement also include operating expenses, so the numbers above will not tie with the Historical Income Statement precisely. Operating expenses are calculated from the actual expenses incurred by the lessor. DaVita pays its pro rata share. Operating expenses do vary year by year.

Using all this information, DaVita also provides the following table to link information found in the Sixth Amendment to its Vancouver lease agreement to the lease expense found in its updated Appendix 9 pro forma Revenue and Expense Statement:

MONTHLY RENT COST FROM 2021 TO 2024 - FROM 4TH, 5TH, AND 6TH AMENDMENTS:

		Monthly rent		
From	To	Original space	Expansion space	Total space
6/1/2020	5/31/2021	\$ 15,718.86	\$ 6,146.77	
6/1/2021	5/31/2022			\$ 21,864.07
6/1/2022	5/31/2023			\$ 22,410.67
6/1/2023	5/31/2024			\$ 22,970.94
6/1/2024	5/31/2025			\$ 23,545.21

**ANNUAL RENT, OPERATING EXPENSE, AND LEASE COSTS
FROM 2021 TO 2024 - FROM 4TH, 5TH, AND 6TH AMENDMENTS:**

	Total annual rent	Estimated operating expense per square foot	Total annual operating expense	Total estimated lease cost
2021	\$ 262,376.64	\$ 4.50	\$ 45,886.50	\$ 308,263.14
2022	\$ 266,195.04	\$ 4.50	\$ 45,886.50	\$ 312,081.54
2023	\$ 272,849.93	\$ 4.50	\$ 45,886.50	\$ 318,736.43
2024	\$ 279,671.17	\$ 4.50	\$ 45,886.50	\$ 325,557.67

As shown, operating expenses are assumed to be stable throughout the projection period and will cost an estimated \$4.50 per square foot per year, consistent with the building’s experience upon original lease execution.

On November 24, 2020, DaVita exercised one of its two 5-year renewal options. An executed copy of the renewal is attached as an addendum to Appendix 15. The sixth amendment extends the lease term through May 31, 2026.

As a note, DaVita had (and has) full authority to renew the lease for two additional five-year periods after the original May 21, 2021 expiration. This is found in the Fourth Amendment to the Original lease document, which is provided in Appendix 15, Fourth Amendment, Section 4, “Renewals”. For ease of review, DaVita is pasting the relevant portion below. This information is also found on page 850 of DaVita’s original application:

4. **Renewals.** Lessee shall retain its right and option to renew this Lease for two additional periods of five years each and add one additional period of five years each, next immediately ensuing after the expiration of the Extended Term and any subsequent renewal period by notifying Lessor in writing not less than 180 before the expiration of the immediately preceding Extended Term or subsequent renewal term of Lessee’s intention to exercise its option to renew. In the event Lessee fails to provide a renewal notice during such period, Lessor shall notify Lessee in writing within 90 days prior to expiration of the then existing Term or renewal period of Lessee’s option to extend this Lease. Lessee shall then have an additional 30 day period after receipt of Lessor’s notice to exercise its right of renewal. In the event that Lessee so elects to extend this Lease, then, for such extended period of the Term, all of the terms, covenants and conditions of this Lease shall continue to be, and shall be, in full force and effect, except that Rent shall adjusted pursuant to Section 4 of the Lease.

Based on the assumptions and clarifications above, DaVita projected the revenue, expenses, and net income for years 2021 through 2024 which are summarized in the table below. [source: December 15, 2020, screening response, Appendix 9R]

**Department’s Table 2
Vancouver Dialysis Center
Projected Revenue and Expenses for Years 2021 - 2024**

	CY 2021	CY 2022	CY 2023	CY 2024
Net Revenue	\$7,328,210	\$7,566,102	\$7,767,217	\$7,857,614
Total Expenses	\$4,839,403	\$4,971,404	\$5,093,651	\$5,148,148
Net Profit / Loss	\$2,488,807	\$2,594,698	\$2,673,566	\$2,709,466

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 the 15-station facility in years 2021 through 2024. The expenses include all costs identified in the assumptions outlined above. Both Medical Director costs and lease costs are explained in the assumptions above.

Department Evaluation

Vancouver Dialysis Center is currently operating with 13 dialysis stations. DaVita based its projected utilization of Vancouver Dialysis Center on its current utilization, plus two additional stations. This approach for an existing facility is reasonable.

As a special circumstance application, WAC 246-310-815(1)(b) requires an applicant to base its revenue projections on the current payer mix and base its expense projections on current expenses. DaVita projects revenues will be higher than expenses at Vancouver Dialysis Center through the third full year of the proposed project. DaVita also based these projections on current operations.

DaVita provide a copy of the executed lease agreement for the site to demonstrate site control. Since DaVita will continue leasing the site, lease costs were included in pro forma revenue and expense statement.

DaVita also provided a copy of the Medical Director Agreement with Pacific Kidney and Hypertension that was executed on May 10, 2015, and the amendment executed in May 2018 that is valid until May 2021. This agreement is reflective of the historical costs identified in the revenue and expense statement through February 2021. Both DaVita and Pacific Kidney and Hypertension have agreed to an early termination of this agreement.

DaVita also provided a copy of its new Medical Director Agreement with The Vancouver Clinic. This agreement begins February 2021 and is effective for ten years—until February 2031. This agreement also includes automatic annual renewals. The costs identified in the Medical Director Agreement can be 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 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.

DaVita, Inc.

For this sub-criterion, DaVita stated that this project requires construction, fixed and moveable equipment, and other fees to add two stations to Vancouver Dialysis Center. DaVita provided its capital cost breakdown shown in the table on the following page. [source: Application, p22]

**Department's Table 3
Vancouver Dialysis Center Estimated Capital Costs**

Item	Total	% of Total
Building Construction	\$321,891	77.9%
Fixed Equipment (not in construction)	\$5,410	1.3%
Moveable Equipment	\$43,139	10.4%
Architect & Engineering Fees	\$17,853	4.3%
Supervision & Site Inspection	\$25,157	6.1%
Total Estimated Capital Costs	\$413,450	100.0%

DaVita clarified that Washington State sales tax is included with the costs above as necessary. Movable equipment includes the additional chairs and machines, as well as the necessary computer equipment, to add stations to Vancouver Dialysis Center. Sales tax is not assessed on dialysis machines. [source: Application, p22]

Specific to costs and charges for health services, DaVita provided the following statements. [source: Application, p23]

“Historical revenue and expense statements, including the current year, are included in Appendix 8. The DaVita Vancouver Dialysis 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 the facility’s current payer mix and current expenses. All major pro forma assumptions are also outlined in Appendix 9.

No existing facility is expected to lose volume or market share below Certificate of Need standards as a result of this project, as Vancouver Dialysis Center is already operating at or near capacity by virtue of its utilization eligibility for a special circumstances application. The proposed facility will operate at utilization levels consistent with required utilization levels. Reimbursements for dialysis services are not subject to or affected by capital improvements and expenditures by providers; the proposed project will have no impact on increases in charges for services within the ESRD planning area.

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 Eleven 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 seven, 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 actual square footage of Vancouver Dialysis Center and the minimum allowable square footage provided in WAC 246-310-800(11). [source: Application, p13]

Department Evaluation

The costs for adding two stations to the 13-station Vancouver Dialysis Center is \$413,450. The costs are comparable to those reviewed in past applications for similar size station addition. The department does not consider the capital expenditure to be excessive for this project.

Documentation provided in the application shows that Vancouver Dialysis's projected Medicare and Medicaid reimbursements equals 27.57% 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 72.43% of net revenue is commercial, HMO and other government.

To demonstrate compliance with WAC 246-310-800(11), Vancouver Dialysis Center's allowable maximum treatment floor area square footage for a 15-station facility is 4,025. DaVita's project will use 2,553 square feet. DaVita's project does not exceed the maximum treatment floor area square footage allowable.

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

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

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

DaVita, Inc.

DaVita identified a capital expenditure of \$413,450 to add two stations to Vancouver Dialysis Center. 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: Application, p22 and Appendix 6]

DaVita also provided a copy of its audited financial statements for years 2017, 2018, and 2019 to demonstrate sufficient reserves to finance the project. [source: Application, Appendix 10]

Department Evaluation

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

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

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

Based on the source information reviewed and agreement to the conditions identified in the conclusion section of this evaluation, the department concludes that 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.

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

DaVita, Inc.

If this project is approved, DaVita expects the additional stations would be operational by the end of August 2021. Year 2021 would be a partial year of operation with 14 dialysis stations and full calendar year one is 2022 and full calendar year three is 2024. The table below provides a breakdown of projected FTEs for historical year 2019, current year 2020 and projected years 2021 through 2024. [source: December 15, 2020, screening response, p3]

**Department’s Table 4
Vancouver Dialysis Center Historical, Current, and Projected FTEs**

FTE by Type	CY 2019	CY 2020 Increase*	CY 2021 Increase*	CY 2022 Increase*	CY 2023 Increase*	CY 2024 Increase*	Total
Administrator	1.24	0.03	0.01	0.00	0.03	0.02	1.33
Administrative Assistant	0.91	0.28	0.19	0.00	0.00	0.00	1.00
Medical Social Worker	0.88	0.04	0.01	0.00	0.03	0.01	0.89
Dietician	0.79	0.02	0.08	0.00	0.03	0.01	0.89
Registered Nurses	12.44	0.42	0.71	0.41	0.38	0.14	13.08
BioMed Technician	0.50	0.09	0.06	0.00	0.00	0.00	0.65
Other	0.21	0.06	0.09	0.00	0.00	0.00	0.18
Total FTEs	16.97	0.82	0.83	0.41	0.47	0.18	18.02

* numbers in red in columns CY 2020 through CY 24 depict a decrease in FTEs.

The medical director is under contract and not included in the table above. [source: Appendix 3]

DaVita 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, pp22-23]

“DaVita is aware of the challenging labor environment across Washington State. To address this, DaVita has recently added a new people services manager focusing on this geography. DaVita has also implemented internal referral bonuses for key team members such as registered nurses, rolled out an improved onboarding program called STAR and set up a series of pay increases and bonuses as new teammates meet training milestones to get new staff operational as efficiently as possible while maximizing retention in a very competitive labor environment.

DaVita anticipates no difficulty in recruiting the necessary personnel to continue to staff DaVita Vancouver Dialysis Center. Based on our experience operating facilities in the planning area, DaVita anticipates that staff from the existing Vancouver Dialysis Center and geographically adjacent facilities will serve patients at the expanded Vancouver Dialysis Center. Moreover, DaVita has been repeatedly recognized as a Top Employer and a Military Friendly Employer (davita.com/about/awards) and offers a competitive wage and benefit package to employees. DaVita posts openings nationally both internally and external to DaVita.”

Department Evaluation

Information provided in the application demonstrates that DaVita is a well-established provider of dialysis services in Washington State and in Clark County. Vancouver Dialysis Center has been operational since approximately June 2007. [source: Vancouver Dialysis Center facility file]

The facility is currently operating with 17.79 FTEs. For this project, DaVita is proposing to add less than one FTE. The two-station increase does not require a substantial addition of staff.

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

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

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

DaVita, Inc.

DaVita provides dialysis services throughout Washington State, including its Vancouver Dialysis Center in the Clark County ESRD planning area. If this project is approved, Vancouver Dialysis Center’s total incenter stations will increase from 12 to 14. DaVita provided the following statements regarding services that would be provided on site and those provided off site. [source: Application, pp27-28]

“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 also provided a listing of vendors it currently has ancillary and support agreements with for Vancouver Dialysis Center. [source: Application, Appendix 11]

Applicant’s Table

Agreement	Vendor
Extensive Facility Maintenance	CBRE
Patient Transfer	Legacy Salmon Creek / Peacehealth SW
Janitorial	CleanNet USA, Inc.
Waste Disposal	Waste Connections
Medical Waste Disposal	Stericycle
Information Management	Iron Mountain
Mutual Emergency Backup Dialysis	Battle Ground, MLK, Gateway
Emergency PD Support	Battle Ground Dialysis Center
Laboratory Services	DaVita Laboratory Services
Stat Laboratory Services	Kaiser
Stat Laboratory Services	Legacy Salmon Creek
Home Training Supplies	Baxter/NxStage
DME Supplies	FMC / Henry Schein
Renal Network	Northwest Renal Network (Network 16)
Transplant Agreements	OHSU, University of Washington, Legacy Good Samaritan
Pest Control	Terminix

Additionally, DaVita provided the following statements regarding the entities it currently has working relationships with for Vancouver Dialysis Center. [source: Application, p28]

“DaVita Vancouver Dialysis Center has a number of strong working relationships that tie it to its community, including a Patient Transfer Agreement with PeaceHealth. Please find a listing of these relationships in Table 18 below.

Applicant’s Table 18 Recreated

Healthcare Facility Relationships	Type of Relationship
<i>Peacehealth Southwest Medical Center</i>	<i>Patient Transfer Agreement</i>

No existing working relationships are expected to change as a result of this project, except for any enhancement due to increased access to dialysis services for other healthcare facilities’ ESRD patients.”

DaVita provided the executed Patient Transfer Agreement between itself and Legacy Salmon Creek Hospital. The agreement was effective on October 16, 2006. The executed agreement identifies annual automatic renewal. [source: Application, Appendix 12]

DaVita also provided a copy of its current and proposed executed Medical Director Agreements. The current agreement is between itself and Pacific Kidney and Hypertension, LLC in Portland, Oregon. The agreement was executed May 10, 2015 and extended in May 2018. DaVita notes that though the agreement appears to extend through May 10, 2021, (at a total cost of \$130,000/annual), both DaVita, Inc. and Pacific Kidney and Hypertension, LLC have agreed to an early termination. As a result, this agreement will expire on February 1, 2021, when the new Medical Director

Agreement is effective. [source: December 15, 2020, screening response, p3 and Appendix 3A, 3B, and 3C]

The new Medical Director Agreement is between DaVita, Inc. and The Vancouver Clinic and is effective on February 1, 2021. This agreement will extend for ten years. The agreement specifically identifies Binaya Khanal, MD as the primary medical director for Vancouver Dialysis Center. The agreement also identifies four additional physicians with pre-approved status to serve in the medical director role if needed. The four physicians are:

Larry K. Lee, MD Sudha Pidikiti, MD Haritha Ravi, MD Andrew D. Reznick, MD

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

Vancouver Dialysis Center has been operating in the Clark County ESRD planning area since approximately June 2007. All ancillary and support services have been established for the dialysis center. DaVita states that no new agreements or revisions to existing agreements are necessary for this project.

Within the application, DaVita discusses an executed Patient Transfer Agreement with Southwest Washington Medical Center; however, the agreement provided in the application is between DaVita, Inc. and Legacy Salmon Creek Hospital. The department considers the reference to Southwest Washington Medical Center to be a clerical error.⁴ Further, the department requires a Patient Transfer Agreement with a local hospital and Legacy Salmon Creek Hospital in Vancouver is local for this project.

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.*

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

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

DaVita, Inc.

DaVita provided the following statements in response to this sub-criterion. [source: Application, pp28-29]

⁴ A clerical error or a scrivener's error is an error due to a minor mistake or advertence and not one that occurs from judicial reasoning or determination. It can be a mistake made in a letter, paper, or document that changes the meaning of the same.

“On October 22, 2014, 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. The Corporate Integrity Agreement expired October 22, 2019. During the five-year term of the agreement, DaVita continued to thrive, and though no longer required to operate pursuant to the agreement, DaVita plans to continue most of the policies and spirit of the agreement.

The applicant has no adverse history of license revocation or decertification in Washington State. DaVita has no criminal convictions related to DaVita’s competency to exercise responsibility for the ownership or operation of its facilities. As previously reported, a DaVita facility in Tennessee was decertified and closed thirteen years ago (2007) and DaVita voluntarily temporarily shut down a facility in Texas twelve years ago (2008). DaVita has also supplied, in Appendix 13, a list of all state regulatory agencies with which it interacts.”

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 2018 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.⁵

- **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.

⁵ Definitions of standard and condition level surveys: <https://www.compass-clinical.com/deciphering-tjc-condition-level-findings/>

“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 2018 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.

Conformance with Medicare and Medicaid Standards

Focusing on years 2018 through 2021, of the 42 operational facilities, 33 were surveyed. Of the 33 surveyed facilities, three had condition level findings. Below provides a brief description of the findings and outcome for the three facilities.

Federal Way Community Dialysis Center

- During the September 2018 survey, surveyors cited the facility for four condition level findings in the areas of patient plan of care, care at home, responsibilities of the medical director, and governance. The citations required plans of correction and one follow up visit in October 2018.
- During the August 2019 survey, surveyors found no standard or condition level deficiencies.

Redondo Heights Dialysis Center

- During the July 2018 survey, surveyors cited the facility for two condition level findings in the areas of patient plan of care and governance. The citations required plans of correction and one follow up visit in September 2018.
- The facility was not surveyed in 2019 and 2020.

Yakima Dialysis Center

- During the April 2018 survey, surveyors cited the facility for four condition level findings in the areas of infection control, patient plan of care, responsibilities of the medical director, and governance. The citations required plans of correction and one follow up visit in May 2018.
- During the October 2019 survey, surveyors found no standard or condition level deficiencies.

CMS Star Rating for Washington State Centers

As of the writing of this evaluation, DaVita operates a total of 42 dialysis centers in Washington State, and of those 41 had a CMS star rating. The average star rating for the 41 facilities is 4.4. Specific to Vancouver Dialysis Center, its star rating is 5. For the remaining dialysis center, Lynnwood Dialysis Center, it has not been operational long enough to obtain a star rating.

DaVita provided an executed Medical Director Agreement with The Vancouver Clinic. The agreement identifies Binaya Khanal, MD as the medical director and identifies four additional

physicians as pre-approved for medical director responsibilities. The four physicians are listed below. [source: Application, Appendix 3]

- Ravi Haritha, MD
- Larry K. Lee, MD
- Sudha Pidikiti, MD
- Andrew D. Reznick, MD

Using data from the Medical Quality Assurance Commission, the department found that all five physicians are compliant with state licensure and have no enforcement actions on their licenses.

DaVita provided a listing of credentialed staff, which includes: five physicians, one certified dietician, ten certified hemodialysis technicians, one social worker, one licensed nurse, and seven 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 staff associated with the 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 expansion of this dialysis center would not have a negative effect on DaVita's compliance.

Based on the information above, DaVita demonstrated that this expansion would be in conformance with the applicable state licensing requirements; and that it would likely continue to meet conditions of participation required by Medicaid and Medicare. 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.

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

DaVita, Inc.

DaVita provided the following statements in response to this sub-criterion. [source: Application, pp29-30]

“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 19 includes an example of DaVita's Physician, Community and Patient Services offered through DaVita's Kidney Smart Education Program. Appendix 12 includes a copy of the transfer

agreement between DaVita Vancouver Dialysis Center and an area care 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

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 Clark County for Vancouver Dialysis Center. Additionally, DaVita's project would promote continuity in the provision of healthcare services in the Clark County ESRD planning area by increasing the number of stations at Vancouver Dialysis Center.

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 this project **meets this sub-criterion**.

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

Department Evaluation

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

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

Based on the source information reviewed and agreement to the conditions identified in the conclusion section of this evaluation, the department concludes that the 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. Under WAC 246-310-818(11) this step does not to apply Special Circumstance applications.

Step One

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

Step Two

For this sub-criterion, DaVita discussed the options of doing nothing or adding stations through this special circumstance application, below is DaVita's discussion. [source: Application p31]

“Alternative 1: Do nothing, that is do not apply for two additional special circumstances stations in Clark County to expand Vancouver Dialysis Center. Currently, DaVita Vancouver Dialysis Center is a very busy facility, with utilization of over 5.0 patients per station in the most recent six months, and thus has little additional capacity to provide access to Clark County patients. With strong and consistent demand for access to DaVita's services and without expansion, 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: Expand the Vancouver Dialysis Center by two (2) stations. The existing Vancouver facility is operating in excess of 5.0 patients per station. An expansion of two (2) stations under special circumstances review can be completed quickly and cost-efficiently but, most importantly, will provide crucial access for patients. Additionally, DaVita Vancouver is a 5-Star rated facility by CMS that has the benefit of a proven track record in operational effectiveness and clinical excellence. This alternative was selected.”

Department Evaluation

DaVita provided a comprehensive discussion of why adding stations in this planning area is the appropriate alternative. Specifically, Vancouver Dialysis Center is a 13-station facility and highly utilized in the Clark County planning area. For this reason, DaVita did not consider any other options than to add dialysis station capacity.

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

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

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

Department Evaluation

For special circumstance applications, this sub-criterion is evaluated in conjunction with WAC 246-310-220(2) above and is considered met.

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

DaVita, Inc.

DaVita provided the following response for this sub-criterion. [source: Application, p31]

“DaVita Vancouver Dialysis Center will meet all current energy conservation standards. In addition, expansion will allow full use of the expanded facility designed to meet current energy utilization requirements. DaVita is also pursuing renovation of existing lighting systems nationwide and installing energy-efficient LED lighting in all facilities.”

Department Evaluation

DaVita’s project does not require construction; however, the additional stations have the potential to improve delivery of dialysis services to the residents of the Clark County ESRD planning area. Consistent with the special circumstance rules, DaVita projects to be operating the additional stations within six months of approval. **This sub-criterion is met.**