

May 22, 2025

Susie Litts – Director, Special Projects
DaVita Inc. – North Star Division Office
Sent via email only: susie.litts@davita.com

RE: Certificate of Need Application #25-12 – Department's Evaluation

Susie Litts:

We have completed the review of the Certificate of Need application submitted by Total Renal Care, Inc., a subsidiary of DaVita Inc. The application proposes to add five dialysis stations to its existing kidney dialysis center, DaVita Federal Way located within the King County 5 ESRD Planning Area. Attached is a written evaluation of the application.

For the reasons stated in the attached 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 five dialysis stations to DaVita Federal Way Community Dialysis, resulting in a facility total of twenty-four (24) dialysis stations. The facility will remain at its current location in Federal Way and will continue to provide the following services: in-center hemodialysis, hemodialysis for visitors, an isolation dialysis station, a permanent bed station, and treatment shifts beginning after 5:00 p.m.

The post-project breakdown of dialysis stations is shown below:

| Station Type | CMS Certified Stations | Stations Counted for Station Use and Methodology |
|--------------------------------|------------------------------|--|
| General Use In-Center Stations | 22 | 22 |
| Permanent Bed Station | 1 | 1 |
| Exempt Isolation Station | 1 | 0 |
| Total Stations | 24 | 23 |

Susie Litts – Director, Special Projects Certificate of Need Application #25-12 May 22, 2025 Page 2 of 2

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 which requires a new Certificate of Need.
- 2. DaVita, Inc. shall finance this project using existing cash reserves, as described in the application.

Approved Costs:

The approved capital expenditure for this project is \$163,360. This includes costs for building construction, fixed and movable equipment, architectural and engineering services, site supervision and inspection, and applicable sales tax. All expenses will be paid from DaVita's cash 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 with information about your appeal rights.

Email your response to the Certificate of Need Program at <u>CN@doh.wa.gov</u>. 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

2024 CYCLE TWO NONSPECIAL CIRCUMSTANCE EVALUATION DATED MAY 22, 2025, FOR THE CERTIFICATE OF NEED APPLICATION SUBMITTED BY TOTAL RENAL CARE INC., A SUBSIDIARY OF DAVITA, INC. PROPOSING TO ADD FIVE DIALYSIS STATIONS TO THE KING COUNTY 5 KIDNEY DIALYSIS PLANNING AREA.

APPLICANT DESCRIPTION

Total Renal Care, Inc., a wholly owned subsidiary of DaVita Inc. (DaVita), is the applicant for this project. DaVita is a publicly held, for-profit Delaware corporation. DaVita is an international provider of dialysis services with corporate offices at 2000 16th Street, in Denver, Colorado [80202]. As of the end of 2023, DaVita operated 2,675 outpatient dialysis centers across 46 states and the District of Columbia.² In Washington State, as of November 1, 2024, DaVita owns and operates forty-seven (47) Certificate of Need (CN)-approved dialysis facilities and four (4) Home-only dialysis centers. DaVita is governed by its Board of Directors, which meets quarterly. [sources: Application, pp3-6; and Washington State Secretary of State website]

PROJECT DESCRIPTION

This project proposes the expansion of DaVita Federal Way Community Dialysis (DaVita Federal Way), located at 1015 South 348th Street, Federal Way, Washington [98003], within the King County 5 ESRD Planning Area (King 5). DaVita Federal Way was most recently approved by CN on December 11, 2018, for the addition of two dialysis stations.³

Currently, DaVita Federal Way has seventeen general use in-center dialysis stations, one permanent bed station, and one exempt isolation station. A breakdown of the current number of stations is shown in the following table. [sources: Application, p11; and CN #1755]

| Station Type | CMS Certified Stations | Stations Counted for Station Use and Methodology | |
|---------------------------------------|---------------------------|--|--|
| General Use In-Center Stations | 17 | 17 | |
| Permanent Bed Station | 1 | 1 | |
| Exempt Isolation Station ⁴ | 1 | 0 | |
| Total Stations | 19 | 18 | |

Adding five dialysis stations to the facility, results in a total of twenty-two (22) in-center dialysis stations, one (1) permanent bed station, and one (1) exempt isolation station. The facility will remain at its current location and continue to offer the following services: [source: Application, p10]

DaVita Federal Way will provide services for:

- Hemodialysis patients who dialyze in the chronic setting, including those requiring isolation, requiring a permanent bed, or requiring treatment shifts that begin after 5:00 PM
- Peritoneal dialysis training

¹ Total Renal Care, Inc.'s unified business identifier is 601-134-681.

² 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.

³ Certificate of Need #1755

⁴ Defined under WAC 246-310-800(9)

Additional services provided include:

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

If approved, the additional stations are expected to be operational by December 31, 2025, or within six months⁵ of an uncontested CN issuance. [source: Application, p10] DaVita's estimated capital expenditure for this project is \$163,360. These costs include construction, equipment (fixed and movable), architectural and engineering fees, site supervision and inspection, and applicable sales tax. All capital expenses will be paid from DaVita's cash reserves. [source: Application, p19]

For ease of reference in this evaluation the following identifiers will be used:

- King 5: King County 5 ESRD Planning Area
- *DaVita*: The applicant
- DaVita Federal Way: The dialysis facility associated with this application

APPLICABILITY OF CERTIFICATE OF NEED LAW

DaVita's application proposes to add five dialysis stations to an existing dialysis center. This application is subject to Certificate of Need review as an increase in the number of dialysis stations in a kidney disease treatment center under 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 any 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).

Additionally, DaVita must demonstrate compliance with the kidney disease treatment center requirements specified in WAC 246-310-800 through -833. The following criteria do not apply to applications submitted under WAC 246-310-806 (Nonspecial Circumstance), and therefore are not addressed 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 246-310-833: One-time state border kidney dialysis facility station relocation

WAC 246-310-803

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WAC 246-310-803 requires applicants to submit specific data elements to the Certificate of Need Program. For the 2024 concurrent review cycle, this data was due by February 15, 2024. The applicant submitted the required data elements on time.

⁵ This timeline assumes a CN decision on June 1, 2025, and that the resulting certificate is not contested.

TYPE OF REVIEW

As outlined in WAC 246-310-806, the department accepted this application under the Kidney Disease Treatment Facilities—Nonspecial Circumstances Concurrent Review Cycle #2 for calendar year 2024. In accordance with WAC 246-310-806(8), the department converted the review to a regular review timeline. A chronological summary of the application's review follows below.

APPLICATION CHRONOLOGY

| Action | DaVita |
|---|-------------------|
| Letter of Intent Submitted | October 31, 2024 |
| Application Submitted | December 2, 2024 |
| Department's Pre-review Activities including | |
| DOH First Screening Letter | December 19, 2024 |
| Applicant's Screening Response Received | February 3, 2025 |
| Beginning of Review | February 17, 2025 |
| End of Public Comment Public comments accepted through the end of public comment No public hearing requested or conducted | March 24, 2025 |
| Rebuttal Comments Deadline ⁶ | April 7, 2025 |
| Department's Anticipated Decision Date | May 22, 2025 |
| Department's Actual Decision Date | May 22, 2025 |

AFFECTED PERSONS

Affected persons are defined under WAC 246-310-010(2). To qualify as an affected person, an individual or entity must first meet the definition of an *interested person* under WAC 246-310-010(34). During the review of this application, two entities requested interested person status. Their eligibility as affected persons is addressed below.

Health Facilities Planning & Development (HFPD)

HFPD is a healthcare consulting firm in the Pacific Northwest, offering planning and strategic advisory services. On February 17, 2025, HFPD submitted a request for interested person status. HFPD did not provide comments on this application and therefore does not qualify as an affected person.

Health Trends

Health Trends, based in Seattle, provides economic and analytical services to healthcare organizations and has operated for over twenty years. The organization submitted a request for interested person status on December 17, 2024. Health Trends does not meet the criteria for interested person status and, therefore, cannot be considered an affected person.

PUBLIC COMMENT AND REBUTTAL

No public comment was received for this application. As a result, the applicant was not eligible to submit rebuttal comments. This statement will not be repeated elsewhere in the evaluation.

SOURCE INFORMATION REVIEWED

- DaVita, Inc.'s Certificate of Need application received December 2, 2024
- DaVita, Inc.'s first screening responses received February 3, 2025

⁶ No public comments were received for this project, as a result, no rebuttal comments were submitted.

- 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 King County 5 ESRD planning area posted to its website in April of 2024
- Licensing data provided by the Medical Quality Assurance Commission, Nursing Quality Assurance Commission, and Health Systems Quality Assurance Office of Customer Service
- Quality and survey information found on qcor.cms.gov/, last updated on May 11, 2025
- 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

CONCLUSION

For the reasons stated in this evaluation, the application submitted by DaVita Inc., proposing to add five dialysis stations to the DaVita Federal Way Community Dialysis Center in the King County 5 ESRD Planning Area, is consistent with the applicable criteria of the Certificate of Need Program, provided the applicant agrees to the following in its entirety.

Project Description:

This certificate approves the addition of five dialysis stations to DaVita Federal Way Community Dialysis, resulting in a facility total of twenty-four (24) dialysis stations. The facility will remain at its current location in Federal Way and will continue to provide the following services: in-center hemodialysis, hemodialysis for visitors, an isolation dialysis station, a permanent bed station, and treatment shifts beginning after 5:00 p.m.

The post-project breakdown of dialysis stations is shown below:

| Station Type | CMS Certified Stations | Stations Counted for Station Use and Methodology |
|--------------------------------|------------------------------|--|
| General Use In-Center Stations | 22 | 22 |
| Permanent Bed Station | 1 | 1 |
| Exempt Isolation Station | 1 | 0 |
| Total Stations | 24 | 23 |

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 which requires a new Certificate of Need.
- 2. DaVita, Inc. shall finance this project using existing cash reserves, as described in the application.

Approved Costs:

The approved capital expenditure for this project is \$163,360. This includes costs for building construction, fixed and movable equipment, architectural and engineering services, site supervision and inspection, and applicable sales tax. All expenses will be paid from DaVita's cash reserves.

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 DaVita's project meets the need criteria outlined in WAC 246-310-210. This includes compliance with the kidney disease treatment facility requirements found 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.

Under WAC 246-310-812, kidney disease treatment center applications are evaluated for population-based need and to determine whether existing services and facilities are or will be sufficient and accessible, as required by WAC 246-310-210. The kidney disease treatment center specific numeric methodology used in this determination is outlined in WAC 246-310-812(4), with additional standards provided under 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.⁷

The first step in the methodology is to determine whether linear or exponential regression should be used to project resident in-center station need. This determination is based on the annual growth rate of the dialysis patient population in the planning area over the most recent six-year period. Exponential regression is applied when the area has experienced a growth rate of 6% or more in each of the last five years. If the growth rate is less than 6% in any of those five years, linear regression is used instead. [WAC 246-310-812(4)(a)]

Next, the projected number of stations is calculated using patient projections 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)]

Under WAC 246-310-812(5), the number of projected patients is generally divided by 4.8 to determine the number of dialysis stations needed in a planning area. However, for the counties: Adams, Columbia, Douglas, Ferry, Garfield, Jefferson, Kittitas, Klickitat, Lincoln, Okanogan, Pacific, Pend Oreille, San Juan, Skamania, Stevens, and Wahkiakum, the divisor is 3.2 due to their rural or low-population characteristics. In all cases, the number of projected stations is rounded up to the nearest whole number.

Finally, to determine net need, the number of existing CN-approved stations is subtracted from the projected station need. [WAC 246-310-812(4)(d)] The department calculates the numeric methodology

⁷ 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]

⁸ 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.

for each of the 57 planning areas and posts the results to its website. Below is the discussion of the applicant's numeric methodology.

DaVita, Inc.

DaVita proposes to expand DaVita Federal Way by adding five stations, for a facility total of twentyfour dialysis stations, a count which includes one permanent bed station and one exempt isolation station. DaVita Federal Way will continue to be located in the King 5 planning area. DaVita relied on the numeric methodology posted to the department's website for the planning area which calculates need for five stations in projection year 2028. [source: Application pp14-15]

Department Evaluation of the Numeric Methodology for the King County 5 ESRD Planning Area

The department calculates and publishes numeric methodology results annually for each of the 57 ESRD planning areas. The 2024 methodology was published in April 2024. Based on the area's annual growth rate, the department applied linear regression for the King 5 planning area. The resulting projected patient count was divided by 4.8, per WAC 246-310-812(5).

DaVita Federal Way is one of three dialysis facilities currently operating in the King 5 planning area. Table 1 below summarizes the CN-approved stations in King 5:

Department's Table 1 King County 5 Planning Area Current Station Supply

| Facility | Approved Stations |
|-------------------------------------|--------------------------|
| DaVita Federal Way | 18 |
| DaVita Redondo Heights ⁹ | 18 |
| NKC Federal Way ¹⁰ | 8 |
| Total | 44 |

Based on the department's analysis, 49 dialysis stations will be needed in the King 5 planning area by 2028. The methodology used to determine this need is included in this evaluation as **Appendix A**. As shown in Table 2 below, subtracting the 44 currently approved stations from the projected need results in a net need of five stations by projection year 2025.

Department's Table 2 King County 5 Planning Area Numeric Methodology Summary

| 4.8 in-center patients per station | | | | | |
|--|--------------|---|--|--|--|
| 2028 Projected Minus Current 2025 Net Need | | | | | |
| # of stations | or (Surplus) | | | | |
| 49 | 44 | 5 | | | |

The department concludes DaVita meets the numeric methodology standard.

In addition to meeting numeric need, the department must determine whether existing facilities are sufficiently available or accessible to meet projected demand. 11 The department uses the standards in WAC 246-310-812(5) and WAC 246-310-812(6).

⁹ CN1933

¹⁰ CN1902

¹¹ WAC 246-310-210(1)(b).

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 incenter 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 King 5 planning area, WAC 246-310-812(5) requires all CN approved stations 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.

Three dialysis facilities currently operate in the King 5 planning area. DaVita submitted a utilization table (Table 5) in its application, which is shown below. [source: Application, p14]

| Approxim s Twee | | | | | | | | |
|---|-----------|----------------------|----------------|----------------------------|-----------------------------------|---------------------|------------------------------------|--|
| Table 5 | Quarterly | y Utilization | of Existin | Eligibility Criteria | | | | |
| | | | NWRN 6/30/2024 | | Standard Met? | | | |
| Existing Dialysis Facilities in King 5 | Provider | Approved Stations | Patients | Patients per station | 4.5 patients per station | Operating 3+ years? | Missed Operational Timeline? | |
| DVA FEDERAL WAY 502513 | DVA | 18 | 104 | 5.78 | Y | Y | - | |
| DVA REDONDO HTS Fed Wy 502585 | DVA | 18 | 71 | 3.94 | N | N | Υ | |
| NKC FEDERAL WAY WEST 502594 | NKC | 8 | 43 | 5.38 | Y | Υ | - | |

Applicant's Table

Department Evaluation

WAC 246-310-812(5) requires that data used to assess utilization be drawn from the most recent quarterly modality report issued by the Northwest Renal Network as of the letter of intent submission date. For this application, the letter of intent was submitted on October 31, 2024. Accordingly, the department used data from the second quarter, ending June 30, 2024, which was published on August 15, 2024.

As previously stated, there are three existing facilities operating in King 5. Documentation provided in the June 30, 2024, modality report is consistent with the facility utilization presented by DaVita in their Table 5, shown above.

Based on the information above, the department concludes that DaVita Federal Way meets the utilization standards in WAC 246-310-812(5). **This sub-criterion is met.**

[&]quot;Per Table 5, King 5 is open for applications under the eligibility criteria for this planning area."

(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 reviews an applicant's admission policies, its willingness to serve Medicare and Medicaid patients, and its approach to providing care for individuals unable 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 state that patients will be admitted without regard to race, ethnicity, national origin, age, sex, pre-existing conditions, or physical or mental status.

Medicare certification is used as an indicator of the applicant's willingness to serve elderly patients. While Medicare primarily covers individuals aged 65 and older, it also includes coverage for patients of any age with permanent kidney failure. Similarly, Medicaid certification reflects an applicant's willingness to serve low-income individuals and may include those with disabilities.

A facility's charity care policy should demonstrate its commitment to serving patients who have exhausted all third-party coverage options, such as Medicare or Medicaid, and whose income does not allow them to pay for care, including required deductibles or coinsurance.¹² The policy should also include the process patients must use to access charity care at the facility.

DaVita, Inc.

DaVita provided the following information for this sub-criterion. [source: 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."

DaVita also provided the following policies and procedures for this facility. [source: Application, Appendix 14]

- Accepting End State Renal Disease Patients for Treatment (Admissions Policy)
- Revenue Operations (ROPS) Policy & Procedure (Charity Care Policy)
- Non-Payment Discharge Policy (Involuntary or Voluntary Financial Discharge Policy)
- Patient Rights and Patient's Standards of Conduct, Responsibilities, And Facility Rules
- Patient Behavior Agreements, 30 Day Discharge, Involuntary Discharge or Involuntary Transfer

Medicare and Medicaid Programs

All DaVita dialysis centers are Medicare and Medicaid certified. DaVita indicated that DaVita Federal Way is currently certified under both Medicare and Medicaid and will maintain this certification following project implementation. The facility's provider numbers are:

Medicare Provider Number: 502513 Medicaid Provider Number: 3016128

In support of its ongoing commitment to serve these populations, DaVita based its projected payer mix on historical facility data and current revenue figures by payer. DaVita stated that "[p]ayer mix percentages are not expected to change as a result of this project." [source: Application, p20]

¹² WAC 246-453-010(4).

Applicant's Table

| Table 11 Federal Way +5 Expansion Historical & Projected Payer Mix | Percentage by Revenue | Percentage by Patient | |
|--|--------------------------|--------------------------|--|
| Medicare | 45.28% | 58.27% | |
| Medicaid | 9.68% | 14.26% | |
| Commercial, Other Government, and Other | 45.04% | 27.47% | |
| Total | 100.00% | 100.00% | |

Department Evaluation

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, disability, or payor class..." [source: Application, Appendix 14]

DaVita also provided a policy titled "Revenue Operations (ROPS) Policy & Procedure." The stated purpose of this policy is to "establish policies and procedures for the individualized determination of patient financial need for uninsured patients for services provided by DaVita." This policy includes guidance on how patients may access charity care at DaVita Federal Way. Additionally, DaVita demonstrated its intent to provide charity care by including a "Charitable Care" line item as a deduction from revenue in the facility's pro forma income statement. [source: Application, Appendix 9]

DaVita provided copies of the necessary policies used at all DaVita dialysis centers, which includes DaVita Federal Way. These policies reflect DaVita's commitment to provide adequate access to all residents of the service area. These documents reflect DaVita's continued commitment to ensuring adequate access to all residents of the service area, including underserved populations. The department has reviewed and approved these policies in prior applications and finds them consistent with regulatory expectations. 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) <u>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.</u>
- (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 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(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

DaVita, Inc.

As previously stated, DaVita Federal Way is currently operational, and the additional five stations are expected to be operational by December 31, 2025. [source: Application, p10] calendar year 2026 represents the first full year of operation post-expansion, and calendar year 2028 is the third full year.

Upon completion, DaVita Federal Way will operate 24 stations in total, including 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: Application, Appendix 9]

- *First Full Year:* 2026, based on a first full month in January 2026 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 considered 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 2028), 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 facility census.

Using the assumptions stated above, DaVita projected the number of in-center dialyses and patients for DaVita Federal Way for partial year 2025 and full years 2026-2028. The projections are summarized in the table below. [source: February 3, 20205, screening response, p12]

Applicant's Table

| | Forecast 2025 | Full Year 2026 | Full Year 2027 | Full Year 2028 |
|---|----------------------|-------------------|-------------------|---------------------|
| Total Stations (end of the year - excludes CON-exempt iso st | 18 | 23 | 23 | 23 |
| Total Shifts | 6 | 6 | 6 | 6 |
| Total Chronic Capacity (end of period) | 108 | 138 | 138 | 138 |
| Total Chronic Patients (end of the period) **X of Capacity** | 113 <i>104.6%</i> | 117 84.8% | 121 87.7% | 125 <i>30.6%</i> |
| Average Annual Chronic Patients (avg of beginning & end of | 111.5 | 115.0 | 119.0 | 123.0 |
| Total Chronic Treatments | 16,524 | 17,043 | 17,636 | 18,229 |
| Total Home Patients (end of the period) | 22 | 23 | 24 | 25 |
| Average Annual Home Patients (avg of beginning & end of p | 22.0 | 22.5 | 23.5 | 24.5 |
| Total Home Treatments | 3,260 | 3,335 | 3,483 | 3,631 |
| Total Patients (avg of beginning & end of period) | 133.5 | 137.5 | 142.5 | 147.5 |
| Total Treatments | 19,785 | 20,378 | 21,119 | 21,860 |

DaVita, Inc. provided assumptions for its projected financial statements, which are restated below. [source: Application, Appendix 9]

- Charity Care: estimated at 1.3% of gross revenue, consistent with DaVita's historical experience.
- **Bad Debt:** estimated at 4% of gross revenue, consistent with DaVita's historical experience.
- **Total Treatments:** Total Treatment Volume is 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 (2023) 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: FY26-27 based on contracted, known expenses in latest medical director agreement that runs through 11/30/2027. The proforma assumes both parties agree to the automatic renewal at the current compensation rate.
- Lease Expense: Base rent for the forecast period through month 1 of the projection period (January 2026) is calculated using section 2 of the first lease agreement. Base rent for month 2 through the end of the projection period (February 2026 December 2028) are per section 2 of the second amendment to the lease agreement. Tax and CAM are estimated at \$67,860 based on FY23 expenses.
- 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 37.95% of base salaries and wages based on 2023 data for the facility. No inflation is assumed.

DaVita, Inc. also provided a copy of the lease along with first and second amendments to the lease agreement for DaVita Federal Way. The second amendment of the lease agreement extends the term of the lease through January 31, 2031, and provides an extended rent schedule though the same timeframe. The agreement includes the base rent and associated additional expenses. [source: Application, Appendix 15]

Based on the assumptions and clarifications above, DaVita, Inc. provided projected revenue, expenses, and net income for partial year 2025 and full years 2026 through 2028, summarized below. [source: February 3, 20205, screening response, p12]

Department's Table 3
DaVita Federal Way Dialysis Center
Projected Revenue and Expense Summary for Years 2025 – 2028

| | CY 2025 | CY 2026 | CY 2027 | CY 2028 |
|--------------------------------------|-------------|-------------|-------------|-------------|
| | Pre-Project | Full Year 1 | Full Year 2 | Full Year 3 |
| Total Number of Operational Stations | 18 | 23 | 23 | 23 |
| Net Revenue | \$8,670,187 | \$8,929,968 | \$9,254,694 | \$9,579,420 |
| Total Expenses | 5,700,255 | \$5,893,389 | \$6,080,872 | \$6,267,615 |
| Net Profit / Loss | 2,969,932 | \$3,036,579 | \$3,173,822 | \$3,311,806 |

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

"Net Revenue" is calculated as gross patient revenue minus estimated deductions for charity care and bad debt. "Total Expenses" includes all operating and non-operating costs described in the financial assumptions. Medical Director compensation and lease costs provided are consistent with the supporting agreements. [source: Application, Appendix 3 and Appendix 15]

Department Evaluation

WAC 246-310-827(3)(a) requires an applicant proposing to expand an existing facility to base its revenue and expense projections on its two closest facilities. DaVita identified those facilities as DaVita Redondo Heights and DaVita Tacoma. ¹³ DaVita projects that revenues will cover expenses at DaVita Federal Way through the third full year of the proposed project. DaVita's approach for this project meets the requirements.

¹³ DaVita also notes that "DaVita Auburn Valley is closer than DaVita Tacoma, however per WAC 246-310-827(3)(d), is not considered comparable due to lack of complete Medicare data and has been granted an exemption."

DaVita provided evidence of site control through executed lease documents and documented the associated lease costs in its financial statements. The Medical Director agreement, executed with Pacific Nephrology Associates, P.S., began December 1, 2017, and includes an initial 10-year term with annual automatic renewals. Four physicians are named in the agreement, and DaVita clarified that Yajuan He, MD currently serves as medical director for DaVita Federal Way. Compensation for medical director services, as reflected in the pro forma, aligns with the contract terms.

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 financial feasibility requirements for kidney dialysis facility 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 <u>246-310-800(11)</u> 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.

DaVita estimates a total capital expenditure of \$163,360 for the expansion of DaVita Federal Way. A breakdown of the proposed costs is provided below. [source: Application, p19]

Department's Table 4
DaVita Federal Way Estimated Capital Costs

| Item | Total |
|--|-----------|
| Building Construction | \$12,500 |
| Fixed Equipment | \$2,250 |
| Moveable Equipment | \$121,230 |
| Architect and Engineering Fees | \$5,000 |
| Supervision and inspection of Site | \$8,000 |
| Washington Sales Tax | \$14,380 |
| Total Estimated Capital Expenditure | \$163,360 |

In screening, DaVita clarified that construction costs include finalizing plumbing for the new dialysis stations. [source: February 3, 2025, screening response, p2]

Specific to the project's impact on costs and charges for health services, DaVita provided the following statements. [source: Application, pp19-20]

"The 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 Federal Way Community Dialysis Center's current payor mix and expenses. All major pro forma assumptions are also outlined in Appendix 9.

As reimbursement for dialysis services is 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 increase patient access."

"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."

In accordance with WAC 246-310-815(2), DaVita also provided a comparison of the proposed treatment floor area to the maximum allowed by WAC 246-310-800(11). [source: Application, p12]

Department Evaluation

The total capital cost for expanding DaVita Federal Way is \$163,360. This cost is consistent with those of similar dialysis station expansion projects reviewed and approved by the department. The department does not find the expenditure to be excessive.

Documentation provided in the application shows that Medicare and Medicaid are projected to account for 54.96% of total revenue and 72.53% of patients at DaVita Federal Way. These figures are within the range previously reviewed and approved by the department in past DaVita applications and reflect a reasonable payer mix for a dialysis facility.

The department notes that Medicare and Medicaid typically represent the largest share of dialysis patients nationwide. Under the Centers for Medicare & Medicaid Services (CMS) End-Stage Renal Disease (ESRD) Prospective Payment System (PPS), dialysis facilities receive a bundled payment per treatment. While base rates may be similar within a geographic region, adjustments are made at both the facility and patient level, meaning reimbursement can vary depending on specific characteristics. Additionally, commercial payer reimbursements differ based on provider-specific negotiated rates.

Given this reimbursement structure, the department does not apply a fixed standard for determining whether a project has an "unreasonable impact" on costs. However, based on DaVita's projected revenue and payer mix, the department concludes that the proposed expansion is not likely to cause an unreasonable increase in healthcare costs or charges within the planning area.

To demonstrate compliance with WAC 246-310-800(11), DaVita provided a table showing DaVita Federal Way's allowable maximum treatment floor area square footage for a 22-station facility, with space for one future station is 6,738. DaVita's project will use 3,708 square feet. Therefore, 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 the costs associated with the proposed five-station expansion of DaVita Federal Way are reasonable and unlikely to have an unreasonable impact on the costs and charges for health services in King 5. **This subcriterion is met.**

(3) The project can be appropriately financed.

Chapter 246-310 WAC does not establish specific financing requirements for dialysis projects under WAC 246-310-200(2)(a)(i). Additionally, there are no known recognized standards under WAC 246-310-200(2)(a)(ii) or (b) that prescribe how a project of this scope and size should be financed. Therefore, the department applied its experience and expertise to evaluate whether the proposed financing method is consistent with similar projects previously reviewed.

DaVita, Inc.

DaVita identified a capital expenditure of \$163,360 for the expansion of DaVita Federal Way. The project will be financed using DaVita's corporate reserves. To demonstrate financial capacity and commitment, DaVita submitted a letter from its Chief Operating Officer, Michael Staffieri, affirming operational and financial support for the project. [source: Application, p19 and Appendix 6]

DaVita also submitted audited financial statements for fiscal years 2021, 2022, and 2023 to demonstrate the availability of sufficient financial reserves to fund the project. [source: Application, Appendix 10]

Department Evaluation

DaVita intends to finance the project with its 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 project **meets** the structure and process of care criteria in WAC 246-310-230.

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

Chapter 246-310 WAC does not provide specific criteria for evaluating staffing levels under WAC 246-310-230(1), nor are there recognized standards under WAC 246-310-200(2)(a)(ii) or (b) that define the appropriate number or types of full-time equivalent (FTE) staff for a project of this size and scope. Therefore, the department relied on its experience and expertise to determine whether the applicant's proposed staffing is sufficient to meet expected service needs.

DaVita, Inc.

DaVita anticipates the expanded DaVita Federal Way facility will be operational by December 31, 2025, making 2026 the first full year of operation and 2028 the third. DaVita submitted a table showing historical FTE staffing from 2021 to 2023 and projected staffing through 2028. [source: February 9, 2022, screening response, p4]

Department's Table 5
DaVita Federal Way - Historical, Current, and Projected FTEs

| | Historical | | Forecast | | Projected | | | |
|-----------------|------------|------|----------|------|-----------|------|------|------|
| FTE by Type | 2021 | 2022 | 2023 | 2024 | 2025 | 2026 | 2027 | 2028 |
| Administrator | 0.94 | 0.93 | 1.8 | 1.59 | 1.67 | 1.72 | 1.78 | 1.84 |
| Admin Assistant | 0.94 | 0.88 | 0.96 | 1.16 | 1.21 | 1.25 | 1.3 | 1.34 |
| Social Worker | 1 | 0.93 | 0.81 | 1.06 | 1.11 | 1.15 | 1.19 | 1.23 |
| Dietician | 1.04 | 0.8 | 0.81 | 1.06 | 1.11 | 1.15 | 1.19 | 1.23 |

| | Historical | | | Forecast | | Projected | | |
|--------------|------------|-------|-------|----------|-------|-----------|-------|-------|
| FTE by Type | 2021 | 2022 | 2023 | 2024 | 2025 | 2026 | 2027 | 2028 |
| RN In-Center | 4.2 | 4.15 | 4.32 | 4.32 | 4.53 | 4.67 | 4.83 | 4.99 |
| PCT | 9.07 | 9.6 | 9.49 | 9.49 | 9.94 | 10.25 | 10.6 | 10.96 |
| RN - PD | 0.92 | 1.04 | 0.96 | 1.17 | 1.22 | 1.25 | 1.31 | 1.36 |
| Biomed | 0.56 | 0.46 | 0.51 | 0.48 | 0.48 | 0.6 | 0.6 | 0.6 |
| Other | 0.89 | 1.35 | 1.31 | 1.31 | 1.31 | 1.31 | 1.31 | 1.31 |
| Total | 19.56 | 20.14 | 20.97 | 21.64 | 22.58 | 23.35 | 24.11 | 24.86 |

The medical director is under contract and not included in the table above. [source: Application p22 and Appendix 10]

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, p22]

"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 anemia and inventory management, and new and existing teammate training hours.

FY21-FY23 are actual historical hours, divided by 2080 hours per year to convert to FTE. These are annual averages and will fluctuate during a given year. All other years are developed using FY23 actuals and staffing ratios. Biomed hours relate directly to the number of stations at a facility, so they are relatively stable even as census goes up slightly between FY21-FY23 and increase in FY26 due to the opening of additional stations."

DaVita also provided the following statements related to staff recruitment and retention. [source: Application p23]

"DaVita anticipates the existing staff will continue to operate DaVita Federal Way Community Dialysis. Additionally, based on our experience operating facilities in the planning area, DaVita anticipates that staff from the existing and geographically adjacent facilities will be adequate to serve patients at the expanded clinic when coverage needs require. DaVita uses a community scheduling model which creates a forum to share staffing resources and visibility into needs across a geographic area, thereby improving visibility to available resources for coverage. If that were not enough, DaVita can and would also call upon float teams (dedicated internal teammates or teammates from other areas) or externally contracted resources to travel to the clinic to provide coverage.

While new staff will be required as census grows, DaVita has been repeatedly recognized as a Top Employer and a Military Friendly Employer and offers a competitive wage and benefit package to attract and retain employees. DaVita has recruiters dedicated to recruitment in this geography and posts openings nationally, both internally and external to DaVita. DaVita has also implemented internal referral bonuses for key team members to aid with recruitment. Additionally, DaVita has increased its commitment to international nurse recruitment and sponsorship. Nurses sponsored from abroad have recently started with DaVita and are serving patients in Washington state."

"A Community First and a Company Second", DaVita is committed to providing teammates and families benefits that help connect to what matters most. DaVita offers a wide range of programs and

support to help provide for teammates and their families as well as providing training programs for career growth and advancement. These programs include things such as formal compensation plans which compensate based on skills and responsibilities, new teammate training, tuition reimbursement and assistance programs, and leadership development programs."

When asked how DaVita would respond to unexpected staff shortages, they provided the following statement: [source: February 3, 2025, screening response, pp3-4]

"DaVita anticipates that staff from the existing and geographically adjacent facilities will continue to be adequate to serve patients at the expanded clinic when coverage needs require. DaVita uses a community scheduling model which creates a forum to share staffing resources and visibility into needs across a geographic area, thereby improving visibility to available resources for coverage. If that were not enough, DaVita can and would also call upon float teams (dedicated internal teammates or teammates from other areas) or externally contracted resources to travel to the clinic to provide coverage."

Department Evaluation

DaVita is an established provider of dialysis services in Washington State and is proposing to expand an existing, operational facility. The proposed staffing increase is modest, rising from 22.58 FTEs in 2025 to 24.86 FTEs by 2028, an overall addition of 2.28 FTEs over three years. DaVita intends to rely on its recruitment and retention effort that have proven successful in the past. The department finds the staffing plan to be appropriate and achievable.

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) <u>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.</u>

Chapter 246-310 WAC does not provide specific evaluation criteria under WAC 246-310-230(2), nor are there recognized standards identified under WAC 246-310-200(2)(a)(ii) or (b) that define the appropriate relationships or level of ancillary and support services for a project of this size and type. Therefore, the department assessed the materials submitted in the application using its experience and expertise.

DaVita, Inc.

DaVita currently provides dialysis services at DaVita Federal Way in the King 5 planning area. If this project is approved, DaVita Federal Way will add five in-center dialysis stations to King 5. DaVita provided the following statements regarding services that would be provided on site and those provided off site. [source: Application, p24]

"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 across the country including in Federal Way, Washington. 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 other high-value off-site programs."

DaVita provided a listing of ancillary and support agreements already in place at DaVita Federal Way. [source: Application, Appendix 11]

Applicant's Table

| Agreement | Vendor |
|----------------------------------|--|
| Extensive Facility Maintenance | CBRE |
| Patient Transfer | St Joseph Hospital |
| Janitorial | Clean Net |
| Waste Disposal | Waste Management |
| Medical Waste Disposal | SteriCycle |
| Information Management | Iron Mountain |
| Mutual Emergency Backup Dialysis | Puyallup DaVita, Redondo Heights DaVita, Kent Davita, Auburn Valley DaVita |
| Laboratory Services | DaVita Lab Services |
| Stat Laboratory Services | Quest Dlagnostic |
| Pest Control | Terminix |

DaVita also provided a list of healthcare facilities with which DaVita Federal Way already has working relationships. [source: Application, pp24-25]

Applicant's Table

| Table 14 | |
|------------------------------------|--|
| Healthcare Facility Relationships | Type of Relationship |
| North Auburn Rehabilitation Center | Nursing Home Dialysis Transfer Agreement |
| Garden Terrace | Nursing Home Dialysis Transfer Agreement |
| Life Care Center | Nursing Home Dialysis Transfer Agreement |
| Avalon HealthCare | Nursing Home Dialysis Transfer Agreement |
| Wesley Homes | Nursing Home Dialysis Transfer Agreement |
| St Joseph Hospital | Patient Transfer |
| Virginia Mason | Transplant |
| University of WA Medical Center | Transplant |
| Swedish Medical Center | Transplant |

DaVita provided an executed Patient Transfer Agreement between itself and St. Joseph Hospital and Health Care Center, dated April 23, 1993. In the application, DaVita stated: "This agreement shall continue in effect indefinitely after the initial term, unless terminated by either party." [source: Application, p25 and Appendix 12]

DaVita also provided a copy of the Medical Director Agreement with Pacific Nephrology Associates, P.S., that was executed on December 1, 2017, with an initial term of ten years with annual automatic renewals. The agreement names Yajuan He, MD as the medical director for DaVita Federal Way and lists Di Zhao, MD, Ho Won Lee, MD, and Zheng Ge, MD as additional individuals pre-approved to serve as medical director for DaVita Federal Way.

The Medical Director Agreement identifies roles and responsibilities for both DaVita and the medical director. It also outlines annual and monthly compensation based on the programs available at DaVita

Federal Way. When asked for more information on how the salary is calculated, DaVita provided the following clarification: [source: February 3, 2025, screening response, p6]

"While the Medical Director Agreement establishes rates for all potential modalities at the location, payment is made only on active programs. The department is correct, that the amounts in table 8 total \$120,000 for all modalities. However, as the HHD program is inactive it is not modeled in the proforma and the resulting fee is \$100,000 (80K for chronic plus 20K for PD modalities)."

Department Evaluation

Since DaVita Federal Way is already operational, its ancillary and support services are established and in place. DaVita provided a list of vendors for these services and stated that the existing ancillary and support agreements are not expected to change because of this project.

DaVita submitted an executed Medical Director Agreement with Pacific Nephrology Associates, P.S., which outlines the roles and responsibilities of both parties and includes a compensation structure aligned with the active programs at the facility. The agreement is in effect and automatically renews annually.

DaVita also submitted an executed Patient Transfer Agreement between itself and St. Joseph Hospital and Health Care Center in Tacoma. While the agreement does not specify an effective date, it is dated April 23, 1993, and signed by a representative of St. Joseph Hospital. As stated in the application, this agreement will continue in effect until it is terminated.

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

(3) <u>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.</u>

Chapter 246-310 WAC does not include specific evaluation criteria under WAC 246-310-230(3), nor are there recognized standards as described in WAC 246-310-200(2)(a)(ii) or (b) that direct how a facility must demonstrate Medicare certification and Medicaid eligibility. Therefore, the department evaluated this sub-criterion using its experience and expertise, with a particular focus on the applicant's past performance at other facilities it owns or operates.

WAC 246-310-230(5) is also considered under this sub-criterion, as it pertains to a facility's compliance history. This compliance history is included in the department's determination of whether there is reasonable assurance the proposed project will operate in accordance with applicable requirements.

DaVita, Inc.

DaVita provided the following statement in response to this sub-criterion. [source: Application, p25]

"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 assesses three key areas when evaluating this sub-criterion:

1. Terminated Provider Status

The department reviewed the Centers for Medicare & Medicaid Services (CMS) Terminated Provider Counts Report for calendar years 2022 through 2024 and partial year 2025. This report identifies dialysis facilities that were involuntarily terminated from Medicare participation.

2. Compliance with Medicare and Medicaid Standards:

The department reviewed CMS Survey Activity Reports to assess a dialysis provider's conformance with Medicare and Medicaid standards, with a focus on Washington State facilities. These reports distinguish between standard-level and condition-level deficiencies: ¹⁴

- Standard-level findings involve noncompliance that does not substantially limit the facility's ability to provide adequate care, or which would not jeopardize or adversely affect the health or safety of patients if the deficient practice recurred.
- <u>Condition-level findings</u> represent serious noncompliance that may pose health or safety threats or indicate systemic issues across multiple standards. 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.

3. CMS Star Ratings

The department also reviews the CMS 'star ratings' for Washington State facilities. CMS provides the following overview regarding its star rating for dialysis centers: [source: CMS website]

"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."

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

Terminated Provider Counts Report

The department reviewed the Terminated Provider Counts Report for calendar years 2022 through present. Among all DaVita dialysis centers operating in 46 states and the District of Columbia, none were involuntarily terminated during this period.

¹⁴ Definitions of standard and condition level surveys: https://www.compass-clinical.com/deciphering-tjc-condition-level-findings/

Conformance with Medicare and Medicaid Standards

From 2022 through present, 26 of DaVita's 47 Washington State dialysis facilities were surveyed. Of those 26, six received condition-level findings. Those findings are summarized below. [source: CMS Quality, Certification, and Oversight Reports last updated May 11, 2025]

- **Tacoma Dialysis Center:** During a March 2024 standard survey, surveyors cited the facility for five condition level findings in the areas of *patient assessment, patient plan of care, quality assessment, performance and improvement, MD responsibilities,* and *governance.* The citations required plans of correction, and a follow-up visit in May 2024.
- **Pilchuck Dialysis:** During a December 2024 standard survey, surveyors cited the facility for one condition level finding in the areas of *infection control*. This citation required plans of correction, and a follow-up visit in January 2025.
- **Downtown Spokane Renal Center:** During a January 2025 standard survey, surveyors cited the facility for one condition level finding in the areas of *infection control*. This citation required plans of correction, and a follow-up visit in February 2025.
- Lake Tapps Dialysis Center: During a January 2025 standard survey, surveyors cited the facility for two condition level findings in the areas of *patient assessment* and *patient plan of care*. These citations required plans of correction, and a follow-up visit in March 2025.
- Wenatchee Dialysis Center: During a January 2025 standard survey, surveyors cited the facility for two condition level findings in the areas of water and dialysate quality and quality assessment & performance improvement. These citations required plans of correction, and a follow-up visit in March 2025.
- **Vancouver Dialysis Center:** During a January 2025 standard survey, surveyors cited the facility for two condition level findings in the areas of *infection control* and *physical environment*. The citations required plans of correction, and a follow-up visit in February 2025.

CMS Star Rating for Washington State Centers

As of the date of this evaluation, DaVita operates 47 dialysis centers in Washington State. Of those, 44 have CMS star ratings; the remaining three have not been operational long enough to be rated. The average star rating across the 44 rated facilities is 3.04. [source: CMS Dialysis Facility – Listing by Facility Report, last updated March 24, 2025]

DaVita also provided a copy of the Medical Director Agreement with Pacific Nephrology Associates, P.S., that was executed on December 1, 2017, with an initial term of ten years with annual automatic renewals. The agreement names Yajuan He, MD as the medical director for DaVita Federal Way, and lists Di Zhao, MD, Ho Won Lee, MD, and Zheng Ge, MD as additional individuals that are pre-approved to serve as the medical director for DaVita Federal Way. [source: Application, Appendix 3] The department verified the licensing status of each named physician using data from the Washington State Medical Quality Assurance Commission. All four individuals hold active licenses in good standing with no enforcement actions.

Given this is an existing facility, DaVita provided a list of current staff and their credentials. Using data from the Medical Quality Assurance Commission, the department found that each staff member listed is compliant with state licensure and have no enforcement actions on their licenses.

In review of this sub-criterion the department considered DaVita's compliance history across its Washington State facilities, the Medicare and Medicaid certification records of its operations, and the licensure status of associated medical and clinical staff. Based on this review, the department concludes that DaVita has operated in compliance with the applicable state and federal licensing and certification requirements and that there is reasonable assurance the expanded facility will continue to operate in full compliance. **This sub-criterion is met.**

(4) <u>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.</u>

Chapter 246-310 WAC does not contain specific criteria under WAC 246-310-230(4), as described in WAC 246-310-200(2)(a)(i). There are also no known recognized standards as outlined in WAC 246-310-200(2)(a)(ii) and (b) that direct how to measure unwarranted fragmentation of services or what constitutes appropriate relationships with a service area's healthcare system for a project of this type and size. Therefore, using its experience and expertise, the department assessed the materials submitted in the application.

DaVita, Inc.

DaVita provided the following statement in response to this sub-criterion. [source: Application, pp26-27]

"The proposed expansion of DaVita Federal Way Community Dialysis will have no change to the ability to provide ongoing and quality care in King 5 Planning Area and will not create an unwarranted fragmentation of services. Adding chairs to the clinic will enhance the ability to provide services to the patients in the area due to the expanded capacity and open shift times. All existing services will continue to be served as described in Section II (Project Description) of the application.

To ensure quality of care, DaVita utilizes a Continuous Quality Improvement (CQI) program incorporating 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'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 Federal Way Community Dialysis 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.

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 daily, 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 is an established provider of dialysis services in Washington State, with a demonstrated history of collaboration with other healthcare providers, including within the King County 5 planning area. The proposed project is expected to enhance continuity of care by increasing dialysis capacity at an existing facility, thereby improving patient access without disrupting current services.

The application describes the integration of a Continuous Quality Improvement (CQI) program, interdisciplinary team coordination, and established relationships with hospitals, long-term care providers, and community partners. These features support effective care transitions and mitigate the risk of service fragmentation.

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 this project **meets** 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 whether the application has met the applicable review criteria in WAC 246-310-210 through -230. If the application fails to meet any of these criteria, the project is determined not to be the best alternative and fails this sub-criterion.

Step Two applies if the project has met all applicable criteria. In this step, the department evaluates other alternatives considered by the applicant. If the proposed project is better than or equal to other

options, and no superior alternatives are identified by the department, this criterion is deemed to be met unless multiple competing applications are involved.

Step Three applies only in competitive reviews. If multiple applications are submitted, the department applies any superiority criteria identified in Chapter 246-310 WAC related to the specific project type. This step **does not apply** to the current review, as there were no other applications submitted in the King 5 planning area.

Below is a summary of the three steps reviewed for DaVita's project.

Step One

For this project, DaVita met the applicable review criteria under WAC 246-310-210, -220, and -230. Therefore, the department proceeds to Step Two.

Step Two

For this sub-criterion, DaVita discussed the options below. [source: Application pp27-28]

"Alternative 1: Do nothing. Do not apply for additional stations in the King 5 planning area.

- King 5 continues to grow in ESRD population, with a calculated need for five (5) additional 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 <u>rejected</u> as it does not improve access to care for the community.

Alternative 2a: Expand the existing Redondo Heights facility by five (5) station, or Alternative 2b: Expand the existing Federal Way facility by five (5) stations.

- Capacity: Meets the projected need for the planning area
- Speed: Either clinic can expand in the existing location with minimal infrastructure work, therefore, add these stations quickly and efficiently to increase patient access to dialysis with more shift options.
- Cost: Low cost to expand as building space is available to repurpose. Infrastructure is in place for dialysis and healthcare requirements.

This alternative was selected as the fastest to implement and lowest cost to develop and fully meet the calculated need of five (5) stations. Specifically, option 2B Federal Way was selected as 2A Redondo Heights was determined to be ineligible as it has not been in its current location for required three years.

Alternative 3: Establish a new clinic in the King 5 planning area.

3A: Clinic with five (5) plus one isolation stations

3B: Clinics with five (5) plus one isolation stations, plus transfer chairs from another clinic

- This alternative would take more time to implement and have a higher cost to develop, impacting the speed in which patients would be provided more shift options.
- Capacity: Meets the projected need for the planning area, however, existing clinics have room to expand with less cost.
- Speed: Longer time to develop as site would need to be built or built out for the infrastructure needed for dialysis and healthcare requirements
- Cost: Higher cost option due to shell and or infrastructure buildout
- *This alternative was rejected due to time and cost to implement.*

Alternative 4: Relocate and expand one of the existing clinics by five (5) stations in the King 5 planning area.

- This alternative would take more time and have a higher cost to develop, impacting the speed in which patients would be provided more care options.
- Capacity: Meets the projected need for the planning area, however, existing clinics have room to expand and are centrally located to provide local access for patients.
- Speed: Longer time to develop as site would need to be built or built out for the infrastructure needed for dialysis and healthcare requirements
- Cost: Higher cost option due to shell and or infrastructure buildout
- This alternative was <u>rejected</u> as unnecessary due to available space in existing clinics, and a longer duration and higher cost to implement.

Department Evaluation

The applicant selected Alternative 2B (the project) as the most cost-effective and timely method to meet the projected need for dialysis services in the King 5 planning area. Alternative 1 (do nothing) was rejected because it would limit access and potentially force patients to seek services outside the planning area. Alternative 3 and Alternative 4 were both rejected due to higher costs and longer implementation timelines which would delay critical patient access improvements. While Alternative 2A (expanding Redondo Heights) was considered, this option is ineligible due to not meeting the three-year location requirement.

Therefore, Alternative 2B, the project, was chosen as the most efficient, cost-effective, and immediately actionable solution.

The department concludes that the project submitted by DaVita is the best available alternative for the King County 5 planning area. **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

There is no construction associated with this proposed project. Therefore, this sub-criterion is **not applicable** to the project's evaluation.

(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, p29]

"DaVita Federal Way Community Dialysis was built to meet or exceed the energy conservation standards in place at the time of original construction. The current project does not require physical plant changes; therefore, no plant design changes are anticipated resulting from the award.

The expanded capacity will create staffing efficiencies and increase teammate satisfaction with fewer part time needs. Expanding from 18 to 23 chairs will not require hiring an additional RN as 18 and 23 chairs both require a second RN but at full vs part time shifts.

The expanded capacity will also leverage existing space, which will not require expansion of vendor services and/or cost increases for fixed cost items which may include items such as: rent, pest control and cleaning."

Department Evaluation

This project has the potential to improve delivery of dialysis services to the residents of the King 5 planning area with the addition of dialysis stations in the planning area. The department concludes that **this sub-criterion is met**

APPENDIX A 2024 ESRD NEED METHODOLOGY KING COUNTY 5 ESRD PLANNING AREA



2024 King County 5 ESRD Need Projection Methodology

| | Planning Area | 6 Year Utiliz | zation Data | - Resident | Incenter Pa | tients | |
|---|---------------------------------|---|-------------|------------|-------------|--------|--------|
| | King 5 | 2018 | 2019 | 2020 | 2021 2022 | | 2023 |
| | 98003 | 78 | 92 | 97 | 97 | 103 | 100 |
| | 98023 | 64 | 63 | 74 | 85 | 89 | 84 |
| | TOTALS | 142 | 155 | 171 | 182 | 192 | 184 |
| 246-310-812(4)(a) | Rate of Change | | 9.15% | 10.32% | 6.43% | 5.49% | -4.17% |
| · · · · · · · · · · · · · · · · · | 6% Growth or Greater? | | TRUE | TRUE | TRUE | FALSE | FALSE |
| | Regression Method: | Linear | | | | | |
| 246-310-812(4)(c) | | | Year 1 | Year 2 | Year 3 | Year 4 | Year 5 |
| . , , , | | | 2024 | 2025 | 2026 | 2027 | 2028 |
| Projected Resident Incenter Patients | from 246-310-812(4)(b) | | 200.50 | 208.40 | 216.30 | 224.20 | 232.10 |
| Station Need for | | | | | | | |
| Patients | Divide Resident Incenter by 4.8 | | 41.77 | 43.42 | 45.06 | 46.71 | 48.3 |
| | Rounded to next whole | number | 42 | 44 | 46 | 47 | 49 |
| 246-310-812(4)(d) | subtract (4)(c) from appro | ved stations | | | | | |
| Existing CN Approved S | | Total | 44 | 44 | 44 | 44 | 44 |
| Results of (4)(c) above | | 1 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 | 42 | 44 | 46 | 47 | 49 |
| Net Station Need | | | 2 | 0 | -2 | -3 | |
| Negative number indicates ne | ed for stations | | | | | | |
| Planning Area Facil | ities | | | | | | |
| Name of Center | # of Stations | | | | | | |
| DaVita Fed Way Comm | 18 | | | | | | |
| DaVita Redondo Heights | 18 | | | | | | |
| NKC Federal Way West | 8 | | | | | | |
| Total | 44 | | | | | | |
| | | | | | | | |
| | Network / Comagine ESRI | | 6 data 2018 | 3-2023 | | | |
| Most recent year-end data | a: 2023 posted 02/02/2024 | - | | | | | |



2024 King County 5 ESRD Need Projection Methodology

