



STATE OF WASHINGTON  
**DEPARTMENT OF HEALTH**  
*Olympia, Washington 98504*

February 12, 2021

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RE: Certificate of Need Application #21-18 Puget Sound Kidney Centers  
Skagit County Project

Dear Ms. Crain and Ms. Carona:

We have completed review of the Certificate of Need application submitted by Puget Sound Kidney Centers proposing to add one dialysis station to PSKC Anacortes 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 Puget Sound Kidney Centers agrees to the following in its entirety.

**Project Description:**

This certificate approves the addition of one dialysis station to the six-station PSKC Anacortes, for a facility total of seven dialysis stations. PSKC Anacortes will remain at its current location in Anacortes and continue to provide the following services: in-center hemodialysis, home hemodialysis, home peritoneal dialysis, training and support for dialysis patients, hemodialysis for visitors, an isolation dialysis station, a bed dialysis station, and shifts beginning after 5:00 pm. A breakdown of the dialysis stations after project completion is shown below.

Station Type	CMS Certified Stations	Station Counted for Station Use and Methodology
General Use In-Center Stations	5	5
Permanent Bed Station	1	1
Exempt Isolation Station	1	0
Isolation Station	0	0
<b>Total Stations</b>	<b>7</b>	<b>6</b>

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. Puget Sound Kidney Centers 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. Puget Sound Kidney Centers shall finance this project using existing capital reserves, as described in the application.
3. Puget Sound Kidney Centers shall notify the Certificate of Need Program when the medical social worker identified in this application is issued an active Washington State license.

**Approved Costs:**

The approved capital expenditure for this one-station addition is \$15, 235. This amount represents the costs for moveable equipment. All costs will be paid by Puget Sound Kidney Centers.

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](mailto: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 PUGET SOUND KIDNEY CENTERS PROPOSING TO ADD ONE DIALYSIS STATION TO PSKC ANACORTES LOCATED IN THE SKAGIT COUNTY ESRD PLANNING AREA.**

**APPLICANT DESCRIPTION**

**Puget Sound Kidney Centers**

Puget Sound Kidney Centers is a not-for-profit entity that provides kidney dialysis services in Washington State. Puget Sound Kidney Centers was established in 1981 as a community-based provider in northern Snohomish County, and is governed by a board of directors and 5-member executive team that includes the president/CEO, chief financial officer, chief operating officer, chief medical officer, and an executive director for the Puget Sound Kidney Centers Foundation. [source: Puget Sound Kidney Centers website and Application, p5]

As of the writing of this evaluation, PSKC is approved to own and operate a total of 11 dialysis centers in Washington State. The 11 facilities are, or will be, located in Clark, Island, Kitsap, Skagit, Snohomish, and Pierce counties. PSKC does not own or operate outside of Washington State.

The applicant for this project is Puget Sound Kidney Centers and will be referenced in this evaluation as “PSKC.”

**PROJECT DESCRIPTION**

This project focuses on PSKC’s Anacortes dialysis center which will be referenced in this evaluation as “PSKC Anacortes.” The dialysis center is located at 809 – 31<sup>st</sup> Street in Anacortes [98221] in the Skagit County ESRD planning area. Currently, PSKC Anacortes has five general use dialysis stations, which includes one permanent bed station. The facility also operates one exempt isolation station, for a facility total of six dialysis stations. A breakdown of the current number of stations is shown in the table below. [source: Application, p9 and CN #1727 effective January 1, 2018]

<b>Station Type</b>	<b>CMS Certified Stations</b>	<b>Station Counted for Station Use and Methodology</b>
General Use In-Center Stations	4	4
Permanent Bed Station	1	1
Exempt Isolation Station	1	0
Isolation Station	0	0
<b>Total Stations</b>	<b>6</b>	<b>5</b>

This application proposes to add one dialysis station to PSKC Anacortes resulting in a facility total of seven in-center dialysis stations, including one exempt isolation station. PSKC Anacortes would remain at its current location in Anacortes and would continue to provide the following services. [source: Application, p11]

- Outpatient maintenance hemodialysis.
- Isolation in a private room.
- A bed for patients who are unable to dialyze in an upright position.
- Home peritoneal and home hemodialysis training.
- Back up support treatments for both home hemodialysis and home peritoneal dialysis patients.
- Hemodialysis services for visitors.
- Shift beginning after 5:00 PM.

PSKC's estimated capital expenditure for this station addition project is \$15,235 and all costs are for movable equipment and associated sales tax. All costs would be paid by PSKC's reserves. [source: Application, p23]

Within the application, PSKC determined this evaluation would be released in mid-February 2021. Using that timeline, PSKC estimated the additional station would be operational in March 2021. [source: Application, p10] Under this timeline, full calendar year one is 2022 and full calendar year three is 2024.

### **APPLICABILITY OF CERTIFICATE OF NEED LAW**

PSKC's application proposes to add one dialysis station 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).

PSKC 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**

<b>Action</b>	<b>Puget Sound Kidney Centers</b>
Letter of Intent Submitted	October 1, 2020
Application Submitted	October 30, 2020
Department's Pre-review Activities including <ul style="list-style-type: none"><li>• DOH First Screening Letter</li><li>• Applicant's First Screening Responses Received</li></ul>	November 16, 2020 December 15, 2020
Beginning of Review	December 22, 2020
End of Public Comment <ul style="list-style-type: none"><li>• Public comments accepted through the end of public comment</li><li>• No public hearing requested or conducted</li></ul>	January 21, 2021
Rebuttal Comments Deadline <sup>1</sup>	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, one entity sought affected person status.

### DaVita, Inc.

DaVita Inc. is a national and Washington State provider of dialysis services. For the Skagit County planning area, DaVita operates a six-station dialysis center in Burlington. On December 30, 2020, DaVita, Inc. submitted its request for interested person status. DaVita did not provide comments on this application and, therefore does not qualify as an affected person.

## **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**

- Puget Sound Kidney Centers' Certificate of Need application received October 30, 2020
- Puget Sound Kidney Centers' first screening response received December 15, 2020
- 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 Skagit 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
- Puget Sound Kidney Centers' website at <https://www.pskc.net>
- Comagine Health ESRD Network 16 website at <https://nrn.org>
- Centers for Medicare and Medicaid website at [www.medicare.gov/dialysisfacilitycompare](http://www.medicare.gov/dialysisfacilitycompare)

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<sup>1</sup> No public comments were submitted for this project, as a result, no rebuttal comments were submitted.

**CONCLUSION**

For the reasons stated in this evaluation, the application submitted by Puget Sound Kidney Centers proposing to add one dialysis station to PSKC Anacortes located in the Skagit County ESRD planning area is consistent with applicable criteria of the Certificate of Need Program, provided that the applicant agrees to the following in its entirety.

**Project Description:**

This certificate approves the addition of one dialysis station to the six-station PSKC Anacortes, for a facility total of seven dialysis stations. PSKC Anacortes will remain at its current location in Anacortes and continue to provide the following services: in-center hemodialysis, home hemodialysis, home peritoneal dialysis, training and support for dialysis patients, hemodialysis for visitors, an isolation dialysis station, a bed dialysis station, and shifts beginning after 5:00 pm. A breakdown of the dialysis stations after project completion is shown below.

Station Type	CMS Certified Stations	Station Counted for Station Use and Methodology
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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. Puget Sound Kidney Centers 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. Puget Sound Kidney Centers shall finance this project using existing capital reserves, as described in the application.
3. Puget Sound Kidney Centers shall notify the Certificate of Need Program when the medical social worker identified in this application is issued an active Washington State license.

**Approved Costs:**

The approved capital expenditure for this one-station addition is \$15, 235. This amount represents the costs for moveable equipment. All costs will be paid by Puget Sound Kidney Centers.

**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 Puget Sound Kidney Centers 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, PSKC 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.*

### **Puget Sound Kidney Centers**

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

- Six months of utilization data for PSKC Anacortes beginning in April 2020 through September 2020 provided by Comagine Health ESRD Network 16; and
- Single line drawings showing the current stations and support areas of the dialysis center as well as where the new station would be located.

[source: Application, Exhibit 3 and Exhibit 4]

### **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 Skagit County ESRD planning area is April 2020 through September 2020.

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

The single line drawing shows the one additional station 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.*

### **Puget Sound Kidney Centers**

To demonstrate compliance with this sub-criterion, PSKC provided the following table. [source: Application, p15 and Exhibit 4]

*Applicant's Table*

**Table 6**  
**PSKC Anacortes**  
**Monthly Patient Census and Utilization**

	April 2020	May 2020	June 2020	July 2020	August 2020	September 2020
Total in-center stations	5	5	5	5	5	5
Total in-center patients	27	27	28	27	28	27
Patients per Station	5.4	5.4	5.6	5.4	5.6	5.4

*Source: Northwest Renal Network*

**Department Evaluation**

There are three dialysis centers operational in the Skagit County ESRD planning area. One is operated by DaVita, Inc., one is operated by Fresenius Medical Care, and one is PSKC Anacortes, the focus of this evaluation. As discussed under the previous sub-criterion, utilization of PSKC Anacortes exceeds five patients per station for the previous six months. **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.

**Puget Sound Kidney Centers**

To demonstrate compliance with this sub-criterion, PSKC provided the following statements and table. [source: Application, p16]

*“The first three full years of operation is 2022-2024. The requested information is included in Table 7 for the first three full years of operation. The assumptions are included in Exhibit 5.”*

*Applicant's Table*

**Table 7**  
**Projected Utilization, 2020-2024**

	2020 Estimated	2021 Projected Partial year	2022 Projected First Full Year	2023 Projected Second Full Year	2024 Projected Third Full Year
Total in-center stations last day of Year	5	6	6	6	6
Total in-center patients last day of Year	26	28	30	31	32
Total in-center treatments	3,864	4,144	4,440	4,588	4,736
Total home patients	4	5	7	9	11
Total home treatments	714	1,197	2,112	2,628	3,144

*Source: Applicant*

**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 Skagit County ESRD planning area is April 2020 through September 2020. PSKC'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 its application, PSKC 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 projected utilization of PSKC Anacortes with six in-center stations. The calculations show that the dialysis center’s six-month average is 4.56 patients per station. These calculations meet the required minimum average of 4.5 patient 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.

**Puget Sound Kidney Centers**

To demonstrate compliance with this sub-criterion, PSKC provided the following table and statements showing the projected timeline for operation of the additional station. [source: Application, p10]

*“As outlined in WAC 246-310-806, the concurrent review timeline for the Special Circumstances Cycle 2 indicates that decisions will be rendered by mid-February 2021. Assuming a timely decision, and further assuming that project implementation means ready for survey, PSKC anticipates that the project will be implemented in March 2021 as depicted in Table 3.”*

*Applicant’s Table*  
**Table 3**  
**PSKC Anacortes Timeline**

Event	Anticipated Date
Design Complete	Not applicable
Construction Commenced	Not applicable
Construction Completed	Not applicable
Facility Prepared for Survey	March 2021
Stations Operational	March 2021

*Source: Applicant*

**Department Evaluation**

The timeline identified in PSKC’s application projects the one additional station would be operational at PSKC Anacortes within six months of approval. PSKC 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 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.<sup>2</sup> With the passage of the Affordable Care Act (ACA), the amount of charity care is expected to decrease, but not disappear. The policy should also include the process one must use to access charity care at the facility.

### **Puget Sound Kidney Centers**

PSKC provided the following information for this sub-criterion. [source: Application, p17]

*“PSKC strives to ensure that all individuals in need of dialysis services have access to high quality care. PSKC’s New Patient Financial Admission policy, included in Exhibit 6, prohibits discrimination on the basis of race, color, creed, religion, sex, national origin, ancestry, age, marital status, protected veteran status, sexual orientation, gender identity, genetic information, physical or mental disability, or medical condition, ethnicity, sex, or handicap. PSKC reinvests in the communities it serves and does not turn patients away on the basis of income or payment resources. PSKC is committed to caring for the underserved and disenfranchised and is truly a nonprofit provider in every sense of the word. Our policy differentiates us from many other dialysis providers in that we identify patients prospectively and qualify them as eligible for charity care (as opposed to re-categorizing bad debt). We are proud of our policy and appreciate how well it has benefited dialysis patients over the years.”*

PSKC also provided the following policies and procedures for this facility. [source: Application, Exhibit 6]

- Community Service Statement Policy and Procedure
- New Patient Financial Admission Policy and Procedure
- New Patient Admission Policy and Procedure
- Patient Transfer and Discharge Policy and Procedure
- Patient’s Rights and Responsibilities Policy and Procedure

### **Medicare and Medicaid Programs**

PSKC Anacortes is currently Medicare and Medicaid certified. PSKC provided the facility’s Medicare and Medicaid provider numbers and included tables showing the current and projected percentages of revenues by payer, and revenues by patient for PSKC Anacortes. The information is summarized below. [source: Application, p13 and p22]

Medicare Provider Number:	50-2573
Medicaid Provider Number:	2036232

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<sup>2</sup> WAC 246-453-010(4).

Applicant's Table

Table 10  
PSKC Anacortes  
Current and Projected Payer Mix

Payer Mix	Percentage by Revenue	Percentage by Patient
Medicare	82.07%	89.44%
Medicare Managed Care	17.65%	8.91%
Medicaid	0.02%	0.33%
Other: Commercial	0.26%	1.32%
<b>Total</b>	<b>100.0%</b>	<b>100.0%</b>

Source: Applicant

**Department Evaluation**

PSKC has been providing dialysis services to the residents of Washington State for many years. PSKC provided its Admission Policy that provides the assurance PSKC would provide treatment to patients without regard to “race, color, creed, religion, sex, national origin, ancestry, age, marital status, protected veteran status, sexual orientation, gender identity, genetic information, physical or mental disability or medical condition as defined by applicable laws.” [source: Application, Exhibit 6]

All PSKC dialysis centers are Medicare and Medicaid certified. Documentation provided in the application demonstrates that PSKC Anacortes would continue both Medicare and Medicaid certifications. PSKC provided both current and projected Medicare and Medicaid revenues for PSKC Anacortes. [source: Application, p22]

PSKC does not have a policy specifically titled “Charity Care Policy.” However, PSKC provided specific information regarding its admission of patients and charitable care. Additional information regarding charity care is included in PSKC’s audited financial statements. The additional information is restated below. [source: Application, Appendix 1]

“Charity care

*PSKC has a policy of providing care to patients without regard to their ability to pay. Those patients who are unable to pay are identified only after financial information is obtained from the patient and all means of helping them obtain financial assistance have been exhausted. Currently, the charges are waived and thereby excluded from net patient service revenues. PSKC has not determined the amount of charity care provided as the amounts cannot be reasonably estimated.”*

PSKC 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, Attachment 1]

PSKC provided copies of the necessary policies used at all PSKC dialysis centers, which includes PSKC Anacortes. These policies reflect PSKC’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 PSKC currently operates PSKC Anacortes and uses these policies and procedures at this center, the policies provided in the application are executed policies. The department concludes PSKC’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 Puget Sound Kidney Centers 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 PSKC Anacortes is currently operational, sub-sections (1)(a) and (b) above apply to this project.

### **Puget Sound Kidney Centers**

As previously stated, PSKC projects that the additional station would be operational at PSKC Anacortes by the end of March 2021 based on a February 2021 evaluation release date. [source: Application, p10] Under this timeline, calendar year one of this project is 2021 and full year one is 2022; calendar year three is 2024.

Once the additional station is added, PSKC Anacortes would be operating with seven in-center dialysis stations, which includes a permanent bed station and one exempt isolation station. PSKC provided the assumptions used to project in-center treatments and patients. The assumptions are restated below. [source: December 15, 2020, screening response, Revised Pro Forma Financials]

#### “Volumes

- A. *Patients – In-Center. Census was based on anticipated growth for facilities based on PSKC prior experience and the growth rate in new patients produced in application of the methodology in WAC 246-310-812.*
- B. *Patients – Home Program. Increases in patient census by modality were projected based upon PSKC’s historical experience.*
- C. *Treatments – In-Center. Treatments were assumed to average 148 treatments per patient annually to account for missed treatments.*
- D. *Treatments – Home Program. Treatments were based on PSKC experience and assumed an average of 360 treatments per PD patient per year and 156 treatments per HHD patient per year.”*

Using the assumptions stated above, PSKC provided a table of projected in-center dialyses and patients for PSKC Anacortes for years 2021 through 2024. The projections are summarized in the table below. [source: Application, p16]

*Applicant's Table*

**Table 7  
Projected Utilization, 2020-2024**

	2020 Estimated	2021 Projected Partial year	2022 Projected First Full Year	2023 Projected Second Full Year	2024 Projected Third Full Year
Total in-center stations last day of Year	5	6	6	6	6
Total in-center patients last day of Year	26	28	30	31	32
Total in-center treatments	3,864	4,144	4,440	4,588	4,736
Total home patients	4	5	7	9	11
Total home treatments	714	1,197	2,112	2,628	3,144

*Source: Applicant*

PSKC provided the following assumptions for its projected financial statements, which are restated below. [source: December 15, 2020, screening response, Revised Pro Forma Financials]

“Revenues

- A. *Revenues and current payer mix were based on the current experience of the PSKC Anacortes facility for all modalities. Payer mix by patient and revenue was provided in Table 10 of the application.  
Net revenue per treatment is assumed to be \$299.54 for in-center treatments which is the average of the Anacortes facility for the past three years.  
Net revenue per treatment for home treatments is based upon the net revenue by modality for home hemodialysis (\$299.54) and peritoneal dialysis treatments (\$134.80).*
- B. *Charity care is assumed to be .80% of net revenue.*
- C. *Bad debts are assumed to be 1.0% of net revenue.*

Direct Expenses

- A. *Staffing FTEs were based on our staffing model increased for growth as patient population increases. Salaries were based on the expected wages of the Anacortes facility.*
- B. *Benefits were assumed to be 21.20%, which is based on the Anacortes facility expense for the past three years.*
- C. *Medical Director fees are based on medical director agreements applicable to PSKC Anacortes (see Exhibit 8 of the application; \$40,000/year).*
- D. *Professional Fees are based on the 2019 expenses multiplied by the expected percentage PSKC-Anacortes would receive in a corporate allocation across all facilities.*
- E. *Expenses related to patient treatments (medical supplies, pharmacy (including Epogen and Mircera), were based on cost per treatment experience for PSKC - Anacortes.*
- F. *Office and miscellaneous expenses include office supplies, small equipment, information technology expenses (including licenses, software maintenance, and IT-related supplies), equipment rent, and other miscellaneous expenses. These expenses were based on the cost per treatment experience for PSKC-Anacortes.*
- G. *Repairs and Maintenance include maintenance agreements and parts for various operating equipment. These expenses were based on the cost per treatment experience of PSKC Anacortes Housekeeping: These expenses were based on the cost per treatment experience of PSKC-Anacortes*
- H. *Occupancy costs include building repairs and maintenance, and utilities. Building maintenance was estimated using the cost per square foot average of PSKC-Anacortes' prior three years. Utilities were based on the cost per treatment experience of PSKC Anacortes.*

- I. *Communication expenses include telephone (both land and cell), postage, connectivity, and internet costs. They were estimated based on the cost per treatment experience of PSKC-Anacortes' prior three years.*
- J. *Laboratory expenses were based on the contract rate charged for each bundled patient. This rate applies to all of PSKC's facilities.*
- L. *Training: These expenses were based on the cost per treatment experience at PSKC Anacortes.*
- M. *Public relations: Based on actual experience at PSKC-Anacortes.*
- N. *Depreciation expenses were estimated based on the actual useful lives PSKC assigned to certain equipment classifications. Classifications are as follows:*
  - 1. *Building - 40 years*
  - 2. *Building improvements - 15 years*
  - 3. *Medical equipment - 7 years*
  - 4. *Furniture and office equipment - 7 years*

Overhead

- A. *Indirect expenses are estimated based on actual experience by estimating how our allocations would be modified with the additional station at PSKC Anacortes.*
- B. *The Corporate Medical Director fees are based on the corporate medical director agreement multiplied by the expected percentage PSKC-Anacortes would receive in a corporate allocation across all facilities."*

Given that PSKC owns the site where PSKC Anacortes is located, there are no lease costs for the site. [source: Application, p20 and Exhibit 9]

Based on the assumptions above, PSKC 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, Revised Pro Forma Financials]

**Department's Table 1**  
**PSKC Anacortes Projected Revenue and Expenses for Years 2021 - 2024**

	<b>CY 2021</b>	<b>CY 2022</b>	<b>CY 2023</b>	<b>CY 2024</b>
Net Revenue	\$1,407,801	\$1,636,066	\$1,773,142	\$1,910,216
Total Expenses	\$1,622,993	\$1,752,636	\$1,824,605	\$1,897,109
<b>Net Profit / Loss</b>	<b>\$215,192</b>	<b>\$116,570</b>	<b>\$51,463</b>	<b>\$13,107</b>

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

The "Total Expenses" line item includes all expenses related to the projected operation of the seven-station facility in years 2021 through 2024. The expenses include all costs identified in the assumptions outlined above.

**Department Evaluation**

PSKC Anacortes is currently operating with a total of six dialysis stations, which includes one isolation station. PSKC based its projected utilization of PSKC Anacortes on its current utilization, plus one additional station associated with this project. 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. The table above shows that PSKC expects the dialysis center to operate at a net loss in years 2021, 2022, and

2023. It is noted that the net loss is decreasing in each of the years shown, and revenues will cover expenses in the third full year of the proposed project at PSKC Anacortes. PSKC also based these projections on current operations.

PSKC owns the site where the PSKC Anacortes is located and provided documentation from the Skagit County Assessor’s Office demonstrating ownership and site control. As a result, no lease/rent costs are included in the pro forma revenue and expense statement.

PSKC also provided a copy of the Medical Director Agreement. Medical director costs are \$40,000 annually and are consistent with the executed Medical Director Agreement provided in Exhibit 8 of the application.

Based on the above information provided by the applicant, the department concludes that PSKC’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.*

**Puget Sound Kidney Centers**

For this sub-criterion, PSKC stated that this project requires equipment, but no construction, to add one station to PSKC Anacortes. PSKC provided its capital cost breakdown shown below. [source: Application, p21]

**Department’s Table 2  
PSKC Anacortes Estimated Capital Costs**

<b>Item</b>	<b>Total</b>
Moveable Equipment	\$14,862
Washington State Sales Tax	\$373
<b>Total Estimated Capital Costs</b>	<b>\$15,235</b>

Specific to costs and charges for health services, PSKC provided the following statements. [source: Application, p22]

*“The project will not affect charges for services. Importantly, this project will have no effect on billed rates to patients, providers, or payers. PSKC’s charges for dialysis services are not determined by any capital expenditures for an expansion or a new facility.*

*As noted in the CN Program’s published quintiles for dialysis superiority, six of PSKC’s existing seven facilities are in 5th Quintile (the lowest net revenue per treatment quintile), providing further assurance that PSKC strives to reduce the cost of health care for patients.”*



Focusing on WAC 246-310-815(2), PSKC provided a table comparing the actual square footage of PSKC Anacortes and the minimum allowable square footage provided in WAC 246-310-800(11). [source: Application, p12]

### **Department Evaluation**

The costs for adding one station to the six-station PSKC Anacortes is \$15,235. 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 PSKC Anacortes currently has Medicare and Medicaid reimbursements that equal 99.7% of the revenue at the dialysis center. This amount is reasonable and consistent with percentages reviewed and approved in past dialysis 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 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 PSKC 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 0.26% of net revenue is commercial, HMO and other government.

To demonstrate compliance with WAC 246-310-800(11), PSKC Anacortes's allowable maximum treatment floor area square footage for a 7-station facility is 2,537.5. PSKC's project will use 2,425 square feet. PSKC'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 PSKC's projected costs associated with the one-station addition to PSKC Anacortes would probably not have an unreasonable impact on the costs and charges for healthcare services in the Skagit 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.

**Puget Sound Kidney Centers**

PSKC identified a capital expenditure of \$15,235 to add one station to PSKC Anacortes. The project would be funded using corporate reserves. PSKC provided a letter from its corporate Chief Financial Officer, Ken Kouchi, to demonstrate an operational and financial commitment to the project. [source: Application, p23 and Exhibit 7]

PSKC also provided a copy of its audited financial statements for years 2016, 2017, 2018, and 2019 to demonstrate sufficient reserves to finance the project. [source: Application, Appendix 1]

**Department Evaluation**

PSKC 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 PSKC 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 Puget Sound Kidney Centers 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.

**Puget Sound Kidney Centers**

If this project is approved, PSKC expects the additional station would be operational by the end of March 2021. Under this timeline, 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: Application, p24]

**Department’s Table 3  
PSKC Anacortes Historical, Current, and Projected FTEs for Calendar Years (CY) 2019 - 2024**

FTE by Type	CY 2019	CY 2020 Increase	CY 2021 Increase	CY 2022 Increase	CY 2023 Increase	CY 2024 Increase	Total
Direct Care Manager	1.00	0.00	0.00	0.00	0.00	0.00	1.00
Home Registered Nurse	0.20	0.10	0.00	0.00	0.00	0.00	0.30
Registered Nurses	2.00	0.88	0.00	0.00	0.00	0.00	2.88
Dialysis Technician	2.00	1.00	0.00	0.00	0.00	0.00	3.00
BioMed Technician	0.20	0.00	0.00	0.00	0.00	0.00	0.20
Computer Technician	0.10	0.00	0.00	0.00	0.00	0.00	0.10
Medical Social Worker	0.20	0.18	0.00	0.00	0.00	0.00	0.38
Dietician	0.20	0.18	0.00	0.00	0.00	0.00	0.38
Administrative Assistant	0.38	0.00	0.00	0.00	0.00	0.00	0.38
<b>Total FTEs</b>	<b>6.28</b>	<b>2.33</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>8.60</b>

PSKC's medical director is under contract at a total of \$40,000 annually and is not an employee and is not included in the table above. [source: Application, p 24 and Exhibit 8] The Medical Director Agreement was executed on January 1, 2019, is currently effective and includes automatic annual renewals.

PSKC provided the following statements related to recruitment and retention of staff. [source: Application, p24]

*“In addition to providing exceptional patient care, PSKC offers a competitive wage and benefit package, a positive and supportive work environment, and a philosophy that encourages existing staff to receive training and additional education. While PSKC is aware of a nursing staffing shortage across the State and nation, it has not been a deterrent to PSKC being able to staff our facilities with patient safety as our top priority. PSKC is an excellent place to work with competitive wages or salaries, and a generous benefit plan.*

*PSKC's commitment to, and involvement with the communities we serve, has resulted in many long standing and collaborative relationships with various educational health care programs. This has also opened opportunities for promoting dialysis to new graduates and health care professionals in other specialty areas that might be looking to change specialties. For example, phlebotomists apply for dialysis technician positions, and for dialysis technicians looking to advance their careers and complete RN curriculum, PSKC helps with scholarship support.*

*Further, PSKC's Educational Department provides training and education to various patients, university, and community college health care student populations, and actively promotes positions that are open. This active promotion occurs at community events such as job/health fairs and college nursing program presentations.*

*PSKC has also benefited greatly from “word of mouth” by current employees and use of social media networking sites to attract potential candidates using a more informal or individual approach. PSKC employs these strategies for potential referral sources at all of its facilities.*

*It is also common for nurses and technicians to compare employers, especially when the job market is as strong as it is currently in Western Washington, and using this information, nurses and dialysis technicians continue to choose PSKC as their employer.*

*As noted in response to Question 1, no additional staffing is proposed for this small expansion. However, should additional staffing be needed, based on our historical record and performance, we do not anticipate any difficulties recruiting the additional staff needed. In addition, PSKC does have other nearby facilities from which it can share staff should that be needed.”*

### **Department Evaluation**

Information provided in the application demonstrates that PSKC is a well-established provider of dialysis services in Washington State and in Skagit County. PSKC Anacortes has been operational since March 2016. [source: PSKC Anacortes facility file]

The facility is currently operating with 8.60 FTEs. For this project, PSKC is proposing to add one station to the existing center. The one station increase does not require any additional staff because the facility increased its staff by two FTEs in year 2020.

Based on the above information, the department concludes that PSKC 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.

**Puget Sound Kidney Centers**

PSKC provides dialysis services throughout Washington State, including PSKC Anacortes in the Skagit County ESRD planning area. If this project is approved, PSKC Anacortes’s in-center stations will increase from six to seven. PSKC provided a table showing the ancillary and support services that would be provided on site and those provided off site at the PSKC support center. The information is in the applicant’s table below. [source: Application, p28]

*Applicant’s Table*

**Table 15**

**Existing Ancillary and Support Services for PSKC Anacortes**

Service	Offered Onsite/Offsite
Administration	On site
Human Resources	Off site
Information Systems	Off site
Material Management	On site
Nursing Services	On site
Nutrition Services	On site
Patient Education	On site
Patient Financial Counseling	Off site
Plant Operations	On site
Social Services	On site
Staff Education	Off site
Technical Services	On site

*Source: Applicant*

PSKC also provided a listing of vendors it currently has ancillary and support agreements with for PSKC Anacortes. [source: Application, p27]

*Applicant’s Table*

**Table 14**

**Existing Ancillary and Support Service Agreements**

Agreement Type	Vendor(s)
Electronic Medical Records	Constellation Kidney Group (Infian)
Anemia Management	Metro Medical, Amgen
Laboratory Services	Spectra Laboratory
Required CMS Data Reporting	National Healthcare Safety Network (NHSN), CROWNWeb, NRAA Health Information Exchange (HIE)
Equipment/Materials Management	Amerisource Bergen, Baxter, Henry Schein, Fresenius, Praxair, BBraun, McKesson, Metro Medical (Division of Cardinal Health), Champion, Hospital Therapy Products, MarCor
Transportation Services	Paratransit, Merts Taxi Service, Skagit Transit
Biohazard/Waste Management	Waste Management
Janitorial Services	ZNG Janitorial Service

*Source: Applicant*

Additionally, PSKC provided a listing of the entities it currently has working relationships with for PSKC Anacortes in the areas of hospital, public health, emergency planning, clinicians, transportation, long-term care, and higher education. PSKC further states there will be no changes to any existing working relationships or agreements if this project is approved. [source: Application, pp29-30]

PSKC provided an executed Patient Transfer Agreement between itself and Skagit Valley Hospital in Mount Vernon, within Skagit County. The agreement was effective on October 1, 2011. The executed agreement identifies annual automatic renewal. [source: Application, Exhibit 11]

PSKC also provided a copy of its executed Medical Director Agreement between itself and Parampreet Ghuman, MD. The agreement was executed on January 1, 2019, and is specifically effective for three years, with annual automatic renewals. The Medical Director Agreement identifies roles and responsibilities for both PSKC and Dr. Ghuman. Exhibit B of the agreement identifies the annual and monthly compensation. [source: Application, Exhibit 8]

### **Department Evaluation**

PSKC Anacortes has been operating in the Skagit County ESRD planning area since March 2016. All ancillary and support services have been established for the dialysis center. PSKC states that no new agreements or revisions to existing agreements are necessary 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).

### **Puget Sound Kidney Centers**

PSKC provided the following statements in response to this sub-criterion. [source: Application, p31]

*“PSKC operates all existing programs in conformance with applicable federal and state laws, rules, and regulations. its recent CN decision in Vancouver, Clark County (December 2019) the CN Program reviewed PSKC’s quality and compliance with state and federal requirements. As part of its review, the CN Program considered the CMS star ratings for each of PSKC’s six operational facilities, finding that the existing PSKC facilities had an average current rating of 4.00; PSKC’s average rating is currently 4.17 (with PSKC Anacortes rated a 5 star facility for quality of patient care).”*

### **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.<sup>3</sup>

- Standard Level

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

- Condition Level

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

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

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

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

#### Terminated Provider Counts Report

Focusing on years 2018 through 2021, none of PSKC's dialysis centers were involuntarily terminated from participation in Medicare reimbursement.

#### Conformance with Medicare and Medicaid Standards

Focusing on years 2018 through 2021, all seven of PSKC's operational dialysis centers were surveyed. Of the seven, one center had four condition level findings in year 2018 that required a follow up visit. All seven facilities are in conformance with CMS standards at this time.

#### CMS Star Rating for Washington State Centers

PSKC is approved to own and operate a total of 11 dialysis centers in Washington State. The 11 facilities are, or will be, located in Clark, Island, Kitsap, Skagit, Snohomish, and Pierce counties. Of the 11 facilities, CMS provided star ratings for six facilities. The average star rating for the six facilities

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<sup>3</sup> Definitions of standard and condition level surveys: <https://www.compass-clinical.com/deciphering-tjc-condition-level-findings/>

is 4.17. Specific to PSKC Anacortes, its star rating is 5. For the remaining five PSKC facilities, these centers are either not yet operational or have not been operational long enough to obtain a star rating.

As of the writing of this evaluation, PSKC manages four operational dialysis centers owned by Olympic Peninsula Kidney Centers. The average star rating for these five centers is 3.8.<sup>4</sup>

PSKC provided an executed Medical Director Agreement with Parampreet Ghuman, MD. [source: Application, Exhibit 10] Using data from the Medical Quality Assurance Commission, the department confirmed that Dr. Ghuman holds an active medical license with no enforcement actions.

PSKC provided a listing of credentialed staff, which includes: one physician, seven registered nurses, three hemodialysis technicians, one medical social worker, and one certified dietician. Using data from the DOH Office of Customer Service, the department found, with the exception of the medical social worker, all staff are in full compliance with state requirements, hold active state licenses, and have no conditions or limits on their license. Specific to the medical social worker, Lindsay Holloway, her license has not been issued as of the writing of this evaluation. As a result, if this project is approved, the department would attach a condition requiring PSKC to notify the Certificate of Need Program once the medical social worker license is issued.

In review of this sub-criterion, the department considered the total compliance history of the dialysis facilities owned and operated by PSKC and those Olympic Peninsula Kidney Center facilities managed by PSKC. The department also considered the compliance history of the medical director and current staff of the dialysis center. Based on the information reviewed, the department concludes that PSKC 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 PSKC's compliance.

Based on the information above and agreement with the condition referenced above, PSKC demonstrated that PSKC Anacortes would continue to 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.

### **Puget Sound Kidney Centers**

PSKC provided the following statements in response to this sub-criterion. [source: Application, pp30-31]

*“As with all PSKC facilities, PSKC Anacortes provides a collaborative, comprehensive, and patient-centered approach to the provision of dialysis services. PSKC's unrelenting focus on high-quality, compassionate care, coupled with respect for the patients, staff, and other providers has served the communities well. With this small expansion of PSKC Anacortes, PSKC will continue to maintain all*

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<sup>4</sup> The management agreement between PSKC and Olympic Peninsula Kidney Centers was executed in October 2018. [source: Application, pp7-8]

*existing working relationships and will enter into new relationships to ensure that our care remains outstanding and our patient's care is coordinated.*

*PSKC maintains appropriate relationships with the existing health care system in the Planning Area. Table 16 provided examples of PSKC's existing working relationships with area health care providers. This project will not change any of these existing relationships."*

### **Department Evaluation**

PSKC has been a provider of dialysis services in Washington State for many years. PSKC also has a history of establishing relationships with existing healthcare networks in Skagit County for PSKC Anacortes. Additionally, PSKC's project would promote continuity in the provision of healthcare services in the Skagit County ESRD planning area by increasing the number of stations at PSKC Anacortes.

PSKC 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 Puget Sound Kidney Centers 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, PSKC 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, PSKC provided the following statements. [source: Application, p32]

*“WAC 246-310-818 allows dialysis facilities to request up to two additional stations based on internal utilization; regardless of whether there is need in the planning area. Given the current census at PSKC Anacortes, this project will provide some relief to the continued census pressures at PSKC Anacortes. Therefore, no other alternative was considered.*

*As discussed in response Question #1, WAC 246-310-818 allows providers to submit special circumstance applications based on internal need. The addition of one station at PSKC Anacortes will improve patient access to dialysis services by adding capacity with relatively minimal capital expenditure. There are no legal restrictions related to this proposal and this project will have no effect on either the cost of services or the high quality of care we provide. Finally, minimal staffing is required; ultimately, PSKC Anacortes will operate more efficiently with one more station.”*

### **Department Evaluation**

Specifically, PSKC Anacortes is a small dialysis facility, but is highly utilized. For this reason, PSKC did not consider any other options than to add dialysis station capacity. PSKC asserts that the proposed project will further continuity by both increasing patient access and facility efficiency.

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 PSKC Anacortes in order to promote immediate access to services.

The department concludes that the project submitted by PSKC 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**

Since PSKC’s proposed capital expenditure is solely related to dialysis equipment, this sub-criterion does not apply to this project.

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

### **Puget Sound Kidney Centers**

PSKC provided the following response for this sub-criterion. [source: Application, p33]

*“This project does not require any construction; as such, no changes in the facility’s design are being made. Therefore, this question is not applicable.”*

**Department Evaluation**

PSKC's project does not require construction. The additional station has the potential to improve delivery of dialysis services to the residents of the Skagit County ESRD planning area. Consistent with the special circumstance rules, PSKC projects to be operating the additional station within six months of approval. **This sub-criterion is met.**