



STATE OF WASHINGTON
DEPARTMENT OF HEALTH

September 6, 2013

CERTIFIED MAIL # 7011 1570 0002 7802 6487

H. S. Kelly, President & CEO
Puget Sound Kidney Centers
1019 Pacific Avenue
Everett, WA 98201

Re: CN13-31

Dear Mr. Kelly:

We have completed review of the Certificate of Need application submitted by Puget Sound Kidney Centers proposing to establish a new 12-station dialysis center in Snohomish County planning area #2. For the reasons stated in this evaluation, the application is consistent with 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 establishment of a 12-stations center in Monroe within Snohomish County planning area #2. At project completion, the dialysis center will be approved to certify and operate twelve dialysis stations. The dialysis facility will offer at least home peritoneal dialysis and hemodialysis dialysis. Services to be provided at the facility include in-center hemodialysis and peritoneal dialysis with treatments shifts beginning after 5:00 p.m., a permanent bed station, and an isolation station. A breakdown of all twelve stations is below:

Private Isolation Room	1
Permanent Bed Station	1
Home Training Station	1
Other In-Center Stations	9
Total	12

After the 12-stations are relocated from the 37-station PSKC-Everett, the dialysis center would have 25-stations remaining. A breakdown of the remaining 25-stations is shown below.

PSKC- Everett Dialysis Center

Private Isolation Room	1
Permanent Bed Station	1
Home Training Station	1
Other In-Center Stations	22
Total	25

Conditions:

1. Puget Sound Kidney Centers agrees with 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 must decertify 12-stations from the 37-station Puget Sound Kidney Centers Everett no later than 30 days following the opening of the new 12-station dialysis center. At project completion, 25 dialysis stations would remain in operation at Puget Sound Kidney Centers Everett.

Approved Capital Costs:

The approved capital expenditure associated with this project is \$5,946,783.

Please notify the Department of Health within 20 days of the date of this letter whether you accept the above in its entirety. Your written response should be sent to the Certificate of Need Program, at one of the following addresses.

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

Other Than By Mail:
Department of Health
Certificate of Need Program
111 Israel Road SE
Tumwater, WA 98501

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

Sincerely,

A handwritten signature in blue ink, appearing to read "Steven M. Saxe". The signature is fluid and cursive, with the first name "Steven" being particularly prominent.

Steven M. Saxe, FACHE, Director

Enclosure

EVALUATION DATED SEPTEMBER 6, 2013, FOR THE CERTIFICATE OF NEED APPLICATION SUBMITTED BY PUGET SOUND KIDNEY CENTERS PROPOSING TO ESTABLISH A NEW TWELVE STATION KIDNEY DIALYSIS FACILITY IN SNOHOMISH COUNTY PLANNING AREA #2

APPLICANT DESCRIPTION

Puget Sound Kidney Centers (PSKC) is a not-for-profit kidney dialysis provider established in 1980 as a community-based provider in northern Snohomish County. Currently, PSKC owns and operates four dialysis centers and an acute mobile dialysis services facility in Washington. Listed below are the facilities own or operated by PSKC. [Source: Application, Pages 4 and 5, CN historical files]

Snohomish County	# of Stations
Puget Sound Kidney Centers-Hoyt	Mobile dialysis services
Puget Sound Kidney Center - Everett	37
Puget Sound Kidney Center-South	27
Puget Sound Kidney Center-Smokey Point	28
Island County	
Puget Sound Kidney Center-Whidbey Island	9

PROJECT DESCRIPTION

PSKC proposes to relocate 12-stations from the existing 37-station PSKC-Everett to a new location within the same planning area. The new 12-station facility would be located at 18121 149th SE within the city of Monroe and it would be known as PSKC-Monroe. Services to be provided at PSKC-Monroe include in-center hemodialysis and visitor dialysis, home hemodialysis and peritoneal dialysis training and backup, a permanent bed station, and an isolation station. [Source: Application, pages 2 and 9]

The capital expenditure associated with the establishment of the 12-station facility is \$5,946,783. Of that amount \$4,438,238, (74.6%) is related to land improvement and construction; \$533,558 (9%) is related to both fixed and moveable equipment; \$939,987 (15.8%) is related to architect, engineering, taxes and fees; and the remaining \$35,000 (0.6%) is related to loan interest fees. [Source: Application, page 29]

If this project is approved, PSKC anticipates the new 12-station facility would become operational by April 2014. Under this timeline, calendar year 2015 would be the first full calendar year of operation and 2017 would be year three. [Source: Application and Exhibit 11]

APPLICABILITY OF CERTIFICATE OF NEED LAW

WAC 246-310-289(2) states: *“When an existing facility proposes to relocate a portion of its stations to either another planning area or within the same planning area, a new health care facility is considered to be established under WAC 246-310-020(1).”*

Puget Sound Kidney Center's application is proposing to relocate 12 of 37 stations from Puget Sound Kidney Centers located in Everett within Snohomish County planning area #2. This project is reviewed as the establishment of a new health care facility under the provisions of Revised Code of Washington (RCW) 70.38.105(4)(a) and Washington Administrative Code (WAC) 246-310-020(1)(a) and WAC 246-310-289(2).

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 determinations. It states:

“Criteria contained in this section and in WAC 246-310-210, 246-310-220, 246-310-230, and 246-310-240 shall be used by the department in making the required determinations.

(a) In the use of criteria for making the required determinations, the department shall consider:

- (i) The consistency of the proposed project with service or facility standards contained in this chapter;*
- (ii) In the event the standards contained in this chapter do not address in sufficient detail for a required determination the services or facilities for health services proposed, the department may consider standards not in conflict with those standards in accordance with subsection (2)(b) of this section; and*
- (iii) The relationship of the proposed project to the long-range plan (if any) of the person proposing the project”.*

In the event WAC 246-310 does not contain service or facility standards in sufficient detail to make the required determinations, WAC 246-310-200(2)(b) identifies the types of standards the department may consider in making its required determinations. Specifically WAC 246-310-200(2)(b) states:

“The department may consider any of the following in its use of criteria for making the required determinations:

- (i) Nationally recognized standards from professional organizations;*
- (ii) Standards developed by professional organizations in Washington State;*
- (iii) Federal Medicare and Medicaid certification requirements;*
- (iv) State licensing requirements;*
- (v) Applicable standards developed by other individuals, groups, or organizations with recognized expertise related to a proposed undertaking; and*
- (vi) The written findings and recommendations of individuals, groups, or organizations with recognized expertise related to a proposed undertaking, with whom the department consults during the review of an application”.*

WAC 246-310-280 through 289 contains service or facility specific criteria for dialysis projects that must be used to make the required determinations. To obtain Certificate of Need approval, PSKC must demonstrate compliance with the 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)¹. Additionally, PSKC must demonstrate compliance with the applicable kidney disease treatment center criteria outlined in WAC 246-310-280 through 289.

TYPE OF REVIEW

As directed under WAC 246-310-282(1) the department accepted this application under the Kidney Disease Treatment Centers Concurrent Review Cycle #1 for year 2013. No other kidney disease treatment center applications were received for Snohomish County planning area #2 during Cycle #1. The review was converted to a regular review. A chronological summary of the review activities is shown below.

APPLICATION CHRONOLOGY

Action	Dates
Letter of Intent Submitted	January 31, 2013
Application Submitted	February 28, 2013
Department's pre-review activities including screening and responses	March 5, 2013 through June 15, 2013
Beginning of Review	June 17, 2013
End of Public Comment/No Public Hearing Requested or Conducted	July 1, 2013
Rebuttal Comments ²	August 5, 2013
Department's Anticipated Decision Date	September 19, 2013
Department's Actual Decision Date	September 6, 2013

AFFECTED PERSONS

Washington Administrative Code 246-310-010(2) defines "affected person as:

"...an "interested person" who:

- (a) Is located or resides in the applicant's health service area;
- (b) Testified at a public hearing or submitted written evidence; and
- (c) Requested in writing to be informed of the department's decision."

For this project, no entities sought and received affected person status under WAC 246-310-010.

¹ Each criterion contains certain sub-criteria. The following sub-criteria are not discussed in this evaluation because they are not relevant to this project: WAC 246-310-210(3), (4), (5), (6); WAC 246-310-240(3), WAC 246-310-286; WAC 246-310-287; and WAC 246-310-288.

² The department did not receive any public comment therefore; no rebuttal comments from the applicant were submitted.

SOURCE INFORMATION REVIEWED

- Puget Sound Kidney Centers Certificate of Need application submitted February 28, 2013
- Puget Sound Kidney Centers supplemental information received April 23, 2013, and June 10, 2013
- Years 2006 through 2011 historical kidney dialysis data obtained from the Northwest Renal Network
- Year 2012 Northwest Renal Network 3rd Quarter Data available on October 29, 2012
- Licensing and/or survey data provided by the Department of Health's Inspections and Investigation Office (IIO)
- Certificate of Need historical files
- <http://www.doh.wa.gov/LicensesPermitsandCertificates/MedicalCommission.aspx> - Medical Quality Assurance compliance data
- <http://www.medicare.gov> -Dialysis Facilities Compare
- <http://www.medicare.gov> –Medicare Coverage of Kidney Dialysis and Kidney Transplant Services

CONCLUSION

For the reasons stated in this evaluation, the application submitted by Puget Sound Kidney Centers proposing to establish a new 12-station kidney dialysis center in the city of Monroe within Snohomish County planning area #2 is consistent with the applicable review 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 establishment of a 12-station dialysis center in Monroe within Snohomish County planning area #2. At project completion, the dialysis center will be approved to certify and operate twelve dialysis stations. The dialysis facility will offer at least home peritoneal dialysis and hemodialysis dialysis. Services to be provided at the facility include in-center hemodialysis and peritoneal dialysis with treatments shifts beginning after 5:00 p.m., a permanent bed station, and an isolation station. A breakdown of all twelve stations is below:

PSKC –Monroe Dialysis Center

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Approved Capital Costs:

The approved capital expenditure associated with this project is \$5,946,783.

CRITERIA DETERMINATIONS

A. Need (WAC 246-310-210 and WAC 246-310-284)

Based on the source information reviewed and the applicant's agreement to the conditions stated in the 'conclusion' section of this evaluation, the department determines that the Puget Sound Kidney Centers project has met the applicable need criteria in WAC 246-310-210 and the kidney disease treatment standards in WAC 246-310-289.

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

WAC 246-310-284 requires the department to evaluate kidney disease treatment center applications based on the populations need for the service and determine whether other services and facilities of the type proposed are not, or will not, be sufficiently available or accessible to meet that need as required in WAC 246-310-210. The kidney disease treatment center specific numeric methodology applied is detailed in WAC 246-310-284(4). WAC 246-310-210(1) criteria is also identified in WAC 246-310-284(5) and (6).

Numeric need methodology

WAC 246-310-284 contains the methodology for projecting numeric need for dialysis stations within a planning area. This methodology projects the need for kidney dialysis treatment stations through a regression analysis of the historical number of dialysis patients residing in the planning area using verified utilization information obtained from the Northwest Renal Network.³

The first step in the methodology calls for the determination of the type of regression analysis to be used to project resident in-center station need. [WAC 246-310-284(4)(a)] This is derived by calculating the annual growth rate in the planning area using the year-end number of resident in-center patients for each of the previous six consecutive years, concluding with the base year.⁴ In planning areas experiencing high rates of growth in the dialysis population (6% or greater growth in each of the last five annual change periods), the method uses exponential regression to project future need. In planning areas experiencing less than 6% growth in any of the last five annual change periods, linear regression is used to project need.

Once the type of regression is determined as described above, the next step in the methodology is to determine the projected number of resident in-center stations needed in the planning area based on the planning area's previous five consecutive years NRN data, again concluding with the base year. [WAC 246-310-284(4)(b) and (c)]

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

⁴ WAC 246-310-280 defines base year as "the most recent calendar year for which December 31 data is available as of the first day of the application submission period from the *Northwest Renal Network's Modality Report* or successor report." For this project, the base year is 2011.

WAC 246-310-284(5) identifies that for all planning areas except Adams, Columbia, Douglas, Ferry, Garfield, Jefferson, Kittitas, Klickitat, Lincoln, Okanogan, Pacific, Pend Oreille, San Juan, Skamania, Stevens, and Wahkiakum counties, the number of projected patients is divided by 4.8 to determine the number of stations needed in the planning area. For the specific counties listed above, the number of projected patients is divided by 3.2 to determine needed stations. Additionally, the number of stations projected as needed in the target year is rounded up to the nearest whole number.

Finally, once station need has been calculated for the projected years, the number of CN approved in-center stations are then subtracted from the total need, resulting in a net need for the planning area. [WAC 246-310-284(4)(d)]

PSKC Application of the Numeric Methodology

PSKC did not provide a methodology. Instead, it stated, *“This project does not address a need for additional dialysis capacity in the planning area. Rather, it furthers PSKC’s mission and vision to provide progressive and comprehensive dialysis services in locations convenient to the patients. The establishment of the PSKC-Monroe facility will further this mission and vision. PSKC has been aware for some time of the growing need for dialysis services east of the Everett trestle and the negative effect the increased travel hardship has had on patients traveling from the eastern portion of the Snohomish 2 planning area (Monroe, Snohomish, Gold Bar, and Lake Stevens etc.) to Everett for dialysis services.”* [Source: Application, Page 16]

Department’s Application of the Numeric Methodology

Based on the calculation of the annual growth rate of the planning area, the department used linear regression to project need. Given that the facility would be located in Snohomish County planning area #2, the number of projected patients is divided by 4.8 to determine the number of stations needed in the planning area. The table below is the department’s application of the numeric methodology for the planning area. [Source: Appendix A of this evaluation]

**Table 1
Snohomish County ESRD Planning Area #2 Numeric Methodology**

	Year 2012	Year 2013	Year 2014	Year 2015
In-center Patients	292.40	302.80	313.20	323.60
Patient: Station Conversion Factor	4.8	4.8	4.8	4.8
Total Station Need Rounded Up	61	64	66	68
Minus # CN Approved Stations	58	58	58	58
Net Station Need / (Surplus)	-3	-6	-8	-10

*Negative number indicates need for additional stations

Though the applicant is not proposing adding stations to the planning area, the department’s projections show need for additional dialysis stations in year 2015. The department and PSKC agree that this project is required to obtain a CN before proceeding because this project would result in a new health care facility within the planning area. If approved, the project will not increase the number of CN approved dialysis stations in the planning area.

WAC 246-310-284(1) states that applications for new stations may only address projected station need in the planning area in which the facility is to be located. WAC 246-310-284(2) thru (4) describe the detailed steps then used to calculate the projected station need. Therefore, the numeric need methodology is not applicable to this project.

WAC 246-310-284(5)

WAC 246-310-284(5) requires all CN approved stations in the planning area be operating at 4.8 in-center patients per station before new stations can be added. The most recent quarterly modality report, or successor report, from the Northwest Renal Network (NRN) as of the first day of the application submission period is to be used to calculate this standard. The first day of the application submission period is February 1, 2013. [WAC 246-310-282] The quarterly modality report from NRN available at that time was September 30, 2012, which became available on October 29, 2012. Currently there are two facilities operational in the planning area. The table below shows the utilization of both facilities

**Table 2
NWRN Facility Utilization Data**

Facility Name	# of Stations	# of Pts	Pts/Station
Puget Sound Kidney Center (PSKC)	37	177	4.78
PSKC Everett Dialysis Center	21	46	2.19

Since the applicant is proposing to relocate CN approved stations already counted as available in planning area, the department concludes that **this sub-criterion is not applicable.**

WAC 246-310-284(6)

WAC 246-310-284(6) requires by the third full year of operation, new in-center kidney dialysis stations must reasonably project to be operating a required number of in-center patients per approved station by end of the third full year of operation. PSKC-Monroe would be located in the Snohomish County ESRD planning area #2; therefore, the standard for this criterion is 4.8 in-center patients per approved station. Shown in the table below is PSKC-Monroe third year of operation projected utilization. [Source: Application Exhibit 11]

**Table 3
PSKC-Monroe
Third Full Year Projected (2017) Facility Utilization**

Facility Name	#of Stations	# of Pts	Pts/Station
PSKC -Monroe	12	64	5.33

As shown above, PSKC projected it would meet this standard in year 2017 with all 12 stations operational. The department concludes **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.

PSKC currently provides health care services to residents of Washington State, including low-income, racial and ethnic minorities, handicapped and other underserved groups. To determine whether all residents of Snohomish County ESRD planning area #2 would have access to an applicant's proposed services, the department requires applicants to provide a copy of its current or proposed admission policy.

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 any assurances regarding access to treatment. The admission policy must also include language to ensure all residents of the service area would have access to 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.

To demonstrate compliance with this sub-criterion, PSKC provided a copy of its Administrative Policy and Patient Admission Procedure used at its dialysis centers. The two policies outline the process and guidelines that PSKC uses to admit patients for treatment at the dialysis center. The policies also states that any patient needing treatment will be accepted to any facility without regard to race, creed, color, age, sex, or national origin. [Source: Supplemental Information received June 10, 2013, Attachment 1]

The department uses the facility's Medicaid eligibility or contracting with Medicaid to determine whether low-income residents would have access to the proposed services. PSKC currently provides services to Medicaid eligible patients at its existing dialysis centers. The applicant intends to continue to provide services to Medicaid patients at in PSKC-Monroe. A review of the anticipated revenue sources indicates that the new facility would receive Medicaid reimbursements. [Source: Application, Page12]

The department uses the facility's Medicare certification to determine whether the elderly would have access or continue to have access to the proposed services. PSKC currently provides services to Medicare eligible patients at its existing dialysis centers. PSKC intends to continue to provide services to Medicare patients in PSKC-Monroe. A review of the anticipated revenue sources indicates that the new facility would receive Medicare reimbursements. [Source: Application, Page12]

A facility's charity care policy should confirm that all residents of the service area including low-income, racial and ethnic minorities, handicapped and other underserved groups have, or would have, access to healthcare services of the applicant. The policy should also include the process one must use to access charity care at the facility.

PSKC demonstrated its intent to continue to provide charity care to patients receiving treatment at its facilities by submitting its current Administrative Procedure and Financial Department Procedure that outline the process one would use to access this service. PSKC also included a ‘charity care’ line item as a deduction from revenue within the pro forma income statements documents for the new PSKC-Monroe facility. [Source: Application, Exhibit 11 and Supplemental information received June 10, 2013 and Attachment 1]

Based on the information presented, the department concluded that residents of the planning area would have access to healthcare services at the proposed PSKC-Monroe. **This sub-criterion is met.**

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

Based on the source information reviewed and provided the applicant agree to the conditions stated in the ‘conclusion’ section of this evaluation, the department determines that Puget Sound Kidney Centers project has met the financial feasibility criteria in WAC 246-310-220.

(1) The immediate and long-range capital and operating costs of the project can be met.

WAC 246-310 does not contain specific WAC 246-310-220(1) financial feasibility criteria as identified in WAC 246-310-200(2)(a)(i). There are also no known recognized standards as identified in WAC 246-310-200(2)(a)(ii) and (b) that directs what the operating revenues and expenses should be for a project of this type and size. Therefore, using its experience and expertise the department evaluates if the applicant’s pro forma income statements reasonably project the proposed project is meeting its immediate and long-range capital and operating costs by the end of the third complete year of operation.

As stated in the project description portion of this evaluation, if this project is approved, PSKC anticipates that the new stations would become operational by April 2014. Under this timeline, calendar year 2015 would be the first full calendar of operation and years 2016 and 2017 would be the second and third year. PSKC provided its projected revenue and expense statement for the proposed dialysis center. The table below summarizes that information. [Source: Application Exhibit 11]

Table 4
PSKC-Monroe Dialysis Center
Projected Revenue and Expenses for Full Years 2014-2017

	Partial Year 2014	Year 1 2015	Year 2 2016	Year 3 2017
# of Stations	12	12	12	12
# of Treatments [1]	5,026	10,450	11,656	12,427
# of Patients [2]	50	55	60	64
Utilization Rate [2]	4.17	4.58	5.00	5.33
Net Patient Revenue[1]	\$1,453,060	\$2,608,975	\$2,888,838	\$3,051,103
Total Operating Expenses [1, 3]	\$1,302,164	\$2,315,773	\$2,468,563	\$2,572,882
Net Profit or (Loss)[1]	\$150,896	\$293,202	\$420,275	\$478,221

[1] Includes both in-center and home dialysis patients; [2] in-center patients only; [3] includes bad debt, charity care and allocated costs.

The 'Net Revenue' line item is gross revenue minus any deductions for charity care, bad debt, and contractual allowances. The 'Total Expenses' line item includes salaries and wages, depreciation, and allocated costs for PSKC- Monroe. As shown in Table 4, at the projected volumes identified in the application, PSKC anticipates that the 12-station facility would be operating at a profit in each of the forecast years. PSKC provided an executed statutory warranty deed titled to demonstrate ownership of the property where the proposed dialysis facility would be located. The warranty deed was executed on October 6, 2011. [Source: Application, Exhibit 7]

PSKC provided a copy of its medical director's services agreement for the proposed dialysis center. The agreement is between The Puget Sound Kidney Centers (The Centers) and Emily Huang, MD. The agreement became effective on August 1, 2013, and remains in effect until December 31, 2018. The agreement identifies the annual compensation for the medical director position. Additionally, PSKC's pro-forma financial statement also confirms the annual compensation for the medical director. [Source: Application, Exhibits 2 and 11] Based on the information reviewed, the department concludes **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 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.

The capital expenditure associated with the establishment of 12-station PSKC-Monroe is \$5,946,783. Below is a breakdown of the capital expenditure. [Source: Application, page 29]

Table 5
PSKC-Monroe Capital Cost

Item	Cost	% of Total
Land Improvement and Construction	\$4,438,238	74.6%
Fixed and Moveable Equipment	\$533,558	9.0%
Architect & Engineering	\$939,987	15.8%
Interim Loan Interest	\$25,000	0.6%
Total Project Cost	\$5,946,783	100%

To further demonstrate compliance with this sub-criterion, PSKC provided the sources of its revenue by payer expected at the facility shown in the table on page 12. [Source: April 23, 2013, Supplemental information, Page 4]

Table 6
PSKC-Monroe Source of Patient Revenue

Revenue Source	% of Revenue
Medicare	67%
Medicaid	7%
Medicare Managed Care	13%
Other	13%
Total	100%

The proposed PSKC-Monroe is expected to have 87% of its revenue from Medicare and Medicaid, and Medicare Managed care and the remaining 13% for commercial insurance/HMO. The department concludes that the majority of kidney dialysis revenue is dependent upon entitlement sources that are not cost based reimbursement. Therefore, PSKC’s expectation that will realize majority of its revenue from Medicare and Medicaid is reasonable. The department does not expect the anticipated revenue source to have an unreasonable impact on charges for services.

Based on the information provided, the department concludes that the costs of this project would not result in an unreasonable impact to the costs and charges for health care services. **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.

The capital expenditure associated with the establishment of the 12-station PSKC-Monroe is \$5,946,783. PSKC intends to debt finance up to \$4,000,000 and use cash reserves for the remaining \$1,946,783. PSKC provided a letter from the chair of its board of directors confirming that funding is available. [Source: Supplemental information received June 10, 2013, Attachment 4] Based on the information provided, the department concludes **this sub-criterion is met.**

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

Based on the source information reviewed and provided the applicant agree to the conditions stated in the ‘conclusion’ section of this evaluation, the department determines that PSKC project has met the structure and process (quality) 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 FTEs (full time equivalents) that should be employed for projects of this type or size.

Since PSKC-Monroe would be a new facility, PSKC provided a breakdown of all proposed staff beginning with partial year 2014 through year three (2017). [Source: Application, page 32] A breakdown of the proposed staffing is summarized below.

Table 7
PSKC-Monroe proposed FTE's Year 2014 – 2016

Staff/FTEs	Partial Year 2014	Year 1-2015 Increase	Year 2-2016 Increase	Year 3-2017 Increase	Total FTEs
Medical Director	Professional Services Contract				
Direct Care Manager	1.00	0.00	0.00	0.00	1.00
Home Registered Nurse	0.35	0.10	0.10	0.10	0.65
Registered Nurses	2.00	0.00	1.00	0.00	3.00
Technicians	6.00	0.75	0.75	0.60	8.10
ReUse/Stock Tech	2.00	0.00	0.00	0.00	2.00
Re-Use Tech	0.25	0.00	0.00	0.00	0.25
Lab Tech	0.25	0.00	0.00	0.00	0.25
Computer Tech	0.10	0.00	0.00	0.00	0.10
Social Worker	0.40	0.05	0.05	0.00	0.50
Dietitian	0.50	0.05	0.05	0.05	0.65
Secretary	0.20	0.00	0.00	0.00	0.20
Office Clerk	0.30	0.00	0.00	0.00	0.30
Total FTEs	13.35	0.95	1.95	0.75	17.00

As shown above, PSKC expects to open the facility with 13.35 FTEs and increase staffing as the utilization increases through year 2017. PSKC states it does not anticipate any difficulty recruiting staff because many staff have expressed interest in relocating to PKSC-Monroe. [Source: Application Page 33]

PSKC identified Emily Huang, M.D. to provide medical director coverage for the proposed facility and provided a copy of the executed medical director's agreement. The agreement outlines the roles and responsibilities of the clinic doctors and the PSKC facility. The agreement identifies the term and annual compensation for the medical director services. [source: Application, Exhibit 2] Based on information, the department concluded adequate staffing is available or can be recruited. **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.

Information provided in the application indicates that PSKC currently maintains relationships with the necessary facilities for hospital care and support services for its existing dialysis centers. PSKC provided a listing of the facilities with whom it has existing relationships. Ancillary and support services, such as social services, nutrition services, patient and staff education, financial counseling, material management, administration, and technical services would be provided through staff located at the proposed the facility. [Source: Application, pages 33-34]

PSKC provided a copy of its executed transfer agreement with Providence Everett Medical Center. The document outlines the responsibilities and expectations for PSKC's patients needing transfer to the hospital. Based on the information, the department concludes that PSKC is likely to extend their current relationships with ancillary and support services to include the proposed facility **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 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.

As stated earlier, PSKC is currently a provider of dialysis services within Washington State. As part of its review, the department must conclude that the proposed services would be provided in a manner that ensures safe and adequate care to the public.⁵

Since January 2010, the Department of Health's Investigations and Inspections Office (IIO) has completed four compliance surveys for PSKC facilities in operation. Of the compliance surveys completed, all revealed minor non-compliance issues related to care and management. These non-compliance issues are typical of a dialysis facility and PSKC submitted and implemented acceptable plans of correction. [Source: Compliance history provided by IIO facility files]

PSKC identified Emily Huang, M.D. as the medical director for the proposed PSKC-Monroe. A review of the compliance history for Dr. Huang did not revealed any recorded sanctions. Based on the compliance history of PSKC and the medical director, the department concludes that there is reasonable assurance that the proposed facility would be operated in compliance with state and federal regulations. **This sub-criterion is met.**

⁵ WAC 246-310-230(5).

- (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.

The department considered PSKC's history of providing care to residents in Washington State. The department concludes that the applicant has been providing dialysis services to the residents of Washington State for several years and has been appropriately participating in relationships with community facilities to provide a variety of medical services. Nothing in the materials reviewed by staff suggests that approval of this project would change these relationships. [Source: Application Page 34; CN historical files]

Base on the information, the department conclude that approval of this project would promote continuity in the provision of health care for the planning area, and would not result in an unwarranted fragmentation of services. **This sub-criterion is met.**

- (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.

For this project, this sub-criterion is addressed in sub-section (3) above and **is considered met**

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

Based on the source information reviewed and provided the applicant agree to the conditions stated in the 'conclusion' section of this evaluation, the department determines that PSKC's project 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 the project failed to meet one or more of these criteria then it is determined, it's not the best alternative, and would fail this sub-criterion.

If the project met WAC 246-310-210 thru 230 criteria, the department would move to step two in the process and assess the other options the applicant or applicants considered prior to submitting the application under review. If the department determines the proposed project is better or equal to other options the applicant considered before submitting their application, the determination is either made that this criterion is met (regular or expedited reviews), or in the case of projects under concurrent review, move on to step three.

Step three of this assessment is to apply any service or facility specific criteria (tiebreaker) contained in WAC 246-310. The tiebreaker criteria are objective measures used to compare competing projects and make the determination between two or more equally approvable projects, which is the best alternative. If WAC 246-310 does not contain any service or facility criteria as directed by WAC 246-310-200(2) (a) (i), then the department would look to WAC 246-310-240(2) (a) (ii) and (b) for criteria to make the assessment of the competing proposals. If there are no known recognized standards as identified in WAC 246-310-200(2) (a) (ii) and (b), then using its experience and expertise, the department would assess the competing projects and determine which project should be approved.

Step One

PSKC proposed to establish a new 12-station kidney dialysis facility by relocating existing stations to a new site in Snohomish County planning area #2. The department concludes that the project met the review criteria under WAC 246-310-210, 220, and 230. Therefore, the department moves to step two below.

Step Two

Before submitting this application, PSKC considered two alternatives besides the project. The alternatives considered are summarized below. [Source: Application, Page 36]

- Waiting until DaVita Everett reached 80% utilization before requesting stations at PSKC Everett; and
- Do nothing.

PSKC stated it rejected the options above because neither would improve access to dialysis services for patients who reside in eastern Snohomish County planning area #2. PSKC stated it waited two years for DaVita Everett to reach 80%, but the facility is yet to reach 80% utilization. Therefore, PSKC rejected these options and submitted an application.

Departments Evaluation

Given the options considered by PSKC, and because this application is proposing to relocate existing stations within the planning area, the department did not identify any other alternative to the ones proposed by the applicant. The department concludes the project described is the applicant best available alternative. **This sub-criterion is met.**

Step Three

This step is used to determine the best available alternative between two or more approvable projects. There was no other project submitted in Snohomish County ESRD planning area #2 during Review Cycle #1. Therefore, this step is not applicable to the project.

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

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

WAC 246-310 does not contain specific WAC 246-310-240(2)(a) criteria as identified in WAC 246-310-200(2)(a)(i). There are known minimum building and energy standards that healthcare facilities must meet to be licensed or certified to provide care. If built to only the minimum standards all construction projects could be determined to be reasonable. However, the department, through its experience knows that construction projects are usually built to exceed these minimum standards. Therefore, the department considered information in the applications that addressed the reasonableness of their construction projects that exceeded the minimum standards.

PSKC states it has 32 plus years history of developing and operating dialysis facilities. Information provided within the application states PSKC owns the proposed site and would use debt-financing loan to finance the facility construction costs. The department evaluated the proposed property construction costs under the financial feasibility section of this analysis. In that section of this evaluation, the department concluded, the overall project met the financial feasibility criterion. Based on the information, the department concludes **this sub-criterion is met.**

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

This sub-criterion is evaluated within the financial feasibility criterion under WAC 246-310-220(2). Based on that evaluation, the department concludes **this sub-criterion is met.**

APPENDIX A



2011
Pierce County 4
ESRD Need Projection Methodology

Planning Area	6 Year Utilization Data - Resident Incenter Patients					
Pierce Four	2005	2006	2007	2008	2009	2010
98402	7	10	7	8	8	6
98403	11	10	11	14	14	13
98404	40	43	47	52	52	53
98405	38	41	40	36	40	40
98406	9	7	12	11	12	11
98407	14	12	13	12	13	18
98408	37	44	36	38	25	27
98409	31	28	26	25	31	38
98416	0	0	0	0	0	0
98418	8	15	15	15	17	20
98421	0	0	0	1	0	0
98422	8	11	12	14	17	20
98424	1	2	4	4	5	10
98443	1	2	4	2	3	3
98465	6	3	6	8	3	3
98466	19	20	27	23	21	25
TOTALS	230	248	260	263	261	287

246-310-284(4)(a)	Rate of Change	7.83%	4.84%	1.15%	-0.76%	9.96%
	6% Growth or Greater?	TRUE	FALSE	FALSE	FALSE	TRUE
	Regression Method:	Linear				

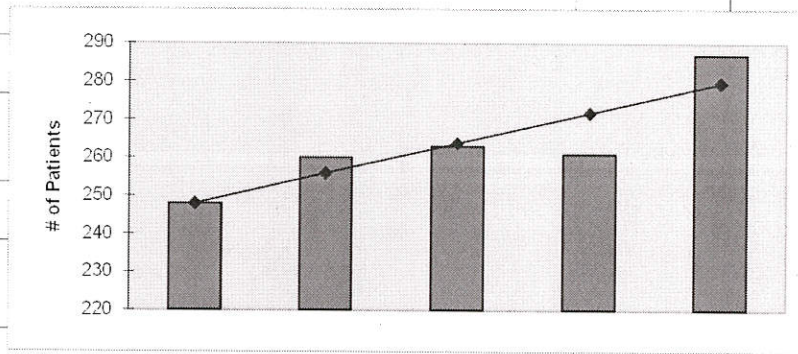
246-310-284(4)(c)		Year 1	Year 2	Year 3	Year 4
		2011	2012	2013	2014
Projected Resident Incenter Patients	from 246-310-284(4)(b)	287.50	295.40	303.30	311.20
Station Need for Patients	Divide Resident Incenter Patients by 4.8	59.8958	61.5417	63.1875	64.8333
	Rounded to next whole number	60	62	64	65

246-310-284(4)(d)	subtract (4)(c) from approved stations				
Existing CN Approved Stations		63	63	63	63
Results of (4)(c) above	-	60	62	64	65
Net Station Need		3	1	-1	-2
Negative number indicates need for stations					

246-310-284(5)			
Name of Center	# of Stations	Patients	(Patients per Station)
DaVita - Tacoma	13	60	4.62
St. Joseph Eastside	12	0	0.00
St. Joseph Medical Cent	38	257	6.76
Total	63	257	

Source: Northwest Renal Network data 2005-2010
 Most recent year-end data: 2010 year-end data as of 02/16/2011
 Most recent quarterly data as of the 1st day of application submission period: 4th quarter 2010 as of 02/16/2010

x	y	Linear
2006	248	248
2007	260	256
2008	263	264
2009	261	272
2010	287	280
2011		287.50
2012		295.40
2013		303.30
2014		311.20



SUMMARY OUTPUT

Regression Statistics	
Multiple R	0.877344628
R Square	0.769733596
Adjusted R Square	0.692978129
Standard Error	7.888810641
Observations	5

ANOVA

	df	SS	MS	F	Significance F
Regression	1	624.1	624.1	10.02838779	0.050606659
Residual	3	186.7	62.23333333		
Total	4	810.8			

	Coefficients	Standard Error	t Stat	P-value	Lower 95%	Upper 95%	Lower 95.0%	Upper 95.0%
Intercept	-15599.4	5009.280461	-3.114099943	0.052712939	-31541.16609	342.3660942	-31541.16609	342.3660942
X Variable 1	7.9	2.494660966	3.166762983	0.050606659	-0.039124572	15.83912457	-0.039124572	15.83912457

RESIDUAL OUTPUT

Observation	Predicted Y	Residuals
1	248	0
2	255.9	4.1
3	263.8	-0.8
4	271.7	-10.7
5	279.6	7.4