

STATE OF WASHINGTON DEPARTMENT OF HEALTH

October 25, 2012

CERTIFIED MAIL # 7011 1570 0002 7809 5414

Jeff Lehman
Executive Director
Olympic Peninsula Kidney Center
2613 Wheaton way
Bremerton, WA 98310

RE: CN 12-25

Dear Mr. Lehman:

We have completed review of the Certificate of Need (CN) application submitted by Olympic Peninsula Kidney Center posing to establish a four station kidney dialysis facility in the city of Bremerton in Kitsap County. 'For the reasons stated in the enclosed decision, the department has concluded that the project as described below is consistent with the applicable CoN review criteria. The Department is prepared to issue a CoN for this project provided Olympic Peninsula Kidney Center agrees to the following in its entirety:

Project Description:

This certificate approves the establishment of dialysis facility known as OPKC Care Coordination Unit. OPKC Coordination Unit is approved to certify and operate a maximum of four stations. The four dialysis stations will be transferred from the OPKC-Bremerton facility. At project completion OPKC-Bremerton will be approved to certify and operate a maximum of 15 stations. Services to be provided at the OPKC Care Coordination Unit include in-center hemodialysis, nocturnal in-center hemodialysis, home dialysis orientation, training, and support, and backup hemodialysis for home dialysis patients. The station breakdown for the two affected facilities is listed below:

Care Coordination Unit	Count
Isolation Room stations	1
Hemodialysis stations	3
Total	4

OPKC - Bremerton	Count
Home Training stations	2
Hemodialysis stations	13
	15

Conditions:

1. Approved project description as described above. OPKC 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.



Jeff Lehman Executive Director Olympic Peninsula Kidney Center October 25, 2012 Page 2 of 3

- 2. OPKC will provide the Department with an executed copy of the Medical Director Agreement that is consistent with the draft agreement provided within the application for department review and approval prior to commencement of services.
- 3. OPKC will provide the Department with an updated copy of the Transfer Agreement that consistent with the current agreement provided within the application for department review prior to commencement of services.

All OPKC Facilities Condition

- 4. OPKC agrees that if the department, during future application reviews, finds that:
 - a. An OPKC facility is operating or certified for more than the Certificate of Need approved stations, the department will require OPKC to immediately cease operating the un-approved stations. The department may, at its discretion, notify the applicable certifying authority. OR
 - b. An OPKC facility is certified for fewer than the Certificate of Need approved stations, the department will interpret this as a voluntary relinquishment of the stations. The number of approved stations for that facility will be reduced by the number equaling the difference between the Certificate of Need approved stations and the certified amount. For example:

CN Approved Stations	Facility Certified Stations	Difference	New CN Approved Stations for Facility
10	6	4	6

Approved Costs:

The approved capital expenditure associated with this project is \$542,580.

You have two options, either accept or reject the above in its entirety. If you accept the above in its entirety, your application will be approved and a Certificate of Need sent to you. If you reject any provision of the above, you must identify that provision, and your application will be denied because approval would not be consistent with applicable Certificate of Need review criteria. Please notify the Department of Health within 20 days of the date of this letter whether you accept the above in its entirety.

Jeff Lehman Executive Director Olympic Peninsula Kidney Center October 25, 2012 Page 3 of 3

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

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,

Steven M. Saxe, FACHE

Director, Health Professions and Facilities

Enclosure

EVALUATION DATED OCTOBER 25, 2012 OF THE CERTIFICATE OF NEED APPLICATION FROM OLYMPIC PENINSULA KIDNEY CENTER PROPOSING TO RELOCATE FOUR EXISTING DIALYSIS STATIONS TO A NEW CARE COORDINATION UNIT IN KITSAP COUNTY

APPLICANT DESCRIPTION

Olympic Peninsula Kidney Centers (OPKC) is a private, non-profit entity that provides dialysis services through three facilities located in Kitsap County. OPKC is governed by a Board of Directors comprised of medical, civic, and business leaders from the community. An appointed executive director and appointed administrator oversee day-to-day operations of OPKC. [source: OPKC Application, p1] Below is a listing of the three existing OPKC facilities in Kitsap County.

Kitsap

OPKC-Bremerton OPKC-Poulsbo

OPKC-Port Orchard (South Kitsap)

PROJECT DESCRIPTION

OPKC proposes to relocate four dialysis stations from the existing OPKC – Bremerton facility to a new Care Coordination Unit. The new facility will be located at 2740 Clare Avenue in the city of Bremerton, within Kitsap County. The dialysis center would serve the residents of Kitsap County. Services expected to be provided at the Care Coordination Unit include new patient hemodialysis orientation, in-center hemodialysis back-up for home dialysis patients, nocturnal (overnight) in-center hemodialysis, home dialysis training, and support. The facility drawings show space for four dialysis stations, a hemodialysis training area, two other training rooms, and an isolation room. At project completion the OPKC - Bremerton will operate as a 15 station dialysis facility. [source: Application, pp6, 63]

The capital expenditure associated with the Care Coordination Unit is \$542,580. Of that amount 44% is related to construction; 41% for fixed/moveable equipment; and the remaining 15% is related to applicable fees and taxes. [source: Application, p26]

If this project is approved, OPKC anticipates that the stations would be operational by the end of 2013. Under this timeline, year 2014 would be the facility's first full calendar year of operation and 2016 would be year three. [source: Application, p15]

APPLICABILITY OF CERTIFICATE OF NEED LAW

The project is subject to Certificate of Need review as the establishment of a new healthcare 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.

EVALUATION CRITERIA

WAC 246-310-200(1)(a)-(d) identifies the four determinations that the department must make for the application. WAC 246-310-200(2) provides additional direction in 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 the 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 and must be used to make the required determinations.

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). WAC 246-310-280 through 284 contain kidney dialysis specific criteria used to demonstrated compliance with the applicable general need, financial feasibility, structure and process of care, and cost containment.¹

¹ Each criterion contains certain sub-criteria. The following sub-criteria are not discusse0d in this evaluation because they're not relevant to this project: WAC 246-310-210(3), (4), (5), and (6); WAC 246-310-240(3), and WAC 246-310-286, 287, and 288.

APPLICATION CHRONOLOGY

Action	OPKC
Letter of Intent Submitted	January 31, 2012
Application Submitted	February 29, 2012
Department's pre-review Activities including screening and	March 1, 2012
responses	through May 17, 2012
Beginning of Review • public comments accepted throughout review (no public comments were submitted)	May 18, 2012
End of Public Comment	June 22, 2012
Department's Anticipated Decision Date	August 9, 2012
Department's Actual Decision Date	October 25, 2012

TYPE OF REVIEW

As directed under WAC 246-310-282(1) the department accepted this project under the Kidney Disease Treatment Centers-Concurrent Review Cycle #1. No other kidney disease treatment center applications were reviewed for the Kitsap County during the cycle. Therefore, as allowed under WAC 246-310-282(5), this application was converted to a regular review.

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."

Throughout the review of this project, no entities sought or received affected person status under WAC 246-310-010(2).

SOURCE INFORMATION REVIEWED

- Olympic Peninsula Kidney Centers' Certificate of Need application submitted February 29, 2012
- Olympic Peninsula Kidney Centers' supplemental information dated May 14, 2012
- Years 2005 through 2010 historical kidney dialysis data obtained from the Northwest Renal Network
- Year 2011 Northwest Renal Network 3rd Quarter Utilization Data
- Licensing and/or survey documents provided by the Department of Health's Investigations and Inspections Office
- Data obtained from Medicare compare webpage (www.medicare.gov)
- Certificate of Need historical files
- Department of Health / Health Systems Quality Assurance Provider Credential Information

AUTHORIZED STATIONS DETERMINATION –OPKC BREMERTON

OPKC identifies the Bremerton facility as being a 19 station facility. On April 8, 1991 the department issued CN#1042 to add four maintenance (in-center) stations and one home training station. This approval brought the total to 15 stations (14 in-center and one home training). On March 26, 1996 the department issued CN#1144 to OPKC to add two in-center stations and two home training stations to its Bremerton facility. According to the evaluation's project description it states, "These four stations will increase the number of outpatient stations from 13 to 15 and the number of home training stations from two to four. At project completion, the total number of kidney dialysis stations at Olympic Peninsula Kidney Center will be 19." On October 6, 2003 the department issued CN#1273 to OPKC to increase the number of stations at its South Kitsap facility. That CN carried a condition identifying the number and type of stations at the Bremerton facility as well as at the South Kitsap facility. The condition as it relates to the Bremerton facility is as follows:

Type	Number of Stations		
Hemodialysis	16		
Training	3		
Total	19		

This condition was necessary because OPKC had not been operating the Bremerton or the OPKC South Kitsap facility in compliance with this Certificate of Need approval. On January 27, 2009 the department issued an exemption for OPKC Bremerton to relocate all its stations from its then existing site of 2740 Clare Avenue to a new location at 2613 Wheaton Way. In that request it was represented to the department that 19 stations were Medicare certified.

During the course of this review the department identified that the total number of stations CMS recognizes as being certified is 18. The department reviewed its records and found that since 2007, Medicare survey applications submitted by OPKC identify a total of 18 stations. OPKC claims its applications to CMS contained an error and that the correct number should be 19. Even though the department finds this debatable the department will count 19 stations at the Bremerton facility. However, since there appears to be pattern of operating its facilities outside its Certificate of Need approval, if this project is approved, a condition would be necessary that impact all of OPKC's facilities. This condition is also necessary because the floor plan submitted for this current project includes station capacity for seven.

CONCLUSION

For the reasons stated in this evaluation, the application submitted by Olympic Peninsula Kidney Centers proposing to relocate four dialysis stations to a Care Coordination Unit from the existing OPKC – Bremerton facility is consistent with applicable criteria of the Certificate of Need Program, provided Olympic Peninsula Kidney Centers agrees to the following in its entirety:

Project Description:

This certificate approves the establishment of dialysis facility known as OPKC Care Coordination Unit. OPKC Coordination Unit is approved to certify and operate a maximum of four stations. The four dialysis stations will be transferred from the OPKC-Bremerton facility. At project completion OPKC-Bremerton will be approved to certify and operate a maximum of 15 stations. Services to be provided at the OPKC Care Coordination Unit include in-center hemodialysis, nocturnal in-center hemodialysis, home dialysis orientation, training, and

support, and backup hemodialysis for home dialysis patients. The station breakdown for the two affected facilities is listed below:

Care Coordination Unit	Count
Isolation Room stations	1
Hemodialysis stations	3
Total	4

OPKC - Bremerton	Count
Home Training stations	2
Hemodialysis stations	13
	15

Conditions:

- 1. Approved project description as described above. OPKC 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. OPKC will provide the Department with an executed copy of the Medical Director Agreement that is consistent with the draft agreement provided within the application for department review and approval prior to commencement of services.
- 3. OPKC will provide the Department with an updated copy of the Transfer Agreement that consistent with the current agreement provided within the application for department review prior to commencement of services.

All OPKC Facilities Condition

- 4. OPKC agrees that if the department, during future application reviews, finds that:
 - a. An OPKC facility is operating or certified for more than the Certificate of Need approved stations, the department will require OPKC to immediately cease operating the un-approved stations. The department may, at its discretion, notify the applicable certifying authority. OR
 - b. An OPKC facility is certified for fewer than the Certificate of Need approved stations, the department will interpret this as a voluntary relinquishment of the stations. The number of approved stations for that facility will be reduced by the number equaling the difference between the Certificate of Need approved stations and the certified amount. For example:

CN Approved Stations	Facility Certified Stations	Difference	New CN Approved Stations for Facility
10	6	4	6

Approved Costs:

The approved capital expenditure associated with this project is \$542,580.

CRITERIA DETERMINATIONS

A. Need (WAC 246-310-210)

Based on the source information reviewed and the applicant's agreement to the conditions identified in the 'Conclusion' section of this evaluation, the department concludes Olympic Peninsula Kidney Centers' project has met the need criteria in WAC 246-310-210(1) and (2).

(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 centers 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 under WAC 246-310-284(4). WAC 246-310-210(1) criteria is also identified in WAC 246-310-284(5) and (6).

Kidney Disease Treatment Center Methodology WAC 246-310-284

WAC 246-310-284 contains the methodology for projecting numeric need for <u>new</u> dialysis stations within a planning area. In this application, OPKC is proposing to take a portion of previously CN approved stations and relocate them within a new facility away from their current location, but within the same planning area. If approved, the project will not increase the number of CN approved dialysis stations in the planning area. OPKC states, "no new stations are proposed as part of this project." Therefore, no station need was calculated by OPKC for Kitsap County. [source: Application, p15] The department agrees that this project is not proposing to add any <u>new</u> stations to the planning area. Therefore, the numeric need portion of the methodology does not apply to this project.

WAC 246-310-284(1) states that applications for <u>new stations</u> may only address projected station need in the planning area in which the facility is to be located. This project is a new health care facility because it is taking a portion of the approved stations from an existing facility and creating another facility. [WAC 246-310-289(2)] As stated earlier the stations being used to create this new facility are not new to the planning area. Therefore this portion of the need methodology also does not apply 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 incenter patients per station before <u>new</u> stations can be added. In addition to the Care Coordination Unit, OPKC operates the Bremerton in the Kitsap County planning area. 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, 2012. [WAC 246-310-282] The quarterly modality report from NRN available at that time was September 30, 2011, which became available on November 15, 2011. The table below shows the utilization at that time.

Table 1 September 30, 2011 - Facility Utilization Data

Facility Name	# of Stations	# of Pts	Pts/Station
OPKC - Bremerton	19	97	5.11
OPKC - South	11	47	4.27
OPKC - North	8	31	3.88

As indicated above, the OPKC North and South facilities are currently operating below the minimum utilization standard of 4.8 patients per approved station. On first impression this would suggest that this standard is not met and therefore the proposed project should fail this standard. However on closer review of the standard it states that all CN approved stations within the planning must be at the applicable utilization standard before new stations are added to the planning area. The stations involved in this project are already CN approved and located within the planning area. Since the project does not propose to add any new stations to the planning area the department concludes that this sub-criterion is not applicable this project.

WAC 246-310-284(6)

WAC 246-310-284(6) requires new in-center dialysis stations be operating at a required number of in-center patients per approved station by the end of the third full year of operation. For Kitsap County, the requirement is 4.8 in-center patients per approved station. [WAC 246-310-284(6)(a)] As a result, the applicant must demonstrate compliance with this criterion using the 4.8 in-center patient per station.

Although these are not new stations to the planning area, OPKC provided projections for the new facility. OPKC anticipates the new stations would become operational by the end of June 2013. Under this timeline, 2014 would be the facility's first full year of operation and 2016 would be year three. A summary of the applicant's projected utilization for the third year of operation is shown below. [source: Application, p16]

Table 2
Third Year Projected Facility Utilization

Facility Name	Year 3	# of Stations	# of Pts	Pts/Station
OPKC - Care Coordination Unit	2016	4	21	5.25

Based on the above standards and criteria, the project is consistent with applicable criteria of the Certificate of Need Program. **This sub-criterion is met**.

(2) <u>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.</u>

OPKC currently provides health care services to residents of Washington State through three existing dialysis facilities in Kitsap County.

To determine whether all residents of the Kitsap County service area 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.

To demonstrate compliance with this sub-criterion, OPKC provided a copy of its current Patient Admission Policy that is used in their current facilities and would be in affect at the additional facility. The policy outlines the process/criteria that the Care Coordination Unit will use to admit patients for treatment, and ensures that patients will receive appropriate care. The policy also states that all patients with end stage renal disease needing chronic hemodialysis will be considered for treatment at the facility without regard to "income, race, sex, or physical or mental limitations". [source: Application, p17 & Exhibit 7]

To determine whether low-income residents would have access to the proposed services, the department uses the facility's Medicaid eligibility or contracting with Medicaid as the measure to make that determination. To determine whether the elderly would have access or continue to have access to the proposed services, the department uses Medicare certification as the measure to make that determination.

OPKC currently provides services to Medicaid eligible patients in each of their dialysis centers. Details provided in the application demonstrate that OPKC intends to maintain this status. A review of the anticipated revenue indicates that the facility expects to continue to receive Medicaid reimbursements. [source: Application, p24]

OPKC currently provides services to Medicare eligible patients in this dialysis center. Details provided in the application demonstrate that OPKC intends to maintain this status. A review of the anticipated revenues indicates that the facility expects to continue to receive Medicare reimbursements. [source: Application, p24]

OPKC demonstrated its intent to provide charity care to Kitsap County residents by submitting the Charity policy currently used in their existing facilities and would used at the proposed facility. It outlines the process one would use to access services when they do not have the financial resources to pay for required treatments. OPKC also included a 'charity' line item as a deduction from revenue within the pro forma income statements for each proposed facility. [source: May 14, 2012 Supplemental Information, p12]

The department concludes that all residents of the service area would have adequate access to the health services. **This sub-criterion is met**.

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

Based on the source information reviewed and the applicant's agreement to the conditions identified in the 'Conclusion' section of this evaluation, the department concludes that Olympic Peninsula 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.

OPKC anticipates the new stations at the Care Coordination Unit will become operational before the end of 2013. Based on this timeline, fiscal year 2014 would be the facility's first full year of operation. Using the financial information provided as part of the completed application, the table below illustrates the projected revenue, expenses, and net income for 2014 through 2016 for the Care Coordination Unit. [source: May 14, 2012 Supplemental Information, p21]

Table 3
OPKC - Care Coordination Unit
Projected Revenue and Expenses Calendar Years 2014 - 2016

	FY 1 - 2013	FY 2 - 2014	FY 3 - 2015
# of Stations	4	4	4
# of Treatments [1]	2,025	2,625	3,225
# of Patients [1]	13	17	21
Utilization Rate [1]	3.23	4.20	5.15
Net Patient Revenue [1,2]	\$ 2,032,410	\$ 2,442,479	\$ 2,840,828
Total Operating Expense [1]	\$ 1,611,899	\$ 1,761,836	\$ 1,914,995
Net Profit or (Loss) [1]	\$ 420,511	\$ 680,643	\$ 925,833

^[1] Includes in-center patients only; [2] includes bad debt, charity care and allocated costs

As shown above, at the projected volumes identified in the application, OPKC anticipates that the Care Coordination Unit would be operating at a profit in each of the forecast years.

OPKC currently owns the building that will be used to house the relocated stations. The site address is 2740 Clare Avenue in the city of Bremerton. There is no rent costs associated with the proposed location, but building maintenance, utilities, and other facility costs are substantiated in the pro forma financial documents presented. [source: Application, p1 & Exhibit 6; May 14, 2012 Supplemental Information, p15]

Additionally, OPKC provided a draft copy of the Medical Director Agreement between itself and George Evanhoff, M.D. The medical director service costs are included in the pro forma documents. If approved, the department will add a condition requiring OPKC to provide the Department with an executed copy of the Medical Director Agreement that is consistent with the draft agreement provided within the application for department review and approval prior to commencement of services. [source: Application, p34]

Based on the above information, and acceptance of the stated condition, the department concludes that OPKC's projected revenues and expenses are reasonable and can be substantiated. **This subcriterion is met**.

(2) <u>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.</u>

WAC 246-310 does not contain specific WAC 246-310-220(2) 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 an unreasonable impact on costs

and charges would be for a project of this type and size. Therefore, using its experience and expertise the department compared the proposed project's costs with those previously considered by the department.

The capital expenditure associated with the expansion of the Care Coordination Unit is \$542,580 of which 44% is related to construction costs; 41% for additional equipment; and the remaining 15% is related to fees & taxes. The capital cost breakdown is shown below. [source: Application, p26]

Table 4
Estimated Capitals Costs

Item	Cost	% of Total
Construction	\$ 240,000	44%
Fixed & Moveable Equipment	\$ 221,480	41%
Professional Fees	\$ 43,500	8%
Permits / Sales Tax	\$ 37,600	7%
Total Estimated Capital Costs	\$ 542,580	100%

OPKC intends to finance the project entirely from available board reserves. A review of the financial statement provided indicates that OPKC had sufficient cash reserves and assets in the estimates for 2012 and through each of the forecast years fund the project. [source: May 14, 2012 Supplemental Information, pp15-18]

The department recognizes that the majority of reimbursements for dialysis services are through Medicare ESRD entitlements. To further demonstrate compliance with this sub-criterion, OPKC also provided the sources of patient revenue shown below. [source: Application, p24]

Table 5
OPKC-Care Coordination Unit
Sources and Percentages of Revenue

2				
Source of Revenue	% of Revenue			
Medicare	69%			
Medicaid/State	6%			
Other Insurance	25%			
Total	100%			

As shown above, the Medicare and Medicaid entitlements are projected to equal 75% of the revenue at the Care Coordination Unit. The department concludes that since the majority of revenue is dependent upon entitlement sources that are not cost based reimbursement and are not expected 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 subcriterion 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.

As previously stated, the capital expenditure associated with the expansion of OPKC's Care Coordination Unit is \$542,580. OPKC states that the project will be funded from OPKC's available board reserves. A review of OPKC's statements of financial position show the funds necessary to finance the project are available. [source: May 14, 2012 Supplemental Information, pp15-18]

Based on the information provided, the department concludes that approval of this project would not adversely affect the financial stability of OPKC as a whole. **This sub-criterion is met**.

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

Based on the source information reviewed and the applicant's agreement to the conditions identified in the 'Conclusion' section of this evaluation, the department concludes Olympic Peninsula 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 FTEs that should be employed for projects of this type or size. Therefore, using its experience and expertise the department concludes that the planning would allow for the required coverage.

To staff its Care Coordination Unit, OPKC intends to employ all the necessary staff by the end of 2013. A breakdown of the proposed FTEs is shown is below. [source: Application p25]

Table 6
Projected Total FTEs

110jected 10tai 1 125						
	2013	2014	2015	2016		
Staff/FTEs	Partial Yr.	Total	Total	Total		
Medical Director	F	Professional Services Contract				
Mgr.	1.00	1.00	1.00	1.00		
RNs	2.00	2.00	2.00	2.00		
Patient Care Tech	2.00	2.00	2.00	2.00		
Admin	1.00	1.00	1.00	1.00		
Social Wk	0.35	0.35	0.35	0.35		
Dietician	0.35	0.35	0.35	0.35		
Bio Med	0.10	0.10	0.10	0.10		
Total FTE's	6.80	6.80	6.80	6.80		

As shown, OPKC expects to make all of the necessary hires in the initial partial year of the new unit and will maintain those same staffing levels throughout the forecast years. OPKC states that it plans to staff the facility primarily with existing employees. Further, OPKC expects a need to hire

a minimum number of new employees and that "given OPKC's hiring history and reputation in the community" they anticipate little difficult in filling these few positions. [source: Application, p26]

Based on the information reviewed, the department concludes adequate staffing for the Care Coordination Unit 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) 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 information and transfer agreement provided in the application confirms that OPKC maintains the appropriate relationships with ancillary and support services for its existing facilities. Ancillary and support services are currently offered in each of the existing OPKC facilities and this is expected to continue in the proposed Care Coordination Unit. Relationships with providers in the community currently provide support for pharmacy, lab, and radiology services and are expected to be expanded to include the new unit. If approved, the department will add a condition requiring OPKC to provide the Department with an updated copy of the Transfer Agreement that consistent with the current agreement provided within the application for department review prior to commencement of services. [source: May 14, 2012 Supplemental Information, Attachment 4]

Based on this information, and acceptance of the condition above, the department concludes OPKC has access to the necessary ancillary and support services for the proposed facility. **This subcriterion 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.

As stated earlier, OPKC is currently a provider of dialysis services within Washington State, and operates three kidney dialysis treatment centers in the planning area. 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.²

Since January 2007, the Department of Health's Investigations and Inspections Office has completed two certification and compliance surveys for the facilities that OPKC operates. Of the surveys completed, each revealed minor non-compliance issues related to the care and management of the facilities which required plans of correction. These non-compliance issues were typical of a

² WAC 246-310-230(5).

dialysis facility and the plans of correction were fully implemented. [source: Facility survey data provided by the Investigations and Inspections Office]

For medical director services, OPKC provided a draft copy of the Medical Director Agreement between itself and George Evanhoff, M.D. Dr. Evanhoff is currently credentialed to practice in the State of Washington. Proceedings stemming from allegations made in 2009 did not result in disciplinary actions and Dr. Evanhoff was he was released from the requirements of a Stipulation of Informal Disposition in July, 2011. [source: Health Systems Quality Assurance Provider Credential Information]

Given the compliance history of OPKC, and that of the proposed medical director, the department concludes that there is reasonable assurance that the Care Coordination Unit would operate in compliance with state and federal regulations. **This sub-criterion is met**.

(4) <u>The proposed project will promote continuity in the provision of health care, not result in an unwarranted fragmentation of services, and have an appropriate relationship to the service area's existing health care system.</u>

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 OPKC'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 Kitsap County 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 facility would change these relationships.

This project proposes to transfer previously approved stations and does not add any additional capacity to the planning area. Approval of this project is unlikely to result in an unwarranted fragmentation of services. Further, OPKC demonstrated it is likely to maintain the appropriate relationships to the service area's existing health care system within the planning area. **This subcriterion 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.

This sub-criterion is addressed in sub-section (3) above. **This sub-criterion is met.**

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

Based on the source information reviewed and the applicant's agreement to the conditions identified in the 'Conclusion' section of this evaluation, the department concludes Olympic Peninsula Kidney Centers' project has met the cost containment criteria in WAC 246-310-240 (1) and (2).

(1) <u>Superior alternatives, in terms of cost, efficiency, or effectiveness, are not available or practicable</u>. To determine if a proposed project is the best alternative, the department takes a multi-step approach. <u>Step one</u> 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 met WAC 246-310-210 through 230 criteria, the department would move to <u>step two</u> 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 (tie-breaker) criteria contained in WAC 246-310. The tie-breaker criteria are objective measures used to compare competing projects and make the determination between two or more 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

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

Step Two

Within the application, OPKC identified two alternatives before submitting this application. A summary of each and OPKC's rationale for rejection is below. [source: Application, p29]

Alternative 1-Maintain the status quo at the current facility

OPKC states it ruled out this option because of the organization's goal to improve specialty service programming in the planning area. The conclusion was that he proposed facility will better accommodate these efforts.

Alternative 2-Wait for an opportunity to establish a unit with new stations

OPKC states that this option was considered as a means to establish a facility with specialty programming. But, when the need methodology is considered, the standards are not all in compliance to allow for the approval for additional capacity. Therefore, this option was rejected.

OPKC supports their conclusions by stating that the relocating of stations from the existing Bremerton facility to a uniquely designed specialty facility will "meet the need for these specialty services as well as enhances the efficiency and effectiveness of the other facilities". The department did not identify any other alternatives than those proposed by the applicant. Given the

options considered, the department concludes that the project presented is the best available alternative for the community. **This sub-criterion is met**.

Step Three

OPKC was the only entity who submitted an application to address dialysis service in Kitsap County. As a result, step three is not evaluated under this sub-criterion

- (2) *In the case of a project involving construction:*
 - (a) <u>The costs, scope, and methods of construction and energy conservation are reasonable;</u> 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.

As stated in the project description portion of this evaluation, this project involves construction. This sub-criterion is evaluated within the financial feasibility criterion under WAC 246-310-220(2). **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 also evaluated within the financial feasibility criterion under WAC 246-310-220(2). **This sub-criterion is met**.