

**EVALUATION OF THE CERTIFICATE OF NEED APPLICATION SUBMITTED ON BEHALF OF
PUGET SOUND KIDNEY CENTERS PROPOSING TO ADD TWO DIALYSIS STATIONS TO THE
EXISTING FOUR STATION DIALYSIS CENTER KNOWN AS PSKC-WHIDBEY ISLAND**

PROJECT DESCRIPTION

Puget Sound Kidney Centers (PSKC) is a not-for-profit corporation established in 1980 to serve dialysis patients. Currently, PSKC owns and operates four dialysis facilities in Washington State--three in Snohomish County and one in Island County. The four PSKC facilities are listed below. [source: Application, pp1-2 and CN historical files]

Snohomish	City	# of Stations
Puget Sound Kidney Center,	Everett	37
Puget Sound Kidney Center-South	Mountlake Terrace	27
Puget Sound Kidney Center-Smokey Point	Arlington	18
Island		
Puget Sound Kidney Center-Whidbey Island	Oak Harbor	4

This application relates to Island County facility known as PSKC-Whidbey Island (PSKC-WI). PSKC-WI is located at 430 Southeast Midway Boulevard in the city of Oak Harbor. On December 4, 2003, PSKC submitted an application to establish a six station dialysis center in Oak Harbor. On May 25, 2004, PSKC was issued CN #1284 approving the establishment of four stations, rather than the six requested by PSKC. While executing CN #1284 PSKC shelled in six stations at the dialysis center; however, consistent with CN #1284 only four stations became operational. This project proposes to open the two, shelled-in stations. [source: Application, p6, CN historical files]

In the department's May 24, 2004, approval to establish PSKC-WI, the department reduced the furniture and equipment for the dialysis stations to reflect the costs to equip four stations, rather than six. Given that the facility has already been built to accommodate six stations, the capital expenditure for this project is \$48,000, and is solely related to the furniture and dialysis equipment for the two stations. [source: CN historical files and January 10, 2006, supplemental information, p9]

PSKC anticipates that this project would commence immediately after Certificate of Need approval and all six stations would be operational within 30 days of approval. Under this timeline, year 2007 is the facility's first full calendar year of operation. [source: Application, p8]

APPLICABILITY OF CERTIFICATE OF NEED LAW

This project is subject to Certificate of Need review as the increase in the number of dialysis stations at an existing kidney disease treatment facility under the provisions of Revised Code of Washington (RCW) 70.38.105(4)(h) and Washington Administrative Code (WAC) 246-310-020(1)(e).

CRITERIA EVALUATION

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); 246-310-240 (cost containment); and 246-310-280 (the dialysis station projection methodology and standards).¹

APPLICATION CHRONOLOGY

October 27, 2005	Letter of Intent Submitted ²
November 27, 2005	Application Submitted
November 28, 2005 through January 18, 2006	Department's Pre-Review Activities <ul style="list-style-type: none">• 1st screening activities and responses• 2nd screening activities
January 19, 2006	Department Begins Review of the Application <ul style="list-style-type: none">• public comments accepted throughout review• no public hearing requested or conducted
March 13, 2006	Rebuttal Documents Submitted to Department ³
April 27, 2006	Department's Anticipated Decision Date
April 10, 2006	Department's Actual Decision Date

AFFECTED PERSONS

No entities sought or received affected person status under WAC 246-310-010.

SOURCE INFORMATION REVIEWED

- Puget Sound Kidney Centers' Certificate of Need Application received October 27, 2005
- Puget Sound Kidney Centers' supplemental information dated December 21, 2005, and January 10, 2006
- Historical kidney dialysis data obtained from the Northwest Renal Network
- Licensing and/or survey data provided by the Department of Health's Office of Health Care Survey
- Licensing and/or survey data provided by out of state health care survey programs
- Data obtained from Center for Medicare and Medicaid (CMS) "Dialysis Facility Compare" website (<http://www.medicare.gov/Dialysis/home.asp>).
- Data obtained from the Internet regarding health care providers
- Population data obtained from the Office of Financial Management
- Certificate of Need historical files

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), and (6); and WAC 246-310-240(2) and (3).

² PSKC submitted this Certificate of Need application without a valid letter of intent, therefore, consistent with WAC 246-310-080(3) the application was held for the 30-day letter of intent period before being considered a submitted application.

³ Given that no comments were provided in opposition to this project, PSKC did not provide rebuttal comments.

CONCLUSION

For the reasons stated in this evaluation, the application submitted on behalf of Puget Sound Kidney Centers proposing to add two dialysis stations to PSKC-WI is consistent with applicable criteria of the Certificate of Need Program, and a Certificate of Need should be issued.

A. Need (WAC 246-310-210)

Based on the source information reviewed, the department determines that the applicant has met the need criteria in WAC 246-310-210(1) and (2) and the kidney disease treatment facility methodology and standards in WAC 246-310-280.

- (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.*

The Department of Health's Certificate of Need Program uses the methodology found in WAC 246-310-280 for projecting numeric need for dialysis stations within a county. Using verified facility utilization information for Island County for the years 2000 through 2004⁴, the department projects the need for dialysis stations to serve the county. In recent evaluations, the department has evaluated need by examining both linear and non-linear projections of the data. One measure of the accuracy of a regression equation is the determinant of regression, or R^2 . R^2 is a value that describes the relation of actual data to the expected values based on the regression analysis of that data. In general, the closer an equation's R^2 value is to one, the more reliable a regression equation is perceived to be. The department concludes that each value to be estimated should be evaluated using both linear and non-linear regression methods and the regression equation deemed more reliable should be used to predict that data element. In some cases, this will be the non-linear equation; in others, the data may be better described by a linear equation. For those values with small and widely varying numbers, such as the numbers of patients trained for home hemodialysis and peritoneal dialysis, both methods tend to return regression equations with very small R^2 values, indicating that neither method returns a particularly reliable result. For this project, the department determined that the more reliable determinant of regression, or R^2 , was non-linear regression projections for the number of patients and linear regression projections for the number of dialyses. Given that PSKC-WI is the only facility operating in Island County and it does not provide dialysis training services, the department does not project the number of training stations in the county.

The first step in performing this regression analysis is to determine the service area of the project. WAC 246-310-010 provides the following definition of the ESRD service area:

“End-stage renal dialysis (ESRD) service areas means each individual county, designated by the department as the smallest geographic area for which kidney dialysis station need projections are calculated, or other service area documented by patient origin.”

PSKC asserts that the service area is Island County. [source: Application, p3] Based on the service area defined above and within PSKC's previous application for the establishment of PSKC-WI, the department concurs that the service area is Island County.

The department's projections for Island County are shown in Table I on the following page. [source: Department's methodology based upon Northwest Renal Network facility utilization data]

⁴ As of the writing of this evaluation, year 2005 data is not yet verified by the data collector--Northwest Renal Network.

Table I
Department's Dialysis Station Projections
for Island County Based on 2000-2004 Historical Data

Year	Projected Stations	Existing Capacity	Net Need
2006	6	(subtract) 4	2
2007	7		3
2008	7		3

As shown in Table I above, the department projects a net need of two dialysis stations in Island County for year 2006, and the need increases to three stations in 2007 through the end of year 2008.

Using the department's methodology as a starting point and patient origin information for years 2000-2004, PSKC provided its dialysis station projections, which are shown in Table II below. [source: December 21, 2005, supplemental information, p4-5]

Table II
PSKC's Dialysis Station Projections for Island County

Year	Projected Stations	Existing Capacity	Net Need
2006	6	(subtract) 4	2
2007	6		2
2008	6		2

As shown in Tables I and II above, the department and PSKC's projections provide similar results. However, PSKC's projections appear to be based solely on the historical number of patients, while the department bases its projections on both historical patients and historical dialyses. The department concludes need for the two stations requested by PSKC is demonstrated by the numeric methodology.

WAC 246-310-280(4) requires that existing dialysis centers that would stand to lose market share by approval of a project must be operating at 80% capacity of a 3-patient shift, per non-training station, per year, before additional stations may be added. As previously stated, PSKC-WI is the only facility operating in Island County. To evaluate this standard for this application, the department reviewed PSKC-WI's historical patient origin zip code data for PSKC-WI. That review reveals that 100% of PSKC-WI patients reside in Island County. [source: Application p10] As a result, there are no facilities in operation to which this standard should be applied.

WAC 246-310-280(5) requires the department to evaluate whether PSKC-WI projects to be operating at 80% utilization (748.8 dialyses per non-training station) by the end of year three as a six station facility. As stated in the project description portion of this evaluation, if this project is approved, PSKC anticipates commencement of this project immediately and all six stations would be operational within 30 days of approval. Under this timeline, 2006 is the facility's first fiscal year of operation, and year 2007 is the facility's first full calendar year of operation. [source: Application, p8] PSKC provided its projected utilization as a six station facility to be 59% in year 2006; 74% in year 2007, and 83% in year 2008. Based on the above information, this sub-criterion is met.

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

To demonstrate compliance with this sub-criterion, PSKC provided a copy of its current admission and charity care policies for PSKC as a whole, which are used by all four PSKC dialysis facilities. [source: Application, Exhibits 16 and 17]

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 document provided outlines the process/criteria that the dialysis center will use to admit patients for treatment. It is intended to ensure that patients will receive appropriate care at the dialysis center. The Admission Policy states that any patient with end stage renal disease needing chronic hemodialysis will be accepted to any PSKC facility without regard to race, color, ethnicity, religious beliefs, political beliefs, or ability to pay. [source: Application, Exhibit 16]

To determine whether low income residents would have access to the dialysis services at PSKC-WI, 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 to the proposed dialysis center, the department uses Medicare certification as the measure to make that determination.

PSKC-WI is currently operating as a Medicare certified dialysis center and intends to maintain this status. A review of PSKC's current Charity Care Policy identifies the facility's financial resources as including both Medicare and Medicaid revenues. Additionally, PSKC also demonstrated its intent to provide charity care to residents by including a 'charity care' line item as a deduction from revenue within the pro forma financial documents. PSKC's intent to provide charity care is also supported within PSKC's historical financial data which also include a charity care line item. [source: Application, Exhibit 17 and January 10, 2006, supplemental information, Revised Exhibit 8, p9]

Based on the above information, the department concludes that PSKC demonstrated that all residents of the service area would have adequate access to the health services at any of its facilities, including PSKC-WI. This sub-criterion is met.

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

Based on the source information reviewed, the department determines that the applicant 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.

As stated in the project description portion of this evaluation, if this project is approved, PSKC anticipates commencement immediately and the additional two stations would be operational within 30 days of approval. Based on this timeline, year 2007 would be the first full year of operation of PSKC-WI as a six-station facility.

For financial review of applications, the department requests data for the first three full years following project completion, which applicants typically provide using calendar years. Within the PSKC-WI application, PSKC provided a full 36 months following project completion, shown in fiscal years. Based on PSKC's financial information, Table III below illustrates the projected revenue,

expenses, and net income for fiscal years ending (FYE) 2006 through 2008. [source: January 10, 2006, supplemental information, p12]

**Table III
PSKC-Whidbey Island
Projected Revenue and Expenses Fiscal Year End 2006-2008**

	FYE 2006	FYE 2007	FYE 2008
# of Stations	6	6	6
# of Treatments	3,288	4,137	4,680
# of Patients	26	27	30
% of Occupancy (rounded)	59%	74%	83%
Net Patient Revenue	\$ 881,152	\$ 1,108,676	\$ 1,254,194
Total Operating Expense	\$ 752,103	\$ 917,184	\$ 1,027,474
Net Profit or (Loss)	\$ 129,049	\$ 191,492	\$ 226,720
Net Patient Revenue/Treatment	\$ 267.99	\$ 267.99	\$ 267.99
Total Operating Exp./Treatment	\$ 228.74	\$ 221.70	\$ 219.55
Net Profit per Treatment	\$ 39.25	\$ 46.29	\$ 48.44

*Includes overhead expense and deductions for bad debt, charity care, and contractual allowances

As shown in Table III above, at the projected volumes identified in the application, as a six-station facility PSKC-WI would be operating at a profit in all three fiscal years of operation. Based on the above information, the department concludes that the project's revenues are reasonable and 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.

There is no construction associated with adding two stations to the existing four station facility; rather the capital expenditure of \$48,000 is solely related to the furniture and dialysis equipment for the two stations. [source: January 10, 2006, supplemental information, p9]

PSKC also provided the sources of patient revenue shown in the chart shown below. [source: Application, p7]

Source of Revenue	Percentage of Revenue
Medicare	76%
State (Medicaid)	6%
Insurance/HMO	17%
Total	100%

As shown above, the Medicare and State (Medicaid) entitlements equal 82% of the revenue at PSKC-WI. The department concludes that 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. Further, the cost per dialysis for the proposed project was compared to those of recent kidney dialysis proposals, the average cost per dialysis is reasonable.

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 facilities. This sub-criterion is met.

(3) The project can be appropriately financed.

As previously stated, the estimated capital expenditure for adding two stations to PSKC-WI is \$48,000 and is solely related to equipment for the two stations. [source: January 10, 2006, supplemental information, p9] The source of financing for the project will be from PSKC’s reserves. [source: Application, p8]

To demonstrate compliance with this sub-criterion, PSKC provided a letter from the PSKC board of directors demonstrating financial support for the project and PSKC’s historical financial statements for years 2002 through 2004. [source: Application, Exhibits 10 and 18] A review of PSKC’s historical financial statements shows the funds necessary to finance the project are available.

Based on the information provided, the department concludes the expansion of PSKC-WI would not adversely affect the financial stability of PSKC-WI or PSKC 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, the department determines that the applicant 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.

When this application was submitted, PSKC employed approximately 49 registered nurses and 57 patient care technicians at its four facilities in Snohomish and Island counties. [source: Application, p19] Currently, PSKC employs 7.45 FTEs to staff the four-station Island County facility. Increasing from a four-station to a six-station facility, PSKC expects to add 1.5 FTES in the first year and no additional FTEs thereafter. The current FTEs at PSKC-WI and the proposed increase in FTEs are shown in Table IV below. [source: December 21, 2005, supplemental information, p2]

**Table IV
PSKC-Whidbey Island Current and Projected FTEs**

Staff	Current FTEs	Increase	Total FTEs
Clinical Services	5.00	1.50	6.50
Technical Services	1.60	no increase	1.60
Social Services	0.25	no increase	0.25
Nutrition Services	0.25	no increase	0.25
Administrative Services	0.35	no increase	0.35
Total FTE’s	7.45	1.50	8.95

As shown in Table IV on the previous page, PSKC expects the 1.5 FTE increase to occur in the clinical services area of the staffing--specifically, an increase of one FTE dialysis technician and a .5 FTE in RNs. PSKC states it expects no difficulty in recruiting additional staff for the Island County facility because of its central location to easy freeway access to Island, Snohomish, and Skagit

counties. Further, PSKC offers a comprehensive educational and practical training curriculum to prospective employees interested in the dialysis field. [source: Application, pp19-20]

Based on this information, the department concludes that adequate staffing for the additional stations at PSKC-WI is either 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.

Documentation provided in the application confirms that PSKC currently has appropriate relationships with ancillary and support services. Ancillary and support services, such as social services, nutrition services, pharmacy, patient and staff education, financial counseling, human resources, material management, administration, and technical services are provided at one of the PSKC facilities in Snohomish County. [source: Application, p20] Further, PSKC provided copies of its transfer agreements with the local hospital in Island County--Whidbey General Hospital located in Coupeville. [source: Application, p20 and CN historical files]

Based on this information, the department concludes that both PSKC, and specifically PSKC-WI, currently have appropriate relationships with ancillary and support services and approval of this project would not negatively affect those relationships. 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.

As stated in the project description portion of this evaluation, PSKC was established in 1980 and owns or operates four dialysis facilities in Washington State--three in Snohomish County and one in Island County. 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 public⁵. To accomplish this task, the department reviews PSKC's quality of care compliance history for all four facilities.

In the most recent 10 years, the Department of Health's Office of Health Care Survey (OHCS) has completed more than eight compliance surveys for the PSKC facilities in operation.⁶ 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: facility ownership and survey data provided by the Office of Health Care Survey]

For this project, PSKC provided a copy of the existing medical director agreement between itself and Alan Haakenstad, MD. The agreement outlines the roles and responsibilities of both entities and identifies the annual compensation for the medical director responsibilities.⁷ A review of Dr. Haakenstad's compliance history with the Department of Health's Medical Quality Assurance

⁵ WAC 246-310-230(5)

⁶ PSKC-Everett: surveys completed 1997, 2000, & 2003; PSKC-South: surveys completed 1997, 2001, & 2004; PSKC-Smokey Point: initial survey completed 2005; PSKC-WI: initial survey completed 2005.

⁷ The compensation is identified in the pro forma financials provided in the application.

Commission reveals no recorded sanctions. [source: Medical Quality Assurance Commission compliance data]

Based on PSKC's compliance history and the compliance history of the medical director, the department concludes that there is reasonable assurance that the PSKC-WI would continue to be operated in conformance with state and federal regulations. This sub-criterion is met.

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

In response to this criterion, PSKC provided the following statements:

“The majority of patients to be treated at our PSKC-WI facility resides near the center and is followed by physicians whose practice is reasonably near to their homes and/or treatment facility. This improves the likelihood that physicians will see patients at appropriate intervals, and that overall quality and continuity of care will be maximized. (When necessary, physicians can easily visit the dialysis facility to see their patients.) If, on the other hand, patients are forced to travel out of their own community to a dialysis center elsewhere, time and travel logistics could introduce barriers to physician access that did not previously exist, jeopardizing continuity and quality of care.” [source: Application, page 20]

Given that PSKC-WI is the only dialysis center located in Island County, adequate station capacity is necessary to ensure that patients have access to dialysis services in the service area. Without adequate station capacity, patients would be forced to receive dialysis services outside the service area.

Based on the above information, the department concludes that there is reasonable assurance that additional stations in operation at PSKC-WI will assist in PSKC's ability to continue to promote continuity of care. Further, PSKC's relationships within existing health care system will continue and not result in an unwarranted fragmentation of services if this project is approved. 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.

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, the department determines that the applicant has met the cost containment criteria in WAC 246-310-240.

- (1) Superior alternatives, in terms of cost, efficiency, or effectiveness, are not available or practicable.

In response to the department's request to identify other options considered before submitting this project, PSKC provided the following information. [source: Application, p21]

“Outpatient hemodialysis, including both conventional and high flux dialysis, involves three to five hours of treatment, three times weekly, in a staff-assisted environment, with an industry operations standard of three patient shifts per day. Within this treatment modality, there is

little opportunity to pursue different methods of service provision. Other different methods of service provision include home hemodialysis and various forms of home peritoneal dialysis. As a treatment option, our home department that operates out of PSKC-South [located in Mountlake Terrace] currently encourages home hemodialysis or peritoneal dialysis for all suitable patients.”

A review of full-year 2004 and quarterly 2005 NRN data supports PSKC’s statements regarding the availability of home hemo or peritoneal dialysis to those patients suitable for service. Based on the statements provided above, it is clear that any options considered, other than this project, would substantially impact the patients at PSKC-WI and their ability to obtain services within reasonable hours of the day. While PSKC could opt to add a fourth patient shift at PSKC-WI, the department recognizes that the typical hours of this shift--11:00pm to 7:00 am--is not only inconvenient for the patient, it is difficult to staff the center during these hours of operation.

The department further recognizes that this project allows dialysis stations to be located closer to the patients to be served which is consistent with WAC 246-310-280(6)(a). Therefore, on the basis of the information above, the department concurs with the applicant that adding stations to PSKC-WI is the best available option for the community. This sub-criterion is met.