



STATE OF WASHINGTON
DEPARTMENT OF HEALTH

August 25, 2011

CERTIFIED MAIL # 7009 2250 0001 8669 3353

Richard Petrich, Vice President
Planning & Business Development
Franciscan Health System
1142 Broadway, Suite 300
Tacoma, WA 98402

RE: CN11-22

Dear Mr. Petrich:

It has been brought to our attention that the project description in the department's evaluation and offer letter of August 10 for the Gig Harbor dialysis facility contained inaccurate information that was not contained in your application. Therefore, we are enclosing a corrected evaluation showing the changes we made in the evaluation¹. The changes made in the evaluation have been incorporated in the project description below. After review of the revised evaluation, the Certificate of Need Program is still prepared to issue a Certificate of Need for the Gig Harbor dialysis facility provided Franciscan Health System agrees to the following in its entirety.

Project Description:

Franciscan Health System St. Joseph Medical Center–Gig Harbor is approved to certify and operate nine dialysis stations. Services to be provided at the facility include in-center hemodialysis with shifts after 5:00 p.m. The nine-station Franciscan Health System St. Joseph Medical Center–Gig Harbor will include an isolation station. The nine-station breakdown at the facility is listed below:

Private Isolation Room	1
Other In-Center Stations	8
Total	9

Conditions

1. Approved project description as described above

¹ Removed language is shown with a strikethrough and new language is underlined.



2. Prior to adding the three stations Franciscan Health System St. Joseph Medical Center–Gig Harbor must provide a copy of the executed medical director agreement with Neil Hannigan, MD. The executed agreement must be consistent with the draft agreement provided within the application.

Approve Capital Costs

The approved capital expenditure associated with this project is \$75,000.

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.

Your written response should be sent to the Certificate of Need Program, at one of the following addresses.

Mailing Address:

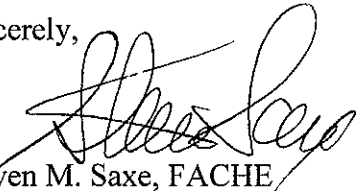
Department of Health
Certificate of Need Program
Mail Stop 47852
Olympia, WA 98504-7852

Other Than By Mail:

Department of Health
Certificate of Need Program
310 Israel Road SE
Tumwater, WA 98501

I apologize for any inconvenience this may have caused. 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

CORRECTED

EVALUATION OF THE CERTIFICATE OF NEED APPLICATION SUBMITTED BY FRANCISCAN HEALTH SYSTEM PROPOSING TO ADD THREE KIDNEY DIALYSIS STATIONS TO THE EXISTING ST. JOSEPH MEDICAL CENTER—GIG HARBOR IN PIERCE COUNTY PLANNING AREA #3.

APPLICANT DESCRIPTION

Catholic Health Initiatives (CHI) a not-for-profit entity is the parent company of Franciscan Health System. CHI through its subsidiary Franciscan Health System (FHS) own or operate one hundred and eighteen facilities in twenty-two states. In Washington FHS own or operates a medical group and eleven healthcare facilities listed below: [Source: Application page 4 and Appendix 1]

Hospitals

Enumclaw Regional Hospital, Enumclaw
St. Anthony Hospital, Gig Harbor
St. Clare Hospital, Lakewood
St. Frances Hospital, Federal Way
St. Joseph Medical Center, Tacoma

Ambulatory Surgery Center

Gig Harbor Ambulatory Surgery Center

Hospice Agency

Franciscan Hospice, Tacoma

Hospice Care Center

FHS Hospice Care Center

Dialysis Centers

Greater Puyallup Dialysis Center, Puyallup
St. Joseph Dialysis Facility, Tacoma
Gig Harbor Dialysis Center, Gig Harbor

Franciscan Medical Group

PROJECT DESCRIPTION

Franciscan Health System dba St. Joseph Medical Center operates a six-station dialysis center known as St. Joseph Medical Center –Gig Harbor in Pierce County Planning Area #3. The six-station center is located at 4700 Point Fosdick Drive NW #101 within city of Gig Harbor. [Source: Application, Page 2] FHS is requesting an exception to allow the addition of three new stations to St. Joseph Medical Center –Gig Harbor (St. Joseph—Gig Harbor). FHS states, *“Given our utilization in excess of 100%, we are requesting to add stations under the exception language contained in WAC 246-310-287. When the Gig Harbor unit was constructed in 2004, it was built to house nine stations. In fact, the extra three stations have been in place since opening. As such, the new stations can be made operational within days of receiving CN approval”*. [Source: Application, Page 7]

Services provided at St. Joseph—Gig Harbor includes ~~home dialysis~~, in-center hemodialysis, ~~peritoneal dialysis~~, with shifts after 5:00 p.m., ~~and training/support for dialysis patients~~. The nine-station dialysis facility would include ~~a permanent bed station and~~ an isolation station. The capital expenditure associated with the three new stations to be added to existing capacity is \$75,000. FHS states all of the estimated capital cost is related to fixed and moveable equipment and sales tax. [Source: Application, Page 26] If this project is approved, St. Joseph—Gig Harbor anticipates the three new stations would become operational immediately. Under this timeline, calendar year 2012 would be the nine stations dialysis center first full year of operation and 2013 and 2014 would be years two and three. [Source: Application, Page 7]

APPLICABILITY OF CERTIFICATE OF NEED LAW

This project is subject to Certificate of Need (CN) review because it increases 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

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 and must be used to make the required determinations. To obtain Certificate of Need approval, FHS 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, FHS must demonstrate compliance with the applicable kidney disease treatment center criteria outlined in WAC 246-310-280 through 287.

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); and WAC 246-310-240(2), (3); and WAC 246-310-288.

APPLICATION CHRONOLOGY

As directed under WAC 246-310-282(1) the department accepted this application under the Kidney Disease Treatment Centers Review Cycle #1. No other kidney disease treatment center application was received for Pierce County planning area #3 during Cycle #1, therefore; the review is converted to a regular review. A chronological summary of the review activities is shown below.

Action	Dates
Letter of Intent Submitted	January 31, 2011
Application Submitted	February 28, 2011
Department's Pre-Review Activities including screening and responses <ul style="list-style-type: none">• Department's 1st Screening• Department's 2nd Screening²	March 4, 2011 Through April 15, 2011
Beginning of Review	April 17, 2011
End of Public Comment	June 21, 2011
Rebuttal Comments ³	N/A
Department's Anticipated Decision Date	August 8, 2011
Department's Actual Decision Date	August 10, 2011
Release of Department's Corrected Decision	August 25, 2011

AFFECTED AND INTERESTED 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, the department did not receive any request for interested or affected person's status.

SOURCE INFORMATION REVIEWED

- Franciscan Health System Certificate of Need application submitted February 28, 2011
- Franciscan Health System 1st supplemental information received May 12, 2011
- Franciscan Health System public comments received June 21, 2011
- Years 2006 through 2010 historical kidney dialysis data obtained from the Northwest Renal Network
- Year 2010 Northwest Renal Network 4th Quarter Data
- Licensing and/or survey data provided by the Department of Health's Office of Investigation and Inspections
- Licensing and/or survey data provided by out of state health care survey programs
- Certificate of Need historical files
- Medical Quality Assurance compliance data

² The department did not conduct a second screening.

³ For this project, the department did not receive public comment.

CONCLUSION

For the reasons stated in this evaluation, the application submitted by Franciscan Health System proposing to expand the existing St. Joseph Medical Center –Gig Harbor in Peirce County planning area #3 by three stations is consistent with applicable criteria of the Certificate of Need Program provided Franciscan Health Systems agrees to the following in its entirety:

Project Description:

Franciscan Health System St. Joseph Medical Center –Gig Harbor is approved to certify and operate nine dialysis stations. Services to be provided at the facility includes ~~home dialysis, in-center hemodialysis, peritoneal dialysis, with~~ shifts after 5:00 p.m., ~~and training/support for dialysis patients.~~ The nine-station Franciscan Health System St. Joseph Medical Center –Gig Harbor will include ~~a permanent bed station and~~ an isolation station. The nine-station breakdown at the facility is listed below:

Private Isolation Room	1
Permanent Bed Station	1
Home Training Station	1
Other In-Center Stations	6 8
Total	9

Conditions

1. Approved project description as described above
2. Prior to adding the three stations Franciscan Health System St. Joseph Medical Center –Gig Harbor must provide a copy of the executed medical director agreement with Neil Hannigan, MD. The executed agreement must be consistent with the draft agreement provided within the application.

Approve Capital Costs

The approved capital expenditure associated with this project is \$75,000.

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

Based on the source information reviewed the department determines that FHS has met the need criteria in WAC 246-310-210(1) and (2) and the kidney disease treatment facility methodology and standards in WAC 246-310-284 and 287.

- (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).

Kidney Disease Treatment Center Methodology WAC 246-310-284

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 regression analysis of the historical number of dialysis patients residing in the planning area using verified utilization information obtained from the Northwest Renal Network.⁴

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.⁵ 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 NWRN data, again concluding with the base year. [WAC 246-310-284(4)(b) and (c)]

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.

⁴ 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]

⁵ 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 2008.

Finally, once station need has been calculated for the project 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)]

FHS Application of the Numeric Methodology

FHS’s application is proposing to add three stations to the existing 6-station St. Joseph—Gig Harbor. FHS did not run the numeric methodology. Instead, FHS provided a copy of the department’s previously posted methodology for the planning area. In its application FHS states, “Per the methodology in WAC 246-310-284(4), contained in Exhibit 6, there is no numeric need for additional dialysis stations in Pierce 3 Dialysis Planning Area. SJMC Gig Harbor is submitting this application consistent with the following exception language in WAC 246-310-287”. [Source: Application, page 17]

Department’s Application of the Numeric Methodology

Based on the calculation of the annual growth rate in the planning area, the department used linear regression to project need. However, the department application of the numeric need methodology did not show any need for dialysis stations in the planning area. Table 1 below summarizes the department’s application of the numeric methodology.

**Table 1
Summary of Department’s Numeric Methodology—
Pierce County Planning area #3**

	Year 2011	Year 2012	Year 2013	Year 2014
In-center Patients	22.00	23.20	24.40	25.60
Patient: Station Conversion Factor	4.8	4.8	4.8	4.8
Total Station Need	4.5833	4.833	5.0833	5.3333
Total Station Need Rounded Up	5	5	6	6
Minus # CN Approved Stations	6	6	6	6
Net Station Need / (Surplus)	1	1	0	0

As shown in Table 1 above, the numeric methodology shows no need in the planning area. The department’s complete numeric methodology for Pierce County ESRD planning area #3 is attached to this evaluation as Appendix A.

During the public comments phase of the application review, FHS provided “public comment” on its own application. Included with this “public comment” were two letters of support from existing dialysis patients. The remaining information contained new information intended to supplement the application materials. This latter information was not considered by the department. The time to supplement the application materials had passed once an application was under review.

The department agrees with FHS that the numeric methodology did not predict need for new dialysis stations in Pierce #3 planning area. Based only on the numeric methodology, this sub-criterion is not met. However, FHS has requested an exception under WAC 246-310-287. This exception permits the department to approve an application in the absence of numeric need provided specific standards are met. The remaining portions of the department’s analysis will include an evaluation of these exception standards.

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. St. Joseph—Gig Harbor is the only facility operating in Pierce County planning area #3. The most recent quarterly modality report from the Northwest Renal Network (NWRN) 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 for this project is February 1, 2011. [WAC 246-310-282] The quarterly modality report from NWRN available at that time was for September 30, 2010, which became available on November 9, 2010. Table 2 below shows St. Joseph—Gig Harbor utilization as of September 30, 2010

**Table 2
Third Quarter NWRN Facility Utilization**

Facility Name	#of Stations	# of Pts	Pts/Station Standard	Pts/Station
St. Joseph—Gig Harbor	6	37	4.8	6.16

As shown in Table 2 above, **this sub-criterion is met.**

WAC 246-310-287(2)(b)

To comply with this exception criterion, FHS asserted that on 12/31/2010, St. Joseph Gig Harbor had 40 patients and was operating at 111% occupancy as a result, the facility opened a fourth patents shift. [Source: Application, Page 7] Within the application, FHS provided reasons why it qualifies for an exception.

Summarized below are some of the reasons used by FHS to support it request for an exception.

- FHS prefers not to operate a fourth shift because it would compromise patients care and public transportation to the facility is limited.
- Negatives outcomes related to scheduling associated with operating a fourth shift will be hard on new patients are often the most sickest.
- With the addition of a fourth shift, the six-station facility is already at capacity and would be full within the next eighteen months.

The nearest dialysis facility is miles away and depending on the time of day, travel times can vary significantly. [Source: Application, Page 14]

Department's Assessments

WAC 246-310-287 (2)(b) requires existing dialysis stations in the dialysis facility be operating at 6 patients/station. The same NWRN quarterly modality report used in Table 2 is used here.

As stated in Table 2, St. Joseph—Gig Harbor is operating at 6.16 patients per station. This above the 6 patients/station requirement of the exception standard. Therefore, FHS's application has **met this exception sub-criterion.**

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. St. Joseph—Gig Harbor is located in Pierce County planning area #3; therefore, the standard for this criterion is 4.8 in-center patients per approved station. St. Joseph—Gig Harbor states that year 2014 will be the third year of operation with nine stations. St. Joseph—Gig Harbor projected utilization for year 2014 is shown in Table 3 below.

Table 3
St. Joseph—Gig Harbor
Third Full Year Projected (2014) Facility Utilization

Facility Name	#of Stations	# of Pts	Pts/Station
St. Joseph Gig Harbor	9	51	5.7

As shown in Table 3 above, St. Joseph—Gig Harbor would be operating at 5.7 patients per station by year 3. [Source: Supplemental information received May 12, 2011, Attachment 2] **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.

FHS is currently a provider of 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 Pierce County planning area #3 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, FHS provided a copy of its current Regional Nephrology Services Franciscan Health System Admission Criteria used at the dialysis center. The policy outlines the process and guidelines that St. Joseph—Gig Harbor uses to admit patients for treatment at the dialysis center. The policy states the dialysis centers will continue to admit and treat patients meeting physiologic criteria for end stage renal disease and will not discriminate as to age, sex, race, religion or sexual preference, physical disability, financial status, or disease. [Source: Application, Appendix 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. FHS currently provides services to Medicaid eligible patients at the existing dialysis center. The applicant intends to continue to provide services to Medicaid patients at the St. Joseph—Gig Harbor. A review of the anticipated revenue sources indicates that the facility expects to continue to receive Medicaid reimbursements.

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. FHS currently provides services to Medicare patients at the existing dialysis center. FHS intends to continue to provide services to Medicare patients at the existing facility. A review of the anticipated revenue sources indicates that it expects to continue to receive Medicare reimbursements.

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.

FHS demonstrated its intent to continue to provide charity care to patients receiving treatment at the St. Joseph—Gig Harbor by submitting its current Uninsured/Underinsured Patient Discount Policy (Charity Care). The charity care policy outlines the process one would use to access services provided at FHS facilities. FHS also included a 'charity care' line item as a deduction from revenue within its pro forma income statement. [Source: Supplemental information received May 12, 2011, Attachment 2] Based on the above information and standards, the department concludes **this sub-criterion is met.**

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

Based on the source information reviewed and agreement to the condition identified in the "conclusion" section of this evaluation, the department determines that FHS 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, FHS anticipates the three new stations would become operational immediately. Under this timeline, calendar year 2012 would be the first full year of operation and 2013 and 2014 would be years two and three. [Source: Application, Page 7] St. Joseph—Gig Harbor provided its projected 3-year revenue and expense statement as a 9-station facility. Table 4 below summarizes that information. [Source: Supplemental information received May 12, 2011, Attachment 2]

**Table 4
St. Joseph—Gig Harbor
Projected Revenue and Expenses for Partial Year and Years 2012-2014**

	Partial Year 2011	Full Year 2012	Full Year 2013	Full Year 2014
# of Stations	9	9	9	9
# of Treatments [1]	7,020	7,332	7,664	7,956
# of Patients [2]	45	47	49	51
Utilization Rate [2]	5.0	5.2	5.4	5.7
Net Patient Revenue[1]	\$2,838,383	\$2,964,533	\$3,090,683	\$3,216,834
Total Operating Expenses [1, 3]	\$1,925,033	\$1,979,689	\$2,026,232	\$2,102,594
Net Profit or (Loss)[1]	\$913,350	\$984,844	\$1,064,451	\$1,114,240
Operating Revenue / Treatment [1]	\$404.33	\$404.33	\$403.27	\$404.33
Operating Exp./ Treatment [1]	\$274.22	\$270.01	\$264.38	\$264.28
Net Profit per Treatment [1]	\$130.11	\$134.32	\$138.89	\$140.05

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

As shown in Table 4 above, St. Joseph—Gig Harbor would be operating at a profit beginning in partial year 2011 though the third year of operation or year 2014. As an existing facility, St. Joseph—Gig Harbor provided an executed lease agreement between Olympic Group LLC and (“Landlord”) and Franciscan Health System—West dba St. Joseph Dialysis Center (“Tenant”). [Source: Application, Appendix 5]

The department’s review of the executed lease agreement shows that rent costs identified in the lease are consistent with the pro-forma financial projections used to prepare the information in Table 4. FHS provided a draft medical director’s services agreement that it anticipates would replace the soon to be expired agreement with Dr. Neil Hannigan the existing medical director for St. Joseph—Gig Harbor. FHS stated it provided a draft medical director agreement to replace current agreement because it did not have enough time to execute a new agreement before submitting its application.

The draft agreement identifies the annual compensation for the medical director position. Additionally, St. Joseph—Gig Harbor pro-forma financial income statement also show the annual compensation for the Medical Director position. [Source: Supplemental information received May12, 2011, Attachment 2] Based on the information, the department concludes that the proposed expansion of St. Joseph—Gig Harbor by three new stations is financially feasible. **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.

FHS identified the capital expenditure associated with the addition of three new stations to St. Joseph—Gig Harbor to be \$75,000. FHS stated all of the estimated capital cost is related to fixed and moveable equipment and sales tax. To further demonstrate compliance with this sub-criterion, St. Joseph—Gig Harbor provided the sources of its patient revenue shown in Table 5 below. [Source: Application, Page 9]

Table 5
St. Joseph—Gig Harbor Source of Revenue

Source of Revenue	% of Revenue
Medicare	75%
State (Medicaid)	4%
Other (Commercial)	21%
Total	100%

St. Joseph—Gig Harbor is expected to have 79% of its revenue from Medicare and Medicaid entitlement programs. These programs are not cost based reimbursement and are not expected to have an unreasonable impact on the charges for services. Based on the department’s review of the application materials, this same conclusion can be made for those with other or commercial insurance patients that make up 21% of the project’s revenue. Therefore, the department concludes that this project would probably not result in an unreasonable impact on the costs and charges for health 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 addition of stations to St. Joseph—Gig Harbor is \$75,000. FHS states, "This project does not involve any construction. The requested three stations already exist in the facility. Even though it is not a current capital expenditure, we have included the original cost of the dialysis machines, chairs, and support equipment. The capital expenditure for this project has already been expended. SJMC Gig Harbor has included the original cost for CN purposes." [Source: Application, Pages 26 and 27]

Based on the information provided, the department concludes that FHS application, proposing to expand the existing St. Joseph—Gig Harbor facility by three new stations can be appropriately financed. **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.

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.

As an existing facility, St. Joseph—Gig Harbor currently has 8.7 FTE's and will add 0.6 FTE's by the third full calendar of operation. The applicant's existing and proposed staffing pattern is summarized in Table 6 below.

**Table 6
St. Joseph—Gig Harbor Current and proposed FTE's 2011 – 2014**

Category	Current Year 2011	Year 1 2012 Increase	Year 2 2013 Increase	Year 3 2014 Increase	Total FTE's
Medical Director	<i>Professional Services Contract</i>				
Nurse Manager	2.6	0.0	0.0	0.0	2.6
Clinical RN Manager	1.0	0.0	0.0	0.0	1.0
Patient care Tech	4.4	0.0	0.0	0.0	4.4
Social Worker	0.3	0.1	0.0	0.1	0.5
Dietician	0.4	0.0	0.0	0.1	0.5
Secretary	0.0	0.0	0.0	0.3	0.3
Number of FTE'S	8.7	0.1	0.0	0.5	9.3

As shown in Table 6 above, FHS expects a small increase in FTE's for St. Joseph—Gig Harbor through year 2014. The only new position the applicant expects to create is a part time secretary, and it does not anticipate any difficulty recruiting for this position. [Source: Application, Page 30]

FHS identified Neil Hannigan, MD as the existing medical director for St. Joseph—Gig Harbor. However, FHS provided a draft medical director's agreement between Neil Hannigan, M.D., P.S., Inc. ("Group"), and Franciscan Health System ("FHS"). FHS stated it provided a draft agreement to replace the existing contract for Dr. Hannigan because it did not have enough time to execute a new agreement. The draft medical director agreement outlines the roles and responsibilities of the medical director and FHS. Additionally, the draft agreement also identifies the annual compensation for the medical director. [Source: Supplemental information, received May 12, 2011, Attachment 1] The department concludes **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 by FHS states that the existing St. Joseph—Gig Harbor already have the appropriate ancillary and support services in place. [Source: Application, page 25] The department expects the applicant will continue to maintain the relationship it has established with providers in the planning area and the current dialysis center.

Based on the information, the department concludes that there is reasonable assurance that St. Joseph—Gig Harbor will continue to have appropriate ancillary and support services with a healthcare provider in Pierce County planning area #3. **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.

FHS is a provider of a variety of health care services in Washington State. Currently FHS owns or operates 11 healthcare facilities in Pierce and King Counties. As part of its review, the department must conclude that the proposed service would be operated in a manner that ensures safe and adequate care to the public.⁶

For Washington State, the Department of Health's Investigations and Inspections Office (IIO) conduct regular surveys. Records indicate that since 2007, IIO completed compliance surveys

⁶ WAC 246-310-230(5).

for each of FHS own or operated healthcare facilities. Each of the compliance survey revealed deficiencies typical for the facility and FHS submitted acceptable plans of corrections and implemented the required actions. Additionally, all five FHS's hospitals currently are accredited by the Joint Commission. [Source: facility survey data provided by the Investigations and Inspections Office and Joint Commission website]

IIO recently completed a re-certification survey of St. Joseph—Gig Harbor⁷. The compliance survey revealed minor non-compliance issues related to the care and management within the unit. These non-compliance issues were typical of a dialysis facility and FHS submitted and implemented acceptable plan of correction. Further, IIO most recently surveyed parts of St. Joseph Medical Center⁸ and that survey revealed some deficiencies for which the hospital submitted a plan of correction. [Source: Office of Health Care Survey Historical Record]

FHS identified Neil Hannigan, MD as the medical director for the existing St. Joseph—Gig Harbor. A review of Dr. Hannigan's compliance history did not show any current or past enforcement actions. [Source: Compliance history provided by Medical Quality Assurance Commission] Given the compliance history of Franciscan Health System, and its subsidiaries and that of Dr. Hannigan, the department concludes there is reasonable assurance St. Joseph—Gig Harbor would continue 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.

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.

In response to this criterion, FHS stated that this project proposes a small expansion of an existing facility and all exiting working relationships will continue. The applicant stated it does not have formal working agreements with any party, but it has long-standing relationships in place with many Pierce County providers. [Source: Application, Page 31] Based on this information, the department concludes the applicant has demonstrated it has, and will continue to have appropriate relationships with the planning area health care delivery systems. **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.

⁷ The last recorded survey was conducted March 2011

⁸ The last recorded hospital survey was conducted March 2011

D. Cost Containment (WAC 246-310-240) and WAC 246-310-288 (Tie Breakers)

Based on the source information reviewed, the department determines that FHS application meet the cost containment criteria in WAC 246-310-240

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

To determine if a proposed project is the best alternative, the department takes a multi-step approach. Step one determines if the application has met the other criteria of WAC 246-310-210 thru 230. If it has failed to meet one or more of these criteria then the project is determined not to be the best alternative, and would fail this sub-criterion.

If the project 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 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

FHS's application proposing to expand the existing 6-station St. Joseph—Gig Harbor by three stations met the review criteria under WAC 246-310-210 based on meeting the exception sub-criteria WAC 246-310-287(2)(b), 220, and 230. Therefore, the department moves to step two below.

Step Two

Besides the project, FHS considered just one option before submitting this application. FHS considered doing nothing until the need methodology project need additional capacity in the planning area. FHS states given its high occupancy, it elected to submit an application requesting an exception.

WAC 246-310-287(1) requires an applicant to meet all other applicable review criteria and standards before an exception can be granted. Throughout this analysis the department determined that this application met the other applicable criteria and standards including the specific exception criterion of WAC 246-310-287(2)(b). The St. Joseph—Gig Harbor facility was built with future expansion in mind. This project does not involve construction and the facility is operating in excess of 6 patients/station. The department concludes this project is the best available alternative. **This sub-criterion and the over-all exception criterion are 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 to add dialysis stations in Pierce County planning area #3 during the Kidney Disease Treatment Centers Review Cycle #1. This step is not applicable to the project.

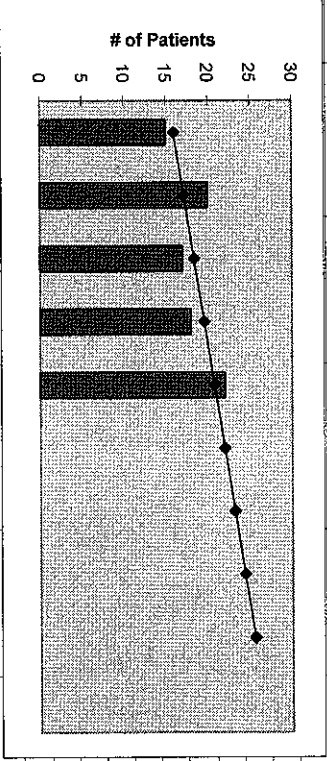
APPENDIX A

Pierce County Planning Area Three
ESRD Need Projection Methodology

Planning Area		6 Year Utilization Data - Resident Incenter Patients					
Pierce Three		2004	2005	2006	2007	2008	2009
	98329	4	2	5	4	3	5
	98332	2	3	3	2	2	3
	98333	0	0	1	2	1	0
	98335	8	7	8	6	9	10
	98349	0	2	2	2	2	4
	98351	1	1	1	0	0	0
	98394	0	0	0	1	1	0
TOTALS		15	15	20	17	18	22
246-310-284(4)(a)	Rate of Change		0.00%	33.33%	-15.00%	5.88%	22.22%
	6% Growth or Greater?		FALSE	TRUE	FALSE	FALSE	TRUE
	Regression Method:	Linear					
246-310-284(4)(c)				Year 1 2010	Year 2 2011	Year 3 2012	Year 4 2013
Projected Resident Incenter Patients	from 246-310-284(4)(b)			22.00	23.20	24.40	25.60
Station Need for Patients	Divide Resident Incenter Patients by 4.8			4.5833	4.8333	5.0833	5.3333
	Rounded to next whole number			5	5	6	6
246-310-284(4)(d)	subtract (4)(c) from approved stations						
Existing CN Approved Stations				6	6	6	6
Results of (4)(c) above				- 5	5	6	6
Net Station Need				1	1	0	0
Negative number indicates need for stations							
246-310-284(5)							
Name of Center	# of Stations	Patients	Utilization (Patients per Station)				
St Joseph - Gig Harbor	6	32	5.33				
Total	6	32					
Source: Northwest Renal Network data 2004-2009							
Most recent year-end data: 2009 year-end data as of 01/26/2010							
Most recent quarterly data as of the 1st day of application submission period: 4th quarter 2009 as of 01/26/2010							

Pierce County Planning Area Three
ESRD Need Projection Methodology

X	Y	Linear
2005	15	16
2006	20	17
2007	17	18
2008	18	20
2009	22	21
2010		22,000
2011		23,200
2012		24,400
2013		25,600



SUMMARY OUTPUT

Regression Statistics	
Multiple R	0.702246883
R Square	0.493150685
Adjusted R Square	0.324200913
Standard Error	2.22110833
Observations	5

ANOVA

	df	SS	MS	F	Significance F
Regression	1	14.4	14.4	2.918918919	0.186080527
Residual	3	14.8	4.933333333		
Total	4	29.2			

	Coefficients	Standard Error	t Stat	P-value	Lower 95%	Upper 95%	Lower 95.0%	Upper 95.0%
Intercept	-2.390	1409.670822	-1.6956431276	0.18856422	-6876.201699	2096.201699	-6876.201699	2096.201699
X Variable 1	1.2	0.702376917	1.708484392	0.186080527	-1.035276824	3.435276824	-1.035276824	3.435276824

RESIDUAL OUTPUT

Observation	Predicted Y	Residuals
1	16	-1
2	17.2	2.8
3	18.4	-1.4
4	19.6	-1.6
5	20.8	1.2