

STATE OF WASHINGTON DEPARTMENT OF HEALTH

August 22, 2013

CERTIFIED MAIL # 7011 1570 0002 7810 2686

Richard Petrich, VP Franciscan Health System 1717 'J' St. Tacoma, Washington 98405

Re: CN12-35

Dear Mr. Petrich:

We have completed review of the Certificate of Need application submitted by Franciscan Health System dba St. Joseph Hospital proposing to add 3 stations to the Gig Harbor facility. For the reasons stated in this evaluation, the application is consistent with applicable criteria of the Certificate of Need Program, provided Franciscan Health System agrees to the following in its entirety.

Project Description:

St. Joseph Medical Center–Gig Harbor Dialysis Center is approved to certify and operate twelve dialysis stations. Services to be provided at St. Joseph Medical Center–Gig Harbor Dialysis Center includes in-center hemodialysis, peritoneal dialysis, home hemodialysis training and treatments shifts beginning after 5:00 p.m., a permanent bed station, and an isolation station. The twelve-station breakdown at the facility is listed below.

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

Conditions

- 1. Approval of the project description as stated above. Franciscan Health System 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. Prior to providing services, Franciscan Health System will provide an executed copy of the lease agreement provided within the application for the department's review and



Richard Petrich, VP Franciscan Health System Certificate of Need Application #12-35 August 22, 2013 Page 2 of 2

approval. The executed lease agreement must be consistent with the draft agreement provided in the application.

Approved Capital Costs

The approved capital expenditure associated with this project is \$788,980.

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

Mailing Address: Department of Health Certificate of Need Program Mail Stop 47852 Olympia, WA 98504-7852 Other Than By Mail: Department of Health Certificate of Need Program 111 Israel Road SE Tumwater, WA 98501

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 AUGUST 22, 2013 FOR THE CERTIFICATE OF NEED APPLICATION SUBMITTED BY FRANCISCAN HEALTH SYSTEM PROPOSING TO ADD THREE KIDNEY DIALYSIS STATIONS TO GIG HARBOR DIALYSIS CENTER IN PIERCE COUNTY PLANNING AREA #3

APPLICANT DESCRIPTION

Franciscan Health System is a healthcare provider based in Tacoma, within Pierce County and is an affiliated of the Catholic Health Initiatives. Franciscan Health System (FHS) provides healthcare services to the residents of Pierce County and surrounding areas. The services provided by FHS are through its seven healthcare facilities located in Pierce and King Counties.

PROJECT DESCRIPTION

FHS's application proposes to add 3 stations to the 9-station dialysis center located within Pierce County ESRD planning area #3 known as St. Joseph Medical Center Gig Harbor. The nine-station dialysis center is located at 4700 Point Fosdick Drive NW #101 within the city of Gig Harbor. [Source: Application, Page 6] For ease of reference, St. Joseph Medical Center Gig Harbor Dialysis Center will be referred to in this evaluation as "SJMC-Gig Harbor."

Services to be provided at SJMC-Gig Harbor include in-center hemodialysis, peritoneal dialysis, home hemodialysis training and treatments shifts beginning after 5:00 p.m. At project completion, the twelve-dialysis stations would include a permanent bed station and an isolation station.

The capital expenditure associated with the addition of 3-stations is \$788,980. Of the \$788,980, capital cost associated with this project, approximately 66% is related to construction and leasehold improvements, 32% is related to both fixed and moveable equipment and taxes and the remaining 2% is related to other project costs unidentified by the applicant. If this project is approved, SJMC-Gig Harbor anticipates the three new stations would become operational in January 2014. Under this timeline, calendar year 2014 would be SJMC-Gig Harbor year one with 12-stations and years 2015 and 2016 would be the second and third year of operation. [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).

EVALUATION CRITERIA

WAC 246-310-200(1)(a)-(d) identifies the four determinations that the department must make for each application. WAC 246-310-200(2) provides additional direction on how the department is to make its determinations. It states:

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

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

(i) The consistency of the proposed project with service or facility standards contained in this chapter;

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

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

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

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

WAC 246-310-280 through 289 contains service and 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 289.

TYPE OF REVIEW

As directed under WAC 246-310-282(1), the department accepted this application under the 2012 Kidney Disease Treatment Centers Review Cycle #2. No other kidney disease treatment center application was received for Pierce County planning area #3 during Cycle #2, therefore; the review is converted to a regular review. A chronological summary of the review activities is on the following page.

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 (3), and WAC 246-310-286, 287, 288 and 289.

APPLICATION CHRONOLOGY

Action	Dates
Letter of Intent Submitted	April 30, 2012
Application Submitted	May 31, 2012
Department's Pre-Review Activities including screening and	June 4 , 2012
responses	through
	October 7, 2012
Beginning of Review	October 8, 2012
End of Public Comment/No Public Hearing Requested or	November 13, 2012^2
Conducted	
Department's Anticipated Decision Date	January 15, 2013
Department's Actual Decision Date	August 22, 2013

AFFECTED PERSONS

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

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

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

SOURCE INFORMATION REVIEWED

- Franciscan Health System Certificate of Need application submitted May 31, 2012
- Franciscan Health System 1st and 2nd supplemental information received August 13, 2012 and October 1, 2012
- Years 2006 through 2011 historical kidney dialysis data obtained from the Northwest Renal Network
- Year 2011 Northwest Renal Network 4th Quarter Data available on February 13, 2012
- Licensing and/or survey data provided by the Department of Health's
- Investigation and Inspections Office
- Licensing and/or survey data provided by out of state health care survey programs
- Certificate of Need historical files
- <u>http://www.doh.wa.gov/LicensesPermitsandCertificates/MedicalCommission.aspx</u> Medical Quality Assurance compliance data
- <u>http://www.medicare.gov</u> Dialysis Facilities Compare

² The department did not receive any public comment. Therefore, no rebuttal comments from the applicant were expected.

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 Dialysis Center in Pierce 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:

St. Joseph Medical Center–Gig Harbor Dialysis Center is approved to certify and operate twelve dialysis stations. Services to be provided at St. Joseph Medical Center–Gig Harbor Dialysis Center includes in-center hemodialysis, peritoneal dialysis, home hemodialysis training and treatments shifts beginning after 5:00 p.m., a permanent bed station, and an isolation station. The twelve-station breakdown at the facility is listed below.

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

Conditions

- 1. Approval of the project description as stated above. Franciscan Health System 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. Prior to providing services, Franciscan Health System will provide an executed copy of the lease agreement provided within the application for the department's review and approval. The executed lease agreement must be consistent with the draft agreement provided in the application.

Approved Capital Costs

The approved capital expenditure associated with this project is \$788,980.

CRITERIA DETERMINATIONS

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

Based on the source information reviewed and provided the applicant agrees to the conditions stated in the "conclusion" section of this evaluation, the department determines that Franciscan Health System 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 289.

(1) <u>The population served or to be served has need for the project and other services and facilities of</u> 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.³

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

Once the type of regression is determined as described above, the next step in the methodology is to determine the projected number of resident in-center stations needed in the planning area based on the planning area's previous five consecutive years 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 <u>except</u> 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

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

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

above, the number of projected patients is divided by 3.2 to determine needed stations. Additionally, the number of stations projected as needed in the target year is rounded up to the nearest whole number.

Finally, once station need has been calculated for the project years, the number of CN approved incenter 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 proposes to add 3 stations to its CN approved 9-station facility in Pierce County planning area #3. The table below shows a summary of the projected need provided by FHS. [Source: Application, May 31, 2012, page 18]

•	Stations
Current Supply	9
Total Supply	9
2015 Projected Need	12
Net Station Need	3

Numeric Need Summary

As shown in the table above, FHS projected that three new stations are needed in the planning area. Below is the department's application of the numeric methodology for Pierce County planning area #3.

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. The table below summarizes the department's application of the numeric methodology.

Summary of Depart		umeric Mo		·
Pierce Cou	Year 2012	Year 2013	# 3 Year 2014	Year 2015
In-center Patients	39.70	44.80	49.90	55.00
Patient: Station Conversion Factor	4.8	4.8	4.8	4.8
Total Station Need	8.278	9.333	10.395	11.458
Total Station Need Rounded Up	9	10	11	12
Minus # CN Approved Stations	9	9	9	9
Net Station Need / (Surplus)	0	1	2	3

As shown in the two tables both FHS and the department show need for an additional three stations 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.

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 new stations can be added. SJMC - Gig Harbor is the only facility operating in Pierce County planning area #3. The most recent quarterly modality report from 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 May 1, 2012. [WAC 246-310-282] The quarterly modality report from NWRN available at that time was for December 30, 2011, which became available on February 13, 2012. The table below shows SJMC - Gig Harbor utilization as of December 31, 2011.

Table 2Third Quarter NWRN Facility Utilization

Facility Name	# of Stations	# of Pts	Pts/Station
SJMC-Gig Harbor Dialysis Center	9	47	5.22

As shown in table above, this sub-criterion is met.

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. SJMC - Gig Harbor is located in Pierce County planning area #3. The standard for this criterion is 4.8 in-center patients per approved station. FHS stated that year 2016 would be SJMC-Gig Harbor third year of operation with twelve stations. The projected utilization for year 2016 is shown in the table below.

Table 3SJMC-Gig Harbor Dialysis CenterThird Full Year Projected (2016) Facility Utilization

Facility Name	#of Stations	# of Pts	Pts/Station
SJMC- Gig Harbor Dialysis Center	12	59	4.9

As shown in table above, SJMC - Gig Harbor would be operating at 4.9 patients per station by year 3. [Source: Supplemental information received October 1, 2012, Attachment 3] **This sub-criterion is met**.

(2) <u>All residents of the service area, including low-income persons, racial and ethnic minorities,</u> 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 the 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. The admission policy must also include language to ensure all residents of the service area would have access to services. This is accomplished by providing an admission policy that states patients would be admitted without regard to race, ethnicity, national origin, age, sex, pre-existing condition, physical, or mental status.

To demonstrate compliance with this sub-criterion, FHS provided a copy of its current Regional Nephrology Services FHS Admission Criteria used at the dialysis center. The policy outlines the process and guidelines that SJMC-Gig Harbor uses to admit patients for treatment at the dialysis center. The policy states the dialysis center 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]

The department uses the facility's Medicare certification to determine whether the elderly would have access or continue to have access to additional services. FHS currently provides services to Medicare eligible patients at its existing dialysis centers. A review of the application shows FHS anticipates it would continue to receive Medicare reimbursements. [Source: Application Pages 3 and 29]

The department uses the facility's Medicaid eligibility or contracting with Medicaid to determine whether low-income residents would have access to the proposed services. FHS currently provides services to Medicaid eligible patients at its existing dialysis centers. The applicant intends to continue to provide services to Medicaid patients at SJMC-Gig Harbor. A review of the application indicates FHS expects to continue to receive Medicaid reimbursements. [Source: Application Pages 3 and 29]

A facility's charity care policy should confirm that all residents of the service area including lowincome, 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 SJMC-Gig Harbor by submitting its current Uninsured/Underinsured Patient Discount Policy (Charity Care). [Source: Application, Appendix 7] 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 October 1, 2012, Attachment 23] 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 provided the applicant agree to the conditions stated in the "conclusion" section of this evaluation, the department determines that FHS has met the financial feasibility criteria in WAC 246-310-220

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

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 by January 2014. Under this timeline, calendar year 2014 would be SJMC-Gig Harbor year one with 12-stations and years 2015 and 2016 would be the second and third year of operation. [Source: Application, Page 7] FHS provided its projected 3-year revenue and expense statement for the 12-station facility. The table below summarizes that information. [Source: Supplemental information received October 1, 2012, Attachment 3]

Projected Revenue and Expenses for Years 2014-2016						
	Calendar Year 1 2014	Calendar Year 2 2015	Calendar Year 3 2016			
# of Stations	12	12	12			
# of Treatments [1]	8,892	9,516	9,984			
# of Patients [2]	54	57	59			
Utilization Rate [2]	4.5	4.8	4.9			
Net Patient Revenue[1]	\$2,629,625	\$2,814,161	\$2,952,562			
Total Operating Expenses [1, 3]	\$2,561,056	\$2,674,280	\$2,803,098			
Operating Income	\$68,569	\$139,881	\$149,464			
Depreciation and Amortization	\$87,066	\$87,066	\$87,066			
Net Profit or (Loss)[1]	(-\$18,497)	\$52,815	\$62,398			

	1 able 4		
S	JMC-Gig Har	bor	
Projected Revenue	and Expenses	for Years 20	14-2016
	Calendar	Calendar	Calendar

T-1-1- 4

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

The 'Net Patient Revenue' line item is gross revenue minus any deductions for charity care, bad debt, and contractual allowances. The 'Total Operating Expenses' line item includes salaries and wages, depreciation, and allocated costs for SJMC-Gig Harbor.

As shown in the table above, SJMC-Gig Harbor would be operating at a loss in year 2014 and a profit beginning in year 2015. As an existing facility, the applicant provided a lease agreement with addendum for portions of office spaces currently used and new spaces to be used for the expansion. Information within the application and supplemental information provided by the applicant shows the existing 9-station facility lease space is 4,550 square feet. For the three stations to be added to existing capacity, the applicant is leasing an additional 752 square feet space adjacent space to the existing facility. Described within supplemental information received from the applicant is an office suite space consisting of 1,089 square feet to be used for this expansion. The applicant stated when all lease spaces are added together at project completion, the 12-station dialysis facility total lease space will be 6,338 square feet.

The existing 9-station facility executed lease agreement initial term ends in year 2014 and it has three renewal options. For the 752 square feet space adjacent to the existing dialysis facility, the lease agreement initial term ends in year 2014 and it has three renewal options. For office suite 107 consisting of 1,089 square feet, the draft lease agreement provided has a ten-year lease option. [Source: Application Page 9, and Lease Agreement Addendum, Page 96 and Supplemental information received October 1, 2012, Page 4, Attachment 1]

The lease agreement with addendum for portions of expanded space is between Olympic Group LLC ("Landlord") and Franciscan Health System-West dba St. Joseph Dialysis Center ("Tenant"). The applicant provided financial information showing lease costs starting in 2014 and beyond. For suite 107 consisting of 1,089 square feet, the draft lease provided by the applicant is between Olympic Group LLC ("Landlord") and Franciscan Health System—West dba St. Joseph Dialysis Center ("Tenant"). [Source: Application, Appendix 6 and supplemental information August 14, 2012, Attachment 1] The department's review of the executed lease with addendum for portions of expanded space and draft lease agreement shows that rental costs identified by the two leases are consistent with the pro-forma financial projections used to prepare the information in table above.

FHS provided a copy of its existing medical director agreement with Dr. Neil Hannigan, the existing medical director for SJMC-Gig Harbor. The medical director agreement outlines the roles and responsibilities for both FHS and Dr. Hannigan and it identifies the annual compensation for the medical director position. Additionally, SJMC-Gig Harbor's pro-forma financial income statement shows the annual compensation for the medical director position. [Source: Application, Exhibit 2] Based on the information reviewed, the department concludes that the proposed expansion of SJMC - 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 SJMC-Gig Harbor to be \$788,980. FHS stated all of the estimated capital costs are related to construction, fixed and moveable equipment, sales tax and other project costs unidentified by the applicant. To demonstrate compliance with this sub-criterion, FHS provided the sources of patient revenue for SJMC-Gig Harbor shown in the table below. [Source: Application Page 29]

SJMC-Gig Harbor Source of Revenue				
Source of Revenue	% of Revenue			
Medicare	75%			
Medicaid	8%			
Other (Commercial)	17%			
Total	100%			

Table 5

SJMC-Gig Harbor is expected to have 83% of its revenue from Medicare and Medicaid reimbursement. 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, the same conclusion can be made for those patients in the other or commercial insurance category that makes up 17% of the applicants project's revenue. 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) <u>The project can be appropriately financed.</u>

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 SJMC - Gig Harbor is \$788,980. FHS states, *"This project will be financed through existing capital reserves of FHS. This is the least costly alternative."* [Source: Application, Page 28] FHS provided a letter signed by the chief financial officer to show that the necessary funds are available. [Source: Supplemental information received August 13, 2012, Attachment 2]

Based on the information provided, the department concludes that the expansion of SJMC-Gig Harbor 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 and provided the applicant agree to the conditions stated in the "conclusion" section of this evaluation, the department determines that the applicant has met the structure and process (quality) of care criteria in WAC 246-310-230.

(1) <u>A sufficient supply of qualified staff for the project, including both health personnel and</u> <u>management personnel, are available or can be recruited.</u>

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, SJMC-Gig Harbor currently has 11 FTE's and will add 4.6 FTE's by the third full calendar of operation. The dialysis facility's existing and proposed staffing pattern is summarized in the table below.

SJMC - Gig Harbor Current and Proposed F1E's 2014 – 2016						
	Current	Year 1	Year 2	Year 3	T ()	
	Year	2014	2015	2016	Total	
Category	2013	Increase	Increase	Increase	FTE's	
Medical Director		Professio	onal Services	Contract		
HD Tech	5.4	2.6	0.0	0.5	8.5	
Nurse Manager	2.8	0.4	0.2	0.3	1.0	
Clinical RN Manager	1.0	0.0	0.0	0.0	1.0	
Unit Secretary	0.6	0.4	0.0	0.0	1.0	
Social Worker	0.6	0.1	0.0	0.0	0.7	
Secretary	0.6	0.1	0.0	0.0	0.7	
Number of FTE'S	11	3.6	0.2	0.8	15.6	

Table 6SJMC - Gig Harbor Current and Proposed FTE's 2014 – 2016

As shown in the table above, FHS expects a small increase in FTE's through year 2016. Within the application, FHS stated "Very little incremental staffing is needed for this project. Therefore, FHS does not anticipate any difficulty in having sufficient staff available for the proposed expansion." [Source: Application, Page 31]

FHS identified Neil Hannigan, MD as the existing medical director for SJMC-Gig Harbor. FHS provided an executed medical director's agreement between Neil Hannigan, M.D., P.S., Inc. ("Group"), and FHS ("FHS"). The medical director agreement outlines the roles and responsibilities of the medical director and FHS. Additionally, the agreement also identifies the annual compensation for the medical director. [Source: Application Exhibit 2] The department concludes **this sub-criterion is met**.

(2) <u>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.</u>
WAC 246-310 does not contain specific WAC 246-310-230(2) as identified in WAC 246-310.

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.

To demonstrate compliance with this sub-criterion, FHS stated it does not maintain formal working agreements with any party, but it has long-standing relationship in place with many Pierce County providers. Additionally, FHS stated the existing SJMC-Gig Harbor already has appropriate ancillary and support services in place because the organizational structure integrates inpatients, outpatients, and home services within a single continuum. The applicant asserted the continuum is supported by an information system that provides patient and clinical data to care providers throughout the system. [Source: Application, page 31]

Based on the information, the department concludes there is reasonable assurance that SJMC-Gig Harbor will continue to have appropriate ancillary and support services with the addition of three stations. **This sub-criterion is met**.

(3) <u>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.</u>
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 and is affiliated with the Catholic Health Initiatives. Currently FHS owns or operates 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.⁵ For Washington State, the Department of Health's Investigations and Inspections Office (IIO) conducts regular surveys. Records indicate that since 2008, IIO completed compliance surveys for each of FHS own or operated healthcare facilities.

Each of the compliance survey revealed deficiencies typical for the type and size of the facility and FHS submitted acceptable plans of corrections and implemented the required actions. Further, all five FHS hospitals are accredited by the Joint Commission. [Source: facility survey data provided by the Investigations and Inspections Office and Joint Commission website] Within the past two years, IIO completed a re-certification survey of SJMC-Gig Harbor⁶ and the compliance survey revealed minor non-compliance issues related to the care and management within the unit. The non-compliance issues were typical of a dialysis facility and FHS submitted and implemented acceptable plan of correction.

Additionally within the past two years, IIO surveyed St. Joseph Medical Center⁷ 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 SJMC-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 FHS, its subsidiaries, and that of Dr. Hannigan, the department concludes there is reasonable assurance SJMC-Gig Harbor will continue be operated in conformance 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</u> <u>unwarranted fragmentation of services, and have an appropriate relationship to the service area's</u> <u>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.

In response to this criterion, FHS stated that this project proposes an expansion of an existing facility and all existing 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) <u>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.</u> For this project, this sub-criterion is addressed in sub-section (3) above and **is considered met**.

⁵ WAC 246-310-230(5)

⁶ The last recorded survey was conducted March 2011

⁷ 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 and provided the applicant agrees to the conditions stated in the "conclusion" section of this evaluation, the department determines that FHS application meet the cost containment criteria in WAC 246-310-240.

(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 thru 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.

<u>Step three</u> 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 9-station SJMC - Gig Harbor by three stations met the review criteria under WAC 246-310-210, 220, and 230. Therefore, the department moves to step two below.

Step Two

Before submitting this application, FHS considered and rejected the alternative of 'do nothing' only. The applicant stated, "Because the Department's CN methodology identifies a need for an additional three stations and our occupancy is already at 80%, just months after receiving CN approval to expand, doing nothing was not an option." [Source: Application, Page 33]

Once FHS chose to expand the dialysis center, submission of an application is required. Since no other options were available to FHS, submission of this application is it best available option. This **sub-criterion is met**.

Step Three

This step is used to determine the best available alternative between two or more approvable projects. There was no other project submitted to add dialysis stations in Pierce County planning area #3 during the Kidney Disease Treatment Centers Review Cycle #2. This step is not applicable to this project.

(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 no known minimum building and energy standards that ESRD facilities must meet in order 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.

FHS proposes to expand an existing "built to suit" facility from a real estate developer. FHS states that the scope and methods of the facility will meet Medicare certification and the local authority construction and energy conservation code. The cost the developer would incur to expand the existing dialysis center building is reflected in the negotiated lease costs provided by FHS. The dialysis lease costs were evaluated in the financial feasibility section of this analysis. Within this evaluation, the department concluded the overall project meet the financial feasibility criterion. Based on the information, the department concludes **this sub-criterion is met**

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

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

APPENDIX A



2012 Pierce County 3 ESRD Need Projection Methodology

And \$6.000							<u></u>
	Planning Area		tion Data - Res				0011
	Pierce Three	2006	2007	2008	2009	2010	2011
	98329	5	4	3	5	7	6
	98332	3	2	2	3	4	4
	98333	1	2	1	0	0	0
	98335	8	6	9	10	12	18
· · · · · · · · · · · · · · · · · · ·	98349	2	2	2	4	3	8
	98351	1	0	0	0	0	0
	98394	0	1	1	0	11	2
	TOTALS	20	17	18	22	27	38
240 240 284(4)(-)			45.000/	E 00%	02.029/	22.73%	40.74%
246-310-284(4)(a)	Rate of Change		-15.00%	5.88%	22.22%		40.74% TRUE
	6% Growth or Greater?		FALSE	FALSE	TRUE	TRUE	IKUE
	Regression Method:	Linear					
	·····						
246-310-284(4)(c)				Year 1	Year 2	Year 3	Year 4
	• · · · · · · · · · · · · · · · · · · ·			2012	2013	2014	2015
Projected Resident							
Incenter Patients	from 246-310-284(4)(b)			39.70	44.80	49.90	55.00
Station Need for							
Patients	Divide Resident Incenter	Patients by	4.8	8.2708	9.3333	10.3958	11.4583
	Rounded to next whole r			9	10	11	1:
246-310-284(4)(d)	subtract (4)(c) from approv	ed stations					
Existing CN Approved S	stations			9	9	9	1
Results of (4)(c) above			-	9	10	11	1:
Net Station Need				0	-1	-2	
Negative number indicates ne	ed for stations						
246-310-284(5)			•				<u>.</u>
Name of Center	# of Stations	Patients	Utilization (F	Patients per	Station)		
St Joseph - Gig Harbor	9	47	5.22				
			/***				
Total	9	47					
Source: Northwest Renal	Natwork data 2006 2011		i i i i i i i i i i i i i i i i i i i				-



2012 Pierce County 3 ESRD Need Projection Methodology

·····			 _					
x	У	Linear			· · ·			
2007	17	14						
2008	18	19	· · ·					
2009	22	24						
2010 2011	27 38	30 35						
2011		39.700						
2012		44.800				-		
2014		49.900						
2015		55.000						
			40					
			35					
SUMMARY OUTPU	Γ		30			•		
		# of Patlents	25		~~~~			
Regression S		atle	20	- Andrew				
Multiple R	0.94186399	of F	15				Annual Annua	
R Square	0.887107776	*	10					
Adjusted R Square	0.849477035		5					
Standard Error Observations	3.321646178	•	0				and a second sec	
Observations			•					
ANOVA	· · · · · · · · · · · · · · · · · · ·							
	df	SS	MS	F	Significance F			
Regression	1	260.1	260.1	23.57401813	0.016679299			
Residual	3	33.1	11.03333333					
Total	4	293.2						
	Coefficients	Standard Error	t Stat	P-value	Lower 95%	[.] Upper 95%	Lower 95.0%	Upper 95.0%
Intercept	-10221.5	2110.247594			-16937,24966			
X Variable 1	-10221.5	1.05039675	4.855308242		1.757168743		1.757168743	
X Valiable								
RESIDUAL OUTPU	Г. 			· · · · · · · · · · · · · · · · · · ·				
Observation	Predicted Y	Residuals						
1	17	3						
2	18.9	-1.9						
3	20.8	-2.8					· ·	
4	22.7	-0.7						
5	24.6	2.4						