

DEPARTMENT OF HEALTH

September 6, 2012

CERTIFIED MAIL # 7011 1570 0002 7808 7334

Richard Petrich, VP Planning and Business Development Franciscan Health Systems 1717 S. J Street Tacoma, Washington 98405

RE: CN 12-18

Dear Mr. Petrich:

We have completed review of Franciscan Health Systems Certificate of Need (CoN) application to establish a 22 station dialysis station within Pierce County Planning Area 4. For the reasons stated in the enclosed decision, the department has concluded that the project as described below is consistent with the applicable CoN review criteria. The Department is prepared to issue a CoN for this project provided Franciscan Health Systems agrees to the following in its entirety:

Project Description:

This certificate approves Franciscan Health System to relocate 22 of the remaining 38 dialysis stations from St. Joseph Medical Center to a new site in Tacoma. At project completion, the facility is approved to certify and operate a total of 22 dialysis stations. The facility will provide the following services: hemodialysis, peritoneal dialysis, shifts after 5:00 p.m., home hemodialysis and peritoneal training and support for dialysis patients. The facility will also have an isolation station, permanent bed station, and two home training stations. The stations are listed below.

Private Isolation Room	1
Permanent Bed Station	1
Home Training Station	2
Other In-Center Stations	18
Total	22



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Conditions:

- 1. Franciscan Health System agrees with the project description stated above Franciscan Health System also agrees that any change to the project description above is a new project that requires a new certificate of need.
- 2. Franciscan Health System is required to decertify 22 of the 38 stations remaining at the hospital within 30 days of the new facility becoming Medicare certified. At project completion, 16 dialysis stations would remain in operation at St. Joseph Medical Center.
- 3. Before providing dialysis services at the new facility, Franciscan Health System will provide to the department for review and approval an executed Medical Director Agreement. The executed Medical Director Agreement must be consistent with the draft agreement provided in the application.

Approved Costs:

The approved capital expenditure associated with this project is \$3,636,423.

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
111 Israel Road SE
Tumwater, WA 98501

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

Sincerely,

Steven M. Saxe, FACHE

Director, Health Professions and Facilities

Enclosure

EVALUATION DATED SEPTEMBER 6, 2012 OF THE CERTIFICATE OF NEED APPLICATION SUBMITTED BY FRANCISCAN HEALTH SYSTEM PROPOSING TO ESTABLISH A NEW 22 STATION DIALYSIS CENTER IN PIERCE COUNTY SUB-SERVICE AREA #4.

APPLICANT DESCRIPTION

Catholic Health Initiatives is the parent corporation of Franciscan Health System (FHS). Through one of its subsidiaries, Catholic Health Initiatives owns 118 health care facilities in 22 states. For Washington State, FHS is the subsidiary that owns or operates 13 health care facilities—five hospitals, four dialysis centers, a skilled nursing facility, an ambulatory surgery center, a home health agency, a Medicare certified hospice agency, and a hospice care center. The health care facilities are listed below. [Source: CN historical files; Application, Appendix 1]

Hospitals

St. Elizabeth Hospital, Enumclaw

St. Anthony Hospital, Gig Harbor

St. Clare Hospital, Lakewood

St. Frances Hospital, Federal Way

St. Joseph Medical Center, Tacoma

Home Health and Hospice Agencies

Franciscan Home Health, Tacoma Franciscan Hospice, Tacoma

Dialysis Centers

Greater Puyallup Dialysis Center, Puyallup St. Joseph Dialysis Facility, Tacoma Gig Harbor Dialysis Center, Gig Harbor SJMC East Tacoma Dialysis Center, Tacoma¹

Ambulatory Surgery Center

Gig Harbor Ambulatory Surgery Center

Hospice Care Center

FHS Hospice Care Center

BACKGROUND INFORMATION AND PROJECT DESCRIPTION

As of the writing of this evaluation, St. Joseph Medical Center (SJMC) operates a 50 station dialysis facility within the hospital at 1717 South 'J' Street in Tacoma. The dialysis center provides a full range of dialysis services to residents in and around Pierce County. On April 26, 2010, FHS was issued CN #1421 approving the establishment of a 12 station dialysis center in East Tacoma by relocating 12 of SJMC's 50 stations. Establishment of this new facility, known as SJMC East Tacoma Dialysis Center, would reduce SJMC's dialysis facility to 38. FHS is in the process of implementing the station relocation. [Source: Application, pp1-3]

This project focuses on the 38 stations that would remain at SJMC's dialysis facility once the 12 station project is complete. FHS proposes to relocate 22 of the 38 remaining stations to establish another dialysis center in Tacoma. The new 22-station facility would be known as FHS South Tacoma Dialysis Center (FHS South Tacoma) and located at 5825 Tacoma Mall Boulevard, Suite 103, in Tacoma. The new facility will offer in-center hemodialysis and visitor dialysis, home hemodialysis and home peritoneal dialysis training and backup, a dedicated bed station, and a dedicated isolation station. If this project is approved, FHS would be required to decertify 22 of the 38 stations remaining at the hospital. At project completion, 16 dialysis stations would remain at SJMC. [Source: Application, pp3 & 6]

¹ Approved by CN#1421 but not yet operational

FHS proposes to lease the site for the FHS South Tacoma. The building is currently under construction and will be fitted for use as a dialysis facility. The project costs for the establishment of the new facility is \$3,636,423. This amount represents the total capital expenditure of \$3,974,035 minus the landlord's costs of \$244,005 and the real estate commission of \$93,611. [Source: Application, p22]

If this project is approved, FHS anticipates the new 22-station facility would become operational by July 2013. Under this timeline, fiscal year 2014 is the first full year of operation and fiscal year 2016 is year three. [Source: Application, p10]

APPLICABILITY OF CERTIFICATE OF NEED LAW

WAC 246-310-289(2) states,

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

Because FHS plans to relocation only 22 of the 38 remaining stations from the SJMC location, this project is reviewed as the establishment of a new health care facility under the provisions of Revised Code of Washington (RCW) 70.38.105 (4)(a) and Washington Administrative Code (WAC) 246-310-020(1)(a).

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 in how the department is to make its determinations. It states:

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

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

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

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

- (i) Nationally recognized standards from professional organizations;
- (ii) Standards developed by professional organizations in Washington State;

(iii) Federal Medicare and Medicaid certification requirements;

(iv) State licensing requirements;

(v) Applicable standards developed by other individuals, groups, or organizations with recognized expertise related to a proposed undertaking; and

(vi) The written findings and recommendations of individuals, groups, or organizations with recognized expertise related to a proposed undertaking, with whom the department consults during the review of an application.

To obtain Certificate of Need (CN) approval, FHS must demonstrate compliance with the applicable criteria found in WAC 246-310-210 (need); 246-310-220 (financial feasibility); 246-310-230 (structure and process of care); 246-310-240 (cost containment). Additionally, the applicant must demonstrate compliance for the project according to relevant sections of WAC 246-310-280 through 287.

CONCURRENT REVIEW CYCLE AND APPLICATION CHRONOLOGY

As directed under WAC 246-310-282(1) the department accepted this project under the 2011 Kidney Disease Treatment Centers-Concurrent Review Cycle #4. No other kidney disease treatment center applications were reviewed for the Pierce County planning area #4 during Review Cycle #4. Therefore, as allowed under WAC 246-310-282(5), this application was converted to a regular review.

Action	Franciscan Health Systems
Letter of Intent Submitted	October 31, 2011
Application Submitted	November 30, 2011
Screening Activities and Responses	November 30, 2011 to February 21, 2012
 Department Begins Review of the Application public comments accepted throughout the review no public hearing requested or conducted 	February 22, 2012
End of Public Comment	March 28, 2012
Rebuttal Documents Received at Department ³	April 11, 2012
Department's Anticipated Decision Date	May 29, 2012
Department's Decision Date	September 6, 2012

AFFECTED PARTIES

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;

² Each criterion contains certain sub-criteria. The following sub-criteria are not discussed in this evaluation because they are not relevant to this project: WAC 246-310-210(3), (4), (5), and (6); and WAC 246-310-288.

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

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

SOURCE INFORMATION REVIEWED

- Franciscan Health System's Certificate of Need application received October 31, 2011
- Franciscan Health System's supplemental information, received February 14, 2012
- Years 2006 through 2010 historical kidney dialysis data obtained from the Northwest Renal Network
- Year 2011 Northwest Renal Network 2nd Quarter Data available on August 15. 2011
- Medical Quality Assurance Commission Credentialing Records
- Licensing and/or survey data provided by the Department of Health's Investigations and Inspections Office (Schedule Detail Report January 2008-May 2012)
- Certificate of Need historical files
- Corporation Search data base provided by Washington Secretary of State Corporations Division
- Joint Commission Website

CONCLUSION

For the reasons stated in this evaluation, the application submitted by Franciscan Health System proposing to relocate 22 of the 38 certified dialysis stations from the existing St. Joseph Medical Center's dialysis unit to a new facility called the FHS South Tacoma Dialysis Center is consistent with application criteria of the Certificate of Need Program, provided Franciscan Health System agrees to the following in its entirety.

Project Description:

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2. Franciscan Health System is required to decertify 22 of the 38 stations remaining at the hospital. At project completion, 16 dialysis stations would remain in operation at St.

Joseph Medical Center.

3. Before providing dialysis services at the new facility, commencement of the project, Franciscan Health System will provide to the department for review and approval an executed Medical Director Agreement. The executed Medical Director Agreement must be consistent with the draft agreement provided in the application.

Approved Costs:

The approved capital expenditure associated with this project is \$3,636,423. This amount represents the total capital expenditure of \$3,974,035 minus the landlord's costs of \$244,005 and the real estate commission of \$93,611.

A. Need (WAC 246-310-210)

Based on the source information reviewed and Franciscan Health System's agreement to the conditions identified in the 'conclusion' section of this evaluation, the department concludes that the applicant has met the applicable need criteria in WAC 246-310-210, the kidney disease treatment standards in WAC 246-310-284 and WAC 246-310-289.

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

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

Kidney Disease Treatment Center Methodology WAC 246-310-284

WAC 246-310-284 contains the methodology for projecting numeric need for dialysis stations within a planning area. This methodology projects the need for kidney dialysis treatment stations through a regression analysis of the historical number of dialysis patients residing in the planning area using verified utilization information obtained from the Northwest Renal Network.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 incenter patients for each of the previous six consecutive years, concluding with the base year. In planning areas experiencing high rates of growth in the dialysis population (6% or greater growth in each of the last five annual change periods), the method uses exponential regression to project future need. In planning areas experiencing less than 6% growth in any of the last five annual change periods, linear regression is used to project need.

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

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

S 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 2010.

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]

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 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's Application of the Numeric Methodology

In response to the necessity of a station need forecast, the applicant states, "no new stations are proposed as part of this project." Further, the applicant continues, "wherein a 'new' facility is being located via a relocation of existing stations, the department has concluded that the need methodology in WAC 246-310-284 is not applicable to these types of projects." Therefore, no station need was calculated by FHS for Pierce County subservice area #4. [Source: Application, p15]

Department's Application of the Numeric Methodology

Based on the calculation of the annual growth rate in the planning area as described above, the department used linear regression to project need. Given that the facility is located in Pierce County, the number of projected patients is divided by 4.8 to determine the number of stations needed in the planning area.

The table below provides a summary of the department's application of the numeric methodology. [Source: Appendix A of this evaluation]

Table 1
Pierce County Planning Area #4
Numeric Methodology Summary

4.8 in-center patients per station					
	2014 Projected # of stations (rounded up)	Minus Current # of stations	2014 Net Need		
DOH	65	63	2		

Though the applicant is not proposing adding stations to the planning area, the department's projections show a need for 2 additional dialysis stations in year 2014.

The department and FHS agree that this project is required to obtain a CN before proceeding because this project would result in a new health care facility within the planning area. What is at issue is whether the stations to be located at the new facility are "new" stations and therefore required to meet all of the review criteria for "new" dialysis stations or whether the stations are existing CN approved capacity and therefore not required to meet these new station requirements. [Source: Application, p6]

In this application, FHS is proposing to take a portion of previously CN approved stations and relocate them within a satellite facility away from their current location within the same planning area. If approved, the project will not increase the number of CN approved dialysis stations in the planning area.

WAC 246-310-284(1) states that applications for <u>new stations</u> may only address projected station need in the planning area in which the facility is to be located. WAC 246-310-284(2) thru (4) describe the detailed steps then used to calculate the projected station need.

The department ran the methodology as prescribed in WAC 246-310-284 that demonstrated a forecasted need in the planning area for additional stations in year 2014. Review of licensing data indicates the 22 stations to be relocated are currently Medicare certified and patients are being treated in them. The department included them as CN approved stations when running the numeric methodology. The department concludes that while a new health care facility would be established, it would not result in new stations to the planning area. Therefore the numeric need methodology is not applicable to this project.

WAC 246-310-284(5)

WAC 246-310-284(5) requires all CN approved stations in the planning area be operating at 4.8 in-center patients per station before new stations can be added. The most recent quarterly modality report, or successor report, from the Northwest Renal Network (NRN) as of the first day of the application submission period is to be used to calculate this standard. The first day of the application submission period is November 1, 2011. [WAC 246-310-282] The quarterly modality report from NRN available at that time was 2nd quarter data, which became available on August 15, 2011. The table below shows the utilization of each facility as of 2nd quarter 2011. In addition to the SJMC unit, DaVita, Inc. operates Tacoma Dialysis Center in the Pierce County subservice area #4 planning area. The table below shows the utilization of both facilities.

Table 2

2nd Quarter 2011 - Facility Utilization Data

Facility Name	# of Stations	# of Pts	Pts/Station
DaVita's Tacoma Dialysis Center	10	57	5.70
SJMC Dialysis Unit	38	256	6.79 ⁶
SJMC Tacoma East ⁷	12	0	0

As indicated above, the SJMC Tacoma East facility is currently operating below the minimum utilization standard of 4.8 patients per approved station. On first impression this would suggest that this standard is not met and the proposed project should fail this standard. The SJMC Tacoma East facility was established by taking 12 stations from SJMC's dialysis unit. Additionally the standard states that all CN approved stations within the planning area must be at the applicable utilization standard before new stations are added to the planning area. The 22 stations involved in this project are already CN approved and located within the planning area. Since the project does not propose to add any new stations to the planning area, the department concludes that this sub-criterion is not applicable to this project.

WAC 246-310-284(6)

WAC 246-310-284(6) requires new in-center dialysis stations be operating at a required number of in-center patients per approved station by the end of the third full year of operation. For the FHS South Tacoma located in Pierce County, the requirement is 4.8 in-center patients per approved station. [Source: WAC 246-310-284(6)(a)] FHS's third full year of operation is fiscal

⁷ Approved by CN#1421, but not yet operational

⁶ This calculation uses all existing patients, but excludes SJMC Tacoma East, therefore this number is overstated

year 2016. Since FHS is not requesting to add <u>new</u> stations to the planning area, the department concludes FHS is not required to meet this standard. The table below shows a summary of the applicant's projected utilization for year 2016 that demonstrates FHS South Tacoma would meet this standard in fiscal year 2016 even though the standard does not apply to this project. [Source: Application, p8]

Table 3
FHS South Tacoma Projected Facility Utilization

£ 11.9 90.	FIIS South Tacoma Trojected Facility					
Year 3	Stations	# of Pts	Utilization			
2016	22	110	5.0			

(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 health care service to residents of the state of Washington including low-income, racial and ethnic minorities, handicapped and other underserved groups. To determine whether all residents of the service area would continue to 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 nephrology services admission criteria that will be used at FHS South Tacoma. The Admission Policy outlines the process/criteria that FHS uses to admit patients for treatment, and ensures that patients will receive appropriate care at the dialysis center. The Admission Policy also states that any patient with end stage renal disease needing chronic hemodialysis will be accepted for treatment at FHS South Tacoma without regard to age, sex, race, religious or sexual preference, physical disability, or financial status. [Source: Application, Exhibit 8]

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 its existing dialysis centers. A review of the anticipated revenue indicates that the facility expects to continue to receive Medicaid reimbursements. FHS provided the expected sources of revenue for the dialysis center which includes approximately 3.5% Medicaid. [Source: Application, p8]

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 eligible patients at its existing dialysis centers. A review of the anticipated revenue indicates that the facility expects to continue to receive Medicare reimbursements. FHS provided the expected sources of revenue for the dialysis center which includes approximately 74.6% Medicare. [Source: Application, p8]

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 provide charity care to residents by submitting its charity care policy that outlines the programs available to patients unable to pay for the required care. Further, FHS included a 'charitable care' line item as a deduction from revenue within the proforma financial documents. [Source: Application, Appendix 2]

Based on the above information, the department concludes that all residents will have reasonable access to the health services at the FHS South Tacoma. **This sub-criterion is met.**

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

Based on the source information reviewed and Franciscan Health System's agreement to the conditions identified in the 'conclusion' section of this evaluation, the department concludes that the applicant has met the financial feasibility criteria in WAC 246-310-220.

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

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.

FHS anticipates commencement of services for this facility to be July 2013. Based on this timeline and the projected release of this evaluation, fiscal year 2014 would be FHS's first full year of operation for the FHS South Tacoma. [Source: Application, p7]

Using the financial information provided in the application, the table below illustrates the projected revenue, expenses, and net income for fiscal years 2014-2016 for FHS South Tacoma. [Source: Application, p126]

Table 4
Proposed FHS South Tacoma
Projected Revenue and Expenses

·	Year 1 - 2014	Year 2 - 2015	Year 3 - 2016
# of stations	22	22	22
# of Treatments	13,200	15,675	18,150
# of Patients	80	95	110
Utilization Rate	3.64	4.32	5.00
Net Patient Revenue	\$5,971,018	\$7,090,585	\$8,210,149
Total Operating Expense [1]	\$4,333,143	\$4,886,817	\$5,440,632
Net Profit or (Loss)	\$1,637,875	\$2,203,768	\$2,769,517

^[1] includes depreciation and amortization expenses

As shown in the table above, at the projected volumes identified in the application FHS anticipates the FHS South Tacoma facility would be operating at a profit in each of the forecast years.

FHS provided a copy of the lease for the facility to be located at 5825 Tacoma Mall Blvd., Suite 103 in the city of Tacoma. The lease provided in the application outlines the initial terms and the annual rent for the space. The annual lease costs are substantiated in the pro forma financial documents presented. [Source: Application, p 127, Exhibit 7 & 9]

As shown in the table above, at the projected volumes identified in the application, FHS South Tacoma would be operating at a profit as a 22-station facility throughout the three years following completion of the project.

Based on the above information, the department concludes that the project's revenues are reasonable and this sub-criterion is met.

(2) The costs of the project, including any construction costs, will probably not result in an unreasonable impact on the costs and charges for health services.

WAC 246-310 does not contain specific WAC 246-310-220(2) financial feasibility criteria as identified in WAC 246-310-200(2)(a)(i). There are also no known recognized standards as identified in WAC 246-310-200(2)(a)(ii) and (b) that directs what an unreasonable impact on costs and charges would be for a project of this type and size. Therefore, using its experience and expertise the department compared the proposed project's costs with those previously considered by the department.

The capital expenditure associated with the establishment of the FHS South Tacoma is \$3,974,035. Of these costs \$3,636,423 are the responsibility of FHS and \$337,611 are the responsibility of the landlord (Tahoma Vista, LLC). The complete capital cost breakdown is shown table 5 [Source: Application, p22,]

Table 5
FHS South Capital Cost Breakdown

Item	Cost	% of Total	
Tenant Improvement Allowance	\$244,000	6%	
Real Estate Commission (landlord expense)	\$93,611	2%	
Construction/	\$1,978,731	50%	
Fixed Equipment	\$1,001,063	25%	
Architect & Engineer Fees	\$212,260	5%	
Permits/Professional Fees	\$117,922	3%	
Sales Tax	\$326,448	8%	
Total Estimated Capital Costs	\$3,974,035	100%	

FHS has selected a site for FHS South Tacoma that is located in a commercial area within the city of Tacoma. The executed lease that is provided in the application outlines the annual rent and a 10 year initial lease term from date of commencement. The lease also provides for two renewal periods of 5 years each. Documents from the Washington Secretary of State office confirm that the landlord and property owner, Tahoma Vista, LLC is registered and authorized to conduct business within Washington State. FHS also supplied confirmation from the city of Tacoma that identifies the location as eligible for commercial activities such as a medical facility.

The department recognizes that the majority of reimbursements for dialysis services are through Medicare ESRD entitlements. To further demonstrate compliance with this sub-criterion, FHS also provided the sources of patient revenue shown in the table below. [Source: Application, p8]

Table 6
Anticipated Revenue Sources

Source of Revenue	% of Revenue		
Medicare	74.6%		
State (Medicaid)	3.5%		
Other Insurance	21.9%		
Total	100.0%		

As shown in the table above, the Medicare and Medicaid reimbursements are projected to equal 78.1% of the revenue at FHS's new facility. The department concludes that since the majority of revenue is dependent upon entitlement sources that are not cost based reimbursement, they are not expected to have an unreasonable impact on charges for services. The remaining 21.9% will be derived through a variety of reimbursement sources.

Based on the information provided, the department concludes that the costs of this project would not result in an unreasonable impact to the costs and charges for health care facilities. This subcriterion is met.

(3) The project can be appropriately financed.

WAC 246-310 does not contain specific source of financing criteria as identified in WAC 246-310-200(2)(a)(i). There are also no known recognized standards as identified in WAC 246-310-200(2)(a)(ii) and (b) that directs how a project of this type and size should be financed. Therefore, using its experience and expertise the department compared the proposed project's source of financing to those previously considered by the department.

The capital expenditure associated with the establishment of the 22 station FHS South Tacoma dialysis facility is \$3,974,034 and FHS's portion of the cost is \$3,636,423. FHS states its portion of the project will be funded from its own reserves. To demonstrate compliance with this subcriterion, FHS provided a letter from the Chief Financial Officer demonstrating the financial commitment to establish the 22-station FHS South Tacoma. The letter assured financial support for the proposed dialysis center through cash reserves available through the organization. FHS provided its most recent audited financial statements for years 2008, 2009, and 2010. A review of FHS's audited statements shows the funds necessary to finance the project are available. [Source: Application, Appendix 2; February 14, 2012 Supplemental Information, Attachment 2]

Based on the information provided, the department concludes that the transfer of 22 dialysis stations to the proposed FHS South Tacoma would not adversely affect the financial stability of FHS as a whole. **This sub-criterion is met.**

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

Based on the source information reviewed and Franciscan Health System's agreement to the conditions identified in the 'conclusion' section of this evaluation, the department concludes 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. Therefore, using its experience and expertise the department assessed the materials included in the application.

The applicant states that since this is a relocation of stations from SJMC, there are no anticipated concerns related to staffing. FHS anticipates the need to add one unit secretary in addition to transferring the necessary staff currently employed at the SJMC unit to the South Tacoma facility. FHS also contends that, "Given the quality and ongoing interest in our existing nephrology services, SJMC anticipates no difficulty in filling this position." [Source: Application, p26]

The table below details the proposed staffing for the South Tacoma facility...

Table 7
FHS South Tacoma Dialysis Center
Proposed Staffing

	2013	2014	2015	2016	Total	
Medical Director	Contract Position					
Clinical Nurse Mgr.	1.10	0.00	0.00	0.00	1.10	
Registered Nurse	3.30	1.10	0.83	0.82	6.05	
Patient Care Tech.	8.26	2.74	2.06	2.07	15.13	
Unit Secretary	1.10	0.00	0.00	0.00	1.10	
Social Worker	0.66	0.44	0.00	0.00	1.10	
Dietician	0.66	0.44	0.00	0.00	1.10	
Total	15.08	4.72	2.89	2.89	25.58	

Source: Application, p25

The department accepts the premise that the relocation of 22 stations to the FHS South Tacoma would have a minimal impact upon staffing demands. The operation of the SJMC facility already requires planning for sufficient, qualified staff outside of the normative turnover of employees.

FHS has identified Melissa Kaptick, MD as the Medical Director for the new facility. FHS provided a copy of the draft medical director agreement between itself and Dr. Kaptick. The agreement outlines the roles and responsibilities of both entities and identifies the annual compensation limits for the medical director responsibilities. If this project is approved, the department will include a condition requiring FHS to provide a copy of the executed medical

director agreement with Dr. Kaptick prior to commencement of services consistent with the draft agreement provided within the application. [Source: Application, p4 and Exhibit 2]

Provided FHS agrees to the Medical Director condition, 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(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.

Statements provided in the application indicate that FHS/SJMC intends to provide social and dietary support for patients within the program. Additionally, typical ancillary and support services used by a dialysis program, such as pharmacy, laboratory, radiology, and blood administration will also be available through SJMC. Since the FHS South Tacoma facility will be integrated into the FHS nephrology program, formal transfer agreements are not necessary; Rather, SJMC or another FHS facility would be utilized for any patients requiring hospital transfer. [Source: Application, p27]

Based on this information, the department concludes that FHS Tacoma South will have the necessary access to ancillary and support services. 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. Currently FHS owns or operates 13 healthcare facilities in Pierce and King Counties and is a provider of dialysis services. 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. 8

FHS will continue to provide Medicare and Medicaid services to the residents of its service areas through the current kidney dialysis treatment centers in operation. SJMC is accredited by Joint Commission and received their last survey on August 16, 2011. The other hospitals operated by are licensed by the state of Washington and accredited by Joint Commission. [Source: Facility survey data provided by the Investigations and Inspections Office, Joint Commission Website]

For Washington State, the Department of Health's Investigations and Inspections Office (IIO) completed a re-certification survey of the dialysis unit at FHS/SJMC in January 2011. The

⁸ WAC 246-310-230(5)

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 plans of correction. This plan of correction was approved in June 2011. Further, IIO's most recent survey of SJMC⁹ in its entirety also revealed no deficiencies beyond those typically expected in a hospital survey. FHS's Gig Harbor dialysis center was surveyed in April 2010 and recertified in March 2011. FHS's Puyallup dialysis center was recertified in May 2009. [Office of Health Care Survey Historical Record]

As stated above, Melissa Kaptick MD will perform the Medical Director duties at the proposed dialysis center. A review of the compliance history of Dr. Kaptick has shown that her credentials are up to date and reveal no recorded sanctions. [Compliance history provided by Medical Quality Assurance Commission]

Given the compliance history of FHS facilities, and the existing medical director, the department concludes that there is reasonable assurance that the dialysis center would continue to operate in conformance with state and federal regulation. 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 states, "FHS has organized its nephrology program such that all services are contained in a single service line. The organizational structure integrates inpatient, outpatient, and home services within a single continuum". The application continues, "This continuum is supported by a computer network which provides appropriate patient and clinical data to care providers throughout the system". Because there are no planned changes or reduction in services, the applicant does not anticipate that the residents in the service area will experience any fragmentation of services. [Source: Application, p27]

The department also considered FHS's history of providing care to residents in Washington State. The department concludes that the applicant has been providing dialysis services to the residents of Washington State for many years and has been appropriately participating in relationships with community facilities to provide a variety of medical services. Nothing in the materials reviewed by staff suggests that approval of this project would change these relationships. [Source: Office of Health Care Survey Historical Record]

⁹ The last recorded hospital Joint Commission survey was conducted August 17, 2011.

Based on this information, the department concludes that approval of this project would not result in an unwarranted fragmentation of services. Further, FHS demonstrated it has, and will continue to have, appropriate relationships to the service area's existing health care system within the planning area. This sub-criterion is met.

(5) There is reasonable assurance that the services to be provided through the proposed project will be provided in a manner that ensures safe and adequate care to the public to be served and in accord with applicable federal and state laws, rules, and regulations.

This subsection is addressed in sub section (3) of this evaluation. The department concludes that there is reasonable assurance that the services to be provided will ensure safe and adequate care to the public and in accord with applicable federal and state laws, rules and regulations. This sub-criterion is met.

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

Based on the source information reviewed and Franciscan Health System's agreement to the conditions identified in the 'conclusion' section of this evaluation, the department concludes that the applicant has met the cost containment criteria in WAC 246-310-240.

(1) <u>Superior alternatives</u>, 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 through 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 (tie-breaker) 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

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

Step Two

FHS considered two options before submitting this application.

- 1. "Status quo" or do nothing.

 FHS rejected this option because of the strong desire to improve access to services by relocating stations to another area of the planning area. By downsizing the hospital based unit, FHS is able to free up space on their tertiary care campus that can be used to provide space that is in high demand. These issues led to the rejection of this option. [Source: Application, p28]
- 2. Downsize the dialysis unit at SJMC without a relocation of stations to a new facility. FHS rejected this option as well. FHS reports that the dialysis unit is currently operating in excess of 85% occupancy and that, "downsizing, without another option for our patients, would result in us having to add a 4th shift and would unnecessarily compromise access". [Source: Application, p28]

The department did not identify any additional options for consideration and the numeric need portion of this evaluation resulted in need, though need was not required for this project. The department did not receive any letters of opposition related to this project. Given the options considered, the department concludes that the project described is the best available alternative for the community. **This sub-criterion is met.**

Step Three

FHS was the only entity who submitted an application to address dialysis service in Pierce County subservice area #4. As a result, step three is not evaluated under this sub-criterion.

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

The department acknowledges that the majority of the capital expenditure for FHS's new 22-station FHS South Tacoma is related to tenant improvements to leased space and the purchase of additional fixed and moveable equipment. The construction costs are reasonable when compared to construction costs of recent kidney dialysis proposals. Therefore, the department concludes this sub-criterion is met.

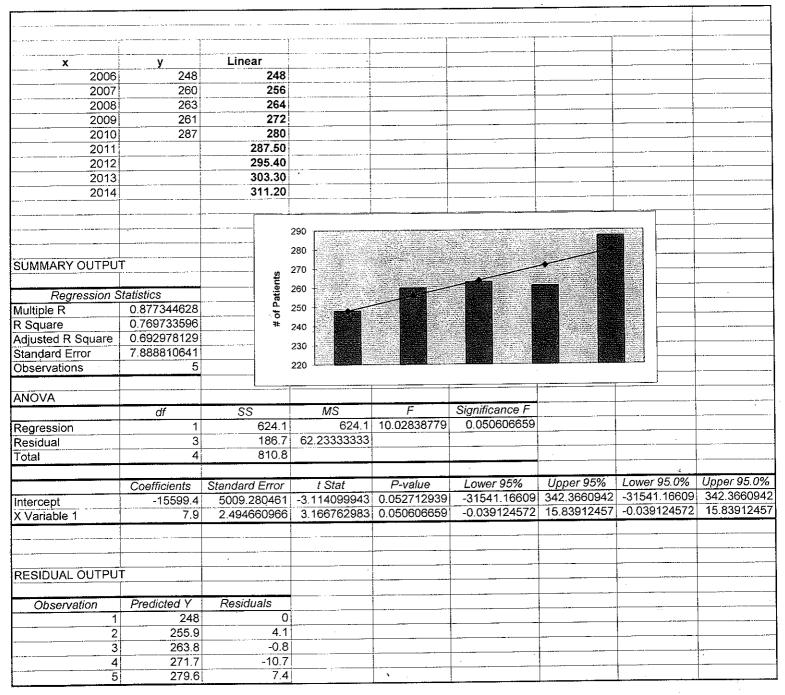
b) The project will not have an unreasonable impact on the costs and charges to the public of providing health services by other persons.

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

APPENDIX A



2011 Pierce County 4 ESRD Need Projection Methodology





2011 Pierce County 4 ESRD Need Projection Methodology

	Diam's Asse	C Voor Hilling	tion Data De	sident Incent	or Patients		
	Planning Area Pierce Four	2005	2006	2007	2008	2009	2010
	98402	7	10	7	8	8	6
	98403	11	10	11	14	14	13
	98404	40	43	47	52	52	53
165 - FT 1048-00-07-17	98405	38	41	40	36	40	40
	98406	9	7	12	11	12	11
	98407	14	12	13	12	13	18
	98408	37	44	36	38	25	27
	98409	31	28	26	25	31	38
	98416	0	0	0	0	0	0
	98418	8	15	15	15	17	20
A CONTRACT OF THE CONTRACT OF	98421	0	0	0	1	0	0
11/2/2017	98422	8	11	12	14	17	20
	98424	1	. 2	4	4	5	10
and the second s	98443	1	2	4	2	3	3
	98465	6	3	6	8	3	3
	98466	19	20	27	23	21	25
	TOTALS	230	248	260	263	261	287
The state of the s							
246-310-284(4)(a)	Rate of Change		7.83%	4.84%	1.15%	-0.76%	9.96%
	6% Growth or Greater?	<u> </u>	TRUE	FALSE	FALSE	FALSE	TRUE
	Regression Method:	Linear					
						,	
246-310-284(4)(c)				Year 1	Year 2	Year 3	Year 4
				2011	2012	2013	2014
Projected Resident							
ncenter Patients	from 246-310-284(4)(b)			287.50	295.40	303.30	311.20
Station Need for							
Patients	Divide Resident Incenter	Patients by	4.8	59.8958	61.5417	63.1875	64.833
	Rounded to next whole r	umber		60	62	64	6
	Tourise to Hoze William					1	
246-310-284(4)(d)	subtract (4)(c) from approv	ed stations			63	63	6
Existing CN Approved S	stations			63 60	62	64	6:
Results of (4)(c) above			-	60	62		0:
Net Station Need				3	1	-1	-
Negative number indicates ne	ed for stations	,					
							•
246-310-284(5)							
Name of Center	# of Stations	Patients		Patients per	Station)		
DaVita - Tacoma	13						
St. Joseph East	12	i					
St. Joseph Medical Cen							
- , ,	63	312	<u> </u>				
Total				: !			
			 				
Source: Northwest Renal	Network data 2005-2010 a: 2010 year-end data as o					1	