

**EVALUATION OF THE CERTIFICATE OF NEED APPLICATION SUBMITTED BY
FRANCISCAN HEALTH SYSTEM PROPOSING TO ESTABLISH A NEW 12 STATION
DIALYSIS CENTER IN PIERCE COUNTY SUBSERVICE AREA #4.**

PROJECT 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 12 health care facilities—five hospitals, three dialysis centers, a skilled nursing facility, an ambulatory surgery center, a Medicare certified hospice agency, and a hospice care center. The health care facilities are listed below. [CN historical files; Application, Appendix 1]

Hospitals

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

Dialysis Centers

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

Skilled Nursing Facility

Franciscan Care Center, Tacoma

Ambulatory Surgery Center

Gig Harbor Ambulatory Surgery Center

Hospice Agency

Franciscan Hospice, Tacoma

Hospice Care Center

FHS Hospice Care Center

This project focuses on St. Joseph Medical Center (SJMC) located at 1717 South ‘J’ Street in Tacoma. The hospital provides Medicare and Medicaid acute care services to residents in and around Pierce County and holds a three-year accreditation with the Joint Commission. FHS proposes to relocate 12 of the existing 50 dialysis stations within the hospital’s dialysis unit to a satellite location. [Application, p7]

The new 12-station facility will be called the SJMC East Tacoma Dialysis Center and will be located at 1415 East 72nd Street, Suite E in Tacoma. The stated purpose is to expand access and to allow for additional space necessary to properly conduct patient education and related support services. The proposed facility will provide patient training and will include isolation bed space. FHS has determined that this is a cost effective and efficient manor to facilitate this additional space necessary and states, “Square footage within the hospital proper is at a premium, and therefore the best way to free up space for the needed enhancements is to downsize the number of stations”. At project completion, FHS will decertify 12 of the 50 stations operated at the hospital. [Application, p7 & 10; October 1, 2009 Supplemental Information, p4; November 10, 2009 Supplemental Information, p1]

The project costs for the establishment of the new facility is \$1,976,936, and is broken down as follows: [Application, p24]

Item	Cost	% of Total
Construction/Leasehold Improvements	\$ 980,259	50%
Fixed & Moveable Equipment	\$ 687,092	35%
Professional Fees	\$ 105,795	5%
Permits	\$ 59,510	3%
Sales Tax	\$ 147,280	7%
Total Estimated Capital Costs	\$ 1,979,936	100.00%

FHS will lease the site for the East Tacoma Dialysis Center. The building is currently under construction and will be fitted for use as a dialysis facility. As a result, if this project is approved, FHS anticipates the new facility will be completed in the Spring of 2011 and to be operational by July 1, 2011. [Application, p11]

BACKGROUND

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 12 of the 50 stations from the SJMC location, the East Tacoma Dialysis Center is considered to be a new health care facility.

APPLICABILITY OF CERTIFICATE OF NEED LAW

This project is subject to Certificate of Need review as establishment of a new heath 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

To obtain Certificate of Need (CN) approval, FHS, Inc. 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).¹ Additionally, the applicant must demonstrate compliance for the project according to relevant sections of WAC 246-310-280 through 287.

¹ Each criterion contains certain sub-criteria. The following sub-criteria are not discussed in this evaluation because they are not relevant to this project: WAC 246-310-210(3), (4), (5), and (6); WAC 246-310-240(3); WAC 246-310-288; and WAC 246-310-284.

APPLICATION CHRONOLOGY

April 30, 2009	Letter of Intent Submitted
May 29, 2009	Application Submitted
May 30, 2009 to November 15, 2009	1 st Screening Activities and Responses and 2 nd Screening Activities and Responses
November 16, 2009	Department Begins Review of Application No Public Hearing Requested
December 21, 2009	Close of Public Comment - No Rebuttal
February 26, 2010	Department's Anticipated Decision Date
April 9, 2010	Department's Decision Date

AFFECTED PARTIES

Throughout the review of this project, no entity met the standards to receive affected person status under WAC 246-310-010

SOURCE INFORMATION REVIEWED

- FHS's Certificate of Need Application, received May 29, 2009
- FHS's supplemental information, received October 1, 2009
- FHS's supplemental information, received November 10, 2009
- Years 2003 through 2008 historical kidney dialysis data obtained from the Northwest Renal Network
- March 2008 Northwest Renal Network Quarterly Data
- Medical Quality Assurance Commission Credentialing Records
- Licensing and/or survey data provided by the Department of Health's Investigations and Inspections Office
- Public comment submitted by FHS
- Certificate of Need historical files

CONCLUSION

For the reasons stated in this evaluation, the application submitted on behalf of FHS, Inc. to relocate 12 of the 50 certified dialysis stations from the existing SJMC dialysis unit to a new facility called the East Tacoma Dialysis Center is consistent with application criteria of the Certificate of Need Program, and a Certificate of Need is approved. At project completion, SJMC would have approval to operate a total of 38 dialysis stations at the hospital and the East Tacoma Dialysis Center will operate 12 dialysis stations.

The total approved costs associated with this project are \$1,979,936.

Terms

1. FHS/SJMC will provide a copy of the executed medical director agreement with Dr. Anel prior to commencement of services consistent with the draft agreement provided within the application.
2. FHS/SJMC will provide the program with a finalized lease that is consistent with the rates and terms outlined in the draft provided with the application.

A. Need (WAC 246-310-210)

Based on the source information reviewed, the department determines that the applicant has met the applicable need criteria in WAC 246-310-210 and the kidney disease treatment standards in 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 contains the methodology for projecting numeric need for dialysis stations within a planning area. This methodology, adopted January 1, 2007, 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.²

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. In planning areas experiencing high rates of growth in the dialysis population (6% or greater growth in each of the last 5 annual change periods), the department 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 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 in the planning area are then subtracted from the total need, resulting in a net need for the planning area. [WAC 246-310-284(4)(d)]

² 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]

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 for by FHS for Pierce County subservice area #4. [Application, p16]

Department's Application of the Numeric Methodology

The Department of Health's CN Program uses the methodology outlined above for projecting numeric need for dialysis stations within a service area when a methodology is prescribed according to the type of application under review. Based on the calculation of the annual growth rate in the planning area as described above, the department also 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.

Table 1 provides a summary of the department's application of the numeric methodology. [Appendix A of this evaluation]

Table 1
Summary of Department's Numeric Methodology

	Year 2009	Year 2010	Year 2011	Year 2012
In-center Patients	287.4	303.2	319.0	334.8
Patient: Station Conv. Factor	4.8	4.8	4.8	4.8
Total Station Need	59.88	63.17	66.46	69.75
Total Station Need Rounded Up	60	64	67	70
Minus # of CN Approved Stations	60	60	60	60
Net Station Need	0	-4	-7	-10

As shown in Table 1, though the applicant is not proposing adding stations to the planning area, projections show a potential need for 10 additional dialysis stations in year 2012.

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. [Application, p7]

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 new stations 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.

Although the department ran the methodology as prescribed that produced a forecasted need in the planning area, this project is not requesting a station increase. The 12 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. In addition to the SJMC unit, DaVita, Inc. operates the Tacoma Dialysis Center in the Pierce County subservice area #4 planning area. The most recent quarterly modality report, or successor report, from the Northwest Renal Network (NRN) as of the first day of the application submission period is to be used to calculate this standard. The first day of the application submission period is May 1, 2009. [WAC 246-310-282] The quarterly modality report from NRN available at that time was December 31, 2008, which became available on January 26, 2009. Table 2 below shows the utilization of each facility as of December 31, 2008.

Table 2
December 31, 2008 - Facility Utilization Data

Facility Name	# of Stations	# of Pts	Pts/Station
DaVita's Tacoma Dialysis Center	10	28	2.80
SJMC Dialysis Unit	50	252	5.04

As indicated above, the DaVita 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 therefore the proposed project should fail this standard. However on closer review of the standard it states that all CN approved stations within the planning must be at the applicable utilization standard before new stations are added to the planning area. The 12 stations involved in this project are already CN approved and located within the planning area. Since the project does not propose to add any new stations to the planning area the department concludes that this sub-criterion is not applicable this project.

WAC 246-310-284(6)

WAC 246-310-284(6) requires new in-center dialysis stations be operating at a required number of in-center patients per approved station by the end of the third full year of operation. For the East Tacoma Dialysis Center located in Pierce County, the requirement is 4.8 in-center patients per approved station. [WAC 246-310-284(6)(a)] FHS's third full year of operation is fiscal year 2014. A summary of the applicant's projected utilization for year 2014 is shown in Table 3 and demonstrates that the East Tacoma Dialysis Center would meet this standard in fiscal year 2014 with all 12 stations operational. [Application, p17]

Table 3
East Tacoma Dialysis Center Projected Facility Utilization

Year 3	Stations	# of Pts	Utilization
FY2014	12	60	5.0

As stated above, the standard requires that all new in-center kidney dialysis stations must reasonably project to be operating at 4.8 patients per station by the third year of operation. The applicant however is not requesting to add new stations to the planning area. Therefore the department concludes FHS is not required to meet the standards regarding utilization rates. FHS must however meet other applicable requirements in WAC 246-310-210(2) regarding access to underserved groups

As a result of these findings, the department concludes that numeric need for additional stations in the service area is not applicable in the review of this application.

- (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 the East Tacoma facility. 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 SJMC East Tacoma without regard to age, sex, race, religious or sexual preference, physical disability, or financial status. [Application, Exhibit 5]

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

FHS currently provides services to Medicare and Medicaid eligible patients at its existing dialysis centers. A review of the anticipated revenue indicates that the facility expects to continue to receive both Medicare and Medicaid reimbursements. [Application, p9]

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 pro forma financial documents. [Application, Exhibit 5 & 6]

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

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

Based on the source information reviewed, the department determines that the applicant has met the financial feasibility criteria in WAC 246-310-220.

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

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 1, 2011. Based on this timeline and the projected release of this evaluation, fiscal year 2012 would be FHS’s first full year of operation for the East Tacoma Dialysis Center. [Application, p11]

Using the financial information provided in the completed application, Table 4 on the following page illustrates the projected revenue, expenses, and net income for fiscal years 2012-2014 for the East Tacoma Dialysis Center. [Application, p6]

Table 4
Proposed East Tacoma Dialysis Center
Projected Revenue and Expenses

	Year 1 - 2012	Year 2 - 2013	Year 3 - 2014
# of stations	12	12	12
# of Treatments	7,020	8,268	9,360
# of Patients	45	53	60
Utilization Rate	3.75	4.42	5.00
Net Patient Revenue	\$ 2,239,942	\$ 2,638,154	\$ 2,986,589
Total Operating Expense [1]	\$ 2,071,193	\$ 2,355,931	\$ 2,568,026
Net Profit or (Loss)	\$ 168,749	\$ 282,223	\$ 418,563
Net Patient Revenue/Treatment	\$ 319.08	\$ 319.08	\$ 319.08
Total Operating Exp./Treatment	\$ 295.04	\$ 284.95	\$ 274.36
Net Profit per Treatment	\$ 24.04	\$ 34.13	\$ 44.72

[1] includes depreciation and amortization expenses

As shown in Table 4, at the projected volumes identified in the application, East Tacoma Dialysis Center would be operating at a profit as a 12-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 East Tacoma Dialysis Center is \$1,976,936, of which 50% is related to construction, 35% for both fixed and moveable equipment; inclusive of the costs needed to purchase the new stations. The complete capital cost breakdown is shown below. [Application, p24, October 1, 2009 Screening Information, p1]

Item	Cost	% of Total
Construction/Leasehold Improvements	\$ 980,259	50%
Fixed & Moveable Equipment	\$ 687,092	35%
Professional Fees	\$ 105,795	5%
Permits	\$ 59,510	3%
Sales Tax	\$ 147,280	7%
Total Estimated Capital Costs	\$ 1,979,936	100.00%

FHS has selected a site for the East Tacoma facility that is located in a commercial area within the City of Tacoma. The draft lease that is provided in the application outlines the annual rent and multiple renewal terms for the space through 2030. Documents were also provided to show that the landlord and property owner, CRH Capital Properties, 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. If approved, a term would be added to requiring FHS to provide the program with a finalized lease that is consistent with the rates and terms outlined in the draft provided with the application. [October 1, 2009 Screening Information, Attachment 1 & 2; November 10, 2009 Screening Information, Attachment 1]

The department recognizes that the majority of reimbursements for dialysis services come through Medicare ESRD entitlements. To further demonstrate compliance with this sub-criterion, FHS also provided the sources of patient revenue shown in Table 5 below. [Application, p8]

Table 5
Anticipated Revenue Sources

Source of Revenue	% of Revenue
Medicare	74
State (Medicaid)	6
Other Insurance	20
Total	100%

As shown above, the Medicare and State (Medicaid) entitlements are projected to equal 80% of the revenue at FHS's new facility. The department concludes that the majority of revenue is dependent upon entitlement sources that are not cost based reimbursement and are not expected to have an unreasonable impact on charges for services. Further, the cost per dialysis treatment for the proposed project was compared to those of recent kidney dialysis proposals, the average cost per dialysis is reasonable.

Based on the information provided, and acceptance of a term related to an executed lease agreement, the department concludes that the costs of this project would not result in an unreasonable impact to the costs and charges for health care facilities. This sub-criterion is met.

(3) The project can be appropriately financed.

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.

To demonstrate compliance with this sub-criterion, FHS provided a letter from the Chief Financial Officer demonstrating the financial commitment to establish the 12-station East Tacoma Dialysis Center. 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 2006, 2007, and 2008. A review of FHS's audited statements shows the funds necessary to finance the project are available. [Application, Appendix 2; October 1, 2009 Supplemental Information, Attachment 8]

Based on the information provided, the department concludes that the transfer of 12 dialysis stations to the proposed East Tacoma Dialysis Center 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, the department determines that the applicant has met the structure and process (quality) of care criteria in WAC 246-310-230.

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

WAC 246-310 does not contain specific WAC 246-310-230(1) criteria as identified in WAC 246-310-200(2)(a)(i). There are also no known recognized standards as identified in WAC 246-310-200(2)(a)(ii) and (b) that directs what specific staffing patterns or numbers of FTEs that should be employed for projects of this type or size. Therefore, using its experience and expertise the department concludes that the planning would allow for the required coverage.

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 clinical nurse manager in addition to the transferring of the necessary staff currently employed at the SJMC unit to the East 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". [Application, p27 & 28]

The Department accepts the premise that the relocation of 12 stations to the East Tacoma Dialysis Center 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 Dr. Ramon Anel as the Medical Director for the new facility. FHS provided a copy of the draft medical director agreement between itself and Dr. Anel. 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 term requiring FHS/SJMC to provide a copy of the executed medical director agreement with Dr. Anel prior to commencement of services consistent with the draft agreement provided within the application. [October 1, 2009 Supplemental Information, Attachment 5]

Pending acceptance of the term requiring an executed Medical Director agreement cited above, 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 intend 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 East Tacoma facility will be associated with FHS, formal transfer agreements are not necessary, rather, SJMC would be the facility of choice for any patients requiring hospital transfer. [Application, p28, October 1, 2009 Supplemental Information, p4]

Based on this information, the department concludes that FHS 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.

As stated earlier, FHS is currently a provider of dialysis services in Washington State. FHS will continue to provide Medicare and Medicaid services to the residents of its service areas throughout the current kidney dialysis treatment centers in operation.

For Washington State, the Department of Health's Investigations and Inspections Office (IIo) recently completed a re-certification survey of the dialysis unit at SJMC. The compliance survey revealed minor non-compliance issues related to the care and management within the unit. These non-compliance issues were typical of a dialysis facility and FHS submitted and implemented acceptable plans of correction. Further, IIo's most recent survey of SJMC³ in its entirety also revealed no deficiencies beyond those typically expected in a hospital survey. [Office of Health Care Survey Historical Record]

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

Given the compliance history of FHS, the dialysis unit, 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 service 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,

³ The last recorded hospital survey was conducted November 30, 2006

“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. [Application, p29]

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. [Office of Health Care Survey Historical Record]

Additionally, the department considers the results of the kidney disease treatment center numeric methodology and standards outlined in WAC 246-310-284. As outlined in the Need discussion above, demonstration of need in the numeric methodology is not required for approval of this application. No new stations are being added to the service area. The 12 stations are currently being used by patients at the SJMC facility.

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

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

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. Additionally, FHS project met the applicable dialysis specific review criteria identified in WAC 246-310-284. Therefore, the department moves to step two below.

Step Two

FHS considered three options before submitting this application.

1. “Status quo” or do nothing.

FHS rejected this option because the dialysis unit is in need of additional space to provide enhanced patient education services. Doing nothing would also do nothing to improve access to services that a separate location may provide. These issues led to the rejection of this option. [Application, p30]

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 create the patient education areas that we desire to have within our program”. FHS states this option creates a hardship on staff and patients. [Application, p30]

3. Establish a new dialysis facility.

The remaining option of establishing a new facility was determined to be the best option by the applicant. The decision to establish a 12-station facility through the transfer of existing stations was presented for two reported reasons. First, 12 stations were determined to provide the efficiencies desired in the operation of the facility. Second, the space created at SJMC would be sufficient to support the patient education areas desired. [Application, p30]

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 12-station East Tacoma Dialysis Center 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 that this 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 that this sub-criterion is met.