



STATE OF WASHINGTON
DEPARTMENT OF HEALTH

June 20, 2011

CERTIFIED MAIL # 7008 1300 0000 7202 9645

Elaine Couture, Chief Executive
Sacred Heart Medical Center & Children's Hospital
101 West 8th Avenue
Spokane, WA 98204

RE: CN11-12

Dear Ms. Couture:

We have completed review of Sacred Heart Medical Center & Children's Hospital proposing to begin performing adult pancreatic transplants. 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 Sacred Heart agrees to the following in its entirety:

Project Description:

Establish an adult pancreas transplant program within Sacred Heart Medical Center and Children's Hospital.

Condition:

1. Approved project as described above.
2. Sacred Heart will provide charity care in compliance with the charity care policies provided in this Certificate of Need application, or any subsequent polices reviewed and approved by the Department of Health. Sacred Heart will use reasonable efforts to provide charity care in an amount comparable to or exceeding the average amount of charity care provided by hospitals in the Eastern Washington Region. Currently, this amount is 1.59% of gross revenue and 3.79% of adjusted revenue. Sacred Heart will maintain records documenting the amount of charity care it provides and demonstrating its compliance with its charity care policies.

Approved Costs:

The approved capital expenditure associated with this project is \$0.00.

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



Elaine Couture, Chief Executive
Sacred Heart Medical Center & Children's Hospital
June 20, 2011
Page 2 of 2


any provision of the above, you must identify that provision, and your application will be denied because approval would not be consistent with applicable Certificate of Need review criteria. Please notify the Department of Health within 20 days of the date of this letter whether you accept the above in its entirety.

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

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

Other Than By Mail:
Department of Health
Certificate of Need Program
310 Israel Road SE
Tumwater, WA 98501

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 OF THE CERTIFICATE OF NEED APPLICATION SUBMITTED ON BEHALF OF
SACRED HEART MEDICAL CENTER AND CHILDREN'S HOSPITAL PROPOSING TO BEGIN
PERFORMING ADULT PANCREAS TRANSPLANTS**

PROJECT DESCRIPTION

Sacred Heart Medical Center and Children's Hospital (Sacred Heart) is a 644¹ bed acute care, not for profit, hospital located in the city of Spokane within Spokane County. Sacred Heart is part of Providence Health & Services that includes 26 hospitals, more than 35 non-acute facilities, and related clinics and educational locations throughout Alaska, Washington, Montana, and Oregon. Sacred Heart provides Medicare/Medicaid acute care services to the residents of Spokane County and surrounding areas, and currently holds an accreditation from the Joint Commission. [Providence website; Application, Exhibit 2; Joint Commission website]

Sacred Heart is proposing to expand their services to include pancreas transplants for adults within a defined tertiary planning area that includes 16 eastern Washington counties and residents from Idaho and Montana. The hospital intends to incorporate the adult pancreatic transplants into their current kidney transplant program. Sacred Heart intends to begin performing adult pancreatic transplants and simultaneous kidney-pancreas transplants upon approval of this application. Sacred Heart reports no capital costs for this service expansion.

APPLICABILITY OF CERTIFICATE OF NEED LAW

This project is subject to Certificate of Need review as the establishment of a new tertiary health service under the provisions of Revised Code of Washington (RCW) 70.38.105(4)(f) and Washington Administrative Code (WAC) 246-310-020(1)(d)(i)(D) and (WAC) 246-310-035(2).

CRITERIA EVALUATION

WAC 246-310-200(1)(a)-(d) identifies the four determinations that the Department must make for the 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 shall consider:

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

In the event 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

¹ This total would be comprised of 511 acute care beds, 72 psychiatric beds, 21 ICN-level II bassinets, and 40 NICU level III bassinets

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 approval, an applicant 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); and 246-310-240 (cost containment). Additionally, WAC246-310 does not contain a need methodology for pancreas transplant programs.²

APPLICATION CHRONOLOGY

Action	Sacred Heart
Letter of Intent Submitted	September 14, 2010
Application Submitted	December 22, 2010
Department’s Pre-Review Activities • Screening activities and responses	December 23, 2010 through March 14, 2011
Beginning of Review	March 15, 2011
End of Public Comment	April 19, 2011
Department's Anticipated Decision Date	June 20, 2011
Department's Actual Decision Date	June 20, 2011

AFFECTED PERSONS

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

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

SOURCE INFORMATION REVIEWED

- Sacred Heart Medical Center and Children's Hospital Certificate of Need application submitted December 22, 2010
- Sacred Heart Medical Center and Children's Hospital supplemental information dated March 4, 2011
- Department of Health's Office of Hospital and Patient Data Systems (HPDS) financial feasibility and cost containment analysis dated May 9, 2011
- Public comment received during the course of the review
- Transplant and waiting list data available through the United Network for Organ Sharing (UNOS)
- Transplant data available through the Organ Procurement and Transplant Network (OPTN)
- American Society of Transplant Surgeons Website (www.ast.org)
- Information cited on the Providence Health & Services website (www.providence.org)
- Certificate of Need Historical files
- Department of Health's Investigation and Inspection's Office (IIO) files

CONCLUSION

For the reasons stated in this evaluation, the Certificate of Need application submitted on behalf of Sacred Heart Medical Center and Children's Hospital to begin performing adult pancreas transplants at the hospital is consistent with the Certificate of Need review criteria, and a Certificate of Need is approved.

Project Description:

Establish an adult pancreas transplant program within Sacred Heart Medical Center and Children's Hospital.

Condition:

Sacred Heart will provide charity care in compliance with the charity care policies provided in this Certificate of Need application, or any subsequent policies reviewed and approved by the Department of Health. Sacred Heart will use reasonable efforts to provide charity care in an amount comparable to or exceeding the average amount of charity care provided by hospitals in the Eastern Washington Region. Currently, this amount is 1.59% of gross revenue and 3.79% of adjusted revenue. Sacred Heart will maintain records documenting the amount of charity care it provides and demonstrating its compliance with its charity care policies.

Approved Costs:

The approved capital expenditure associated with this project is \$0.00.

A. Need (WAC 246-310-210)

Based on the source information reviewed, the department determines that the application is consistent with the applicable need criteria in WAC 246-310-210.

(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.

Because the department does not have an established numeric need projection methodology for organ transplant services, it is incumbent upon the applicant to provide a rational and verifiable analysis of need for the service to be provided. In this application, Sacred Heart examined national, state, and planning area rates of adult pancreas and combined kidney/pancreas transplants to attempt to determine whether a need exists for additional adult pancreatic transplant capacity in Washington.

For the purposes of this tertiary service proposal, Sacred Heart is using a service area which includes 16 counties located on the eastern side of the Cascade Mountain range. Sacred Heart contends that these residents would consider Sacred Heart the likely resource for tertiary services. According to 2009 kidney transplant statistics, Sacred Heart maintains a 50% market share in seven eastern Washington counties where residents were shown to receive transplants³. The remaining counties were included due to geographic location and proximity to Sacred Heart⁴. Further, due to facility data which shows an in-migration of kidney transplant patients from Idaho and Montana, the applicant considers the continued in-migration from these states in the latter steps of the supporting need methodology. [Application, p10]

In its application, Sacred Heart is projecting that the pancreas program will serve at least 6 patients in each of the initial projected years of operation. These patients consist predominately of the combined kidney/pancreas procedure which account for approximately 53 of the 62 pancreas-related patient days. In total, the new pancreas program, combined with growth within the existing kidney transplant program, is projected to add 107 additional patient days in each of the forecast years. Sacred Heart bases this on the computations from an 8-step methodology that considers the use rates of adult residents within the state and potential in-migration. Each of these steps will be discussed in detail below. [Application, p30; March 3, 2011 Supplemental Information, p11 & 28-34]

1. Compile state and national transplant statistics.

Sacred Heart reported the historical incidents of adult pancreas and kidney/pancreas transplants from 2000 to 2009 available through Organ Procurement and Transplant Network (OPTN). The incidents were confined to ages 18 and older for both Washington state and the nation as a whole.

2. Calculate state and national historic use rates.

Historic population statistics were compiled according to Washington State Office of Financial Management (OFM) and United States Census bureau estimates. The department also relies upon population forecasts published by OFM. OFM publishes a set of forecasts known as the “medium-series” county population projections, based on the 2000 census, updated November

³ The Counties include: Benton, Douglas, Franklin, Grant, Okanogan, Spokane, and Walla Walla

⁴ The Counties include: Adams, Asotin, Columbia, Ferry, Garfield, Lincoln, Pend Oreille, Stevens, and Whitman

2007⁵. The figures applied by Sacred Heart appear to apply this same information to determine the adult population totals.

The use rates are separated according to adult pancreas, kidney/pancreas transplants rates, and a total combined use rate.

3. Forecast state and national utilization figures.

Forecasted population figures for 2010 through 2020 were computed from the population figures reported in step 2. The use rates tabulated for 2009 were applied at a constant rate through the forecast years to determine the number of statewide and national incidents of adult pancreas and kidney/pancreas transplants could be expected.

4. Compile Washington state pancreas and kidney/pancreas transplant detail.

Sacred Heart established a 3-year average of the incidents of adult pancreas and kidney/pancreas transplants taking place in Washington. The results are divided by planning area, other Washington, and out of state patients. The information was obtained from the Department of Health Office of Hospital and Patient Data Systems' CHARS (Comprehensive Hospital Abstract Reporting System) database. The Applicant considered data from 2007-2009.

The results supply a 3-year average of the adult pancreas and kidney/pancreas transplants performed within Washington state facilities for both planning area and out-of-state residents.

5. Estimate the projected number of transplants for planning area and out-of state residents.

Applying the 3-year average use rate from step 4 to the projected transplants established in step 3, the Applicant produced the projected adult pancreas and kidney/pancreas transplants for the defined planning area and out-of state residents for all Washington hospitals.

6. Estimate the number of out-of-state resident transplants from Idaho and Montana only.

Again applying the 3-year average use rate from step 4, Sacred Heart produced the projected adult pancreas and kidney/pancreas transplants for the projected out-of state residents specifically from Idaho and Montana.

7. Estimate the projected number of planning area, Idaho, and Montana resident pancreas and kidney/pancreas transplants at SHMC for 2010-2020.

Using 2009 CHARS data, Sacred Heart established the hospital's market share for the planning area and out-of state residents from Idaho and Montana as a measure of the hospital's likely penetration rate. The market share was applied to the combined forecasted totals of potential adult pancreas and kidney/pancreas transplants to establish the likely annual forecast of adult pancreas and kidney/pancreas transplant procedures for SHMC's proposed program.
[Application, p33]

⁵ The November 2007 series was the most current data set available and can be found at <http://www.ofm.wa.gov/pop/estimates.asp> and compiled internally by DOH

8. Prepare patient day forecasts for pancreas and kidney/pancreas transplants at SHMC.

Using 2009 CHARS data, statewide discharge and patient day statistics were compiled and applied to SHMC's projected adult pancreas and kidney/pancreas transplants to establish the potential increase in patient days.

The projections resulting from these steps are summarized below in Table 1.

Table 1
Summary of Sacred Heart's Need Forecast

Adult Transplant	2010	2011	2012	2013	2014	2015	2016
Pancreas Transplants	1	1	1	1	1	1	1
Kidney/Pancreas Transplants	5	5	5	5	5	5	5
Total Procedures	6	6	6	6	6	6	6
Projected Patient Days ⁶	62	62	62	62	62	62	62

When considering the approach and steps taken by the applicant to support their application and with no alternative available in rule, the department can accept the resulting need projection.

The reported instances of transplants can be confirmed by the OPTN and UNOS waiting list. The Sacred Heart 2009 use rate can be confirmed by using reported transplants and population. This rate is applied to, and kept constant throughout the forecast horizon, using the same population data source. Then factoring current market share in the identified tertiary counties and neighboring states, the applicant was able to show sufficient need to justify the new program.

The applicant also states that, "there has been a steady out-migration of pancreas organs out of the state of Washington". LifeCenter data supplied in the application indicates that Washington does regularly export available pancreases. A summary of the pancreas' exported since 2006 indicate a total of 32 were exported out of state; 27 of these going to adult patients. With a new state program, organs currently transported to states such as California and Minnesota may be able to be used in Washington residents. [Application, p26; March 4, 2011 Supplemental Information, p8 & Exhibit 3]

No comment was received from any pancreatic transplant facilities, but a letter of support was submitted by LifeCenter Northwest. As part of their comment, LifeCenter states, "Providence Sacred Heart provides Eastern Washington residents with a wide array of high-quality care. An approved adult pancreas transplant program would build upon these services and increase local access to care for eastern Washington residents".

The department concludes that existing providers of pancreatic transplants, by virtue of their location, are not reasonably available or accessible to the residents of eastern Washington. The department further concludes that establishment of an pancreatic transplant program at Sacred Heart is not likely have adverse affects on the fellowship program at UWMC and could provide increased access for residents of the tertiary service area presented in this application **This sub-criterion is met.**

⁶ The applicant considered the potential for additional kidney transplants with inclusion of a pancreas transplant program and related staff. A total of 107 additional patient days in each of the forecast years is reviewed under WAC 246-310-220.

- (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.

Sacred Heart is currently a provider of health care services to residents of Washington State, including low-income, racial and ethnic minorities, handicapped and other underserved groups. As an acute care hospital, Sacred Heart also currently participates in the Medicare and Medicaid programs. 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, Sacred Heart provided a copy of its current Admission Policy that would continue to be used at the hospital. The policy outlines the process/criteria that Sacred Heart will use to admit patients for treatment or care at the hospital. The applicant states that any patient requiring care will be accepted for treatment at Sacred Heart without regard to "race, color, national origin, sex, marital status, or on the basis of disability or age". [Application, Exhibit 9]

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. Sacred Heart currently provides services to Medicare eligible patients. Documents provided in the application demonstrate that Sacred Heart intends to maintain this status. For this project, a review of the policies and data provided for Sacred Heart identifies the facility's financial pro forma includes Medicare revenues [Application, p17; March 4, 2011 Supplemental Information, p45]

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. Sacred Heart also provides services to Medicaid eligible patients. Documents provided in the application demonstrate that Sacred Heart intends to maintain this practice. For this project, a review of the policies and data provided for Sacred Heart identifies the facility's financial pro forma includes Medicaid revenues [Application, p17; March 4, 2011 Supplemental Information, p45]

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.

Sacred Heart demonstrated its intent to continue to provide charity care to residents by submitting its current charity care policy that outlines the process a patient would use to access this service. Further, Sacred Heart included a 'charity care' line item as a deduction from revenue within the pro forma financial documents for Sacred Heart. [Application, Exhibit 10; March 4, 2011 Supplemental Information, p45]

For charity care reporting purposes, the Department of Health's Hospital and Patient Data Systems program (HPDS), divides Washington State into five regions: King County, Puget Sound (less

King County), Southwest, Central, and Eastern. Sacred Heart is located in Spokane and is one of 21 hospitals located within the Eastern Washington Region. According to 2007-2009 charity care data obtained from HPDS, Sacred Heart has provided slightly less than the average charity care provided in the region, which has increased with the 2009 figures. Sacred Heart' most recent three years (2007-2009) percentages of charity care for gross and adjusted revenues are detailed in Table 3. [HPDS 2007-2009 charity care summaries]

**Table 3
Sacred Heart Charity Care Comparison (2007-2009)**

	3-Year Average for Eastern WA Region	3-Year Average for Sacred Heart
% of Gross Revenue	1.59 %	1.37 %
% of Adjusted Revenue	3.79 %	3.55 %

Sacred Heart's pro forma revenue and expense statements indicate that the hospital will provide charity care at approximately 1.37% of gross revenue and 3.55% of adjusted revenue. RCW 70.38.115(2)(j) requires hospitals to meet or exceed the regional average level of charity care. Since the three-year historical average is below that for the region, the department concludes that a condition related to the percentage of charity care to be provided at Sacred Heart is necessary if this project is approved. [March 4, 2011 Supplemental Information, p45]

With agreement to the condition regarding the amount of charity care provided, the department concludes that all residents, including low income, racial and ethnic minorities, handicapped, and other under-served groups would have access to the services provided by the hospital. **This sub-criterion is met.**

(4) The project will not have an adverse effect on health professional schools and training programs.

In addition to the need methodology detailed above, Sacred Heart discussed the following issues as supportive of the proposed tertiary transplant service. Also addressed is the limited potential adverse effect upon the existing providers on the western side of the state.

- Regional presence and accessibility.

Sacred Heart states that the planning area's residents are underserved when there are no pancreatic transplant providers available in the region. Specifically, the applicant states that, "Currently, residents of eastern Washington, as well as Idaho and Montana, travel across the state to receive care, and some forego care altogether". A letter from a referring nephrologist in Richland appears to confirm this statement. [Application, p23 & Exhibit 7]

- If offered the choice, Planning area residents will prefer to receive all pancreas and kidney/pancreas transplant care closer to home.

Organ transplantation requires a series of events that require time and coordination to accomplish. Patients seeking transplants undergo a series of evaluations and candidate registrations for waiting listings which can lead to an average waiting time of 501 days to qualify, find, and perform an adult pancreas transplant. The distance between the resident, the

hospital, and the donor organ all contribute to a successful outcome. A review of UNOS kidney transplant waiting list data for Sacred Heart⁷ appears to support the ability for Sacred Heart to attract transplant patients with a waiting list averaging over 50 patients from 2006 to 2010. [Application, p13]

Further, patients that require a kidney transplant with an unknown pancreas condition currently need to travel to receive care otherwise provided in the Sacred Heart program. Sacred Heart identifies Swedish Medical Center, the University of Washington Medical Center, and Virginia Mason Medical Center as the three other state facilities CN approved to provide adult pancreatic transplants. Each of these facilities is located in Seattle and Sacred Heart states that, given a choice, “planning area residents will prefer to receive pancreas and kidney/pancreas transplant care closer to home”. [Application, p25 & 34]

- The potential adverse effect the proposed service would have on health professional schools and training programs.

Sacred Heart considered the University of Washington Medical Centers fellowship program for kidney transplants. The applicant provided a review of the minimum volume requirements to maintain the status of a fellowship training site⁸. The applicable results are shown below.

Table 2
American Society of Transplant Surgeons Minimum Volume Requirements

Organ Accreditation	Minimum Annual Volume
Kidney	60
Pancreas ⁹	20

According to UNOS¹⁰ and applicant data, UWMC performed 101 kidney transplants and 12 kidney/pancreas transplants in 2009. UWMC did not perform any pancreas only transplants in 2009. The total individual and combined kidney transplants are well above the minimum standard of 60 reported above; with the Sacred Heart Kidney transplant program currently in operation. [Application, p55]

Based on the information above, the department concludes that the project will not have an adverse effect on health professional schools and training programs. **This sub-criterion is met.**

⁷ United Network for Organ Sharing data for Total Number of Kidney Registrations Added to the Wait List for Reported Washington as of as of April 1, 2011.

⁸ Verified through the ASTS website accreditation standards

⁹ Sacred Heart reports that UWMC currently maintains a fellowship accreditation for only Kidney and Liver transplantation

¹⁰ United Network for Organ Sharing data for Kidney Transplants Performed in Washington Transplant Centers - 2009

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

Based on the source information reviewed, the department determines that the application is consistent with the applicable 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.

To assist the department in its evaluation of this sub-criterion, the office of Hospital and Patient Data Systems (HPDS) provides a summary of the short and long-term financial feasibility of the project, which includes a financial ratio analysis. The analysis assesses the financial position of an applicant, both historically and prospectively. The financial ratios typically analyzed are 1) long-term debt to equity ratio; 2) current assets to current liabilities ratio; 3) assets financed by liabilities ratio; 4) total operating expense to total operating revenue ratio; and 5) debt service coverage ratio. If a project’s ratios are within the expected value range, the project can be expected to be financially feasible. Additionally, HPDS reviews a project’s three-year projected statement of operations.

Though there is no reported capital expenditure for the proposed program, HPDS provided a summary of the balance sheets from the application in Table 4.

**Table 4
Sacred Heart Medical Center Balance Sheets
Providence Sacred Heart Fiscal Year End 2010**

Assets		Liabilities	
Current	196,558,017	Current	133,038,267
Board Designated	230,595,563	Long Term Debt	141,991,874
Property/Plant/Equip	269,505,956	Other	87,278
Other	56,761,410	Equity	478,303,526
Total	753,420,946	Total	753,420,945

Above figures from year end reports sent to DOH

Providence Sacred Heart Medical Center is part of Providence Health and Services. The hospital has adequate resources to initiate this project.

HPDS also compared the financial health of Sacred Heart to the 2009 statewide financial ratio guidelines for hospital operations. The analysis notes, “No assets are involved in this project and a project specific balance sheet was not necessary”. In addition, “For the project the operating expense to operating revenue is much better than average and is above breakeven in the third year”. When reviewing the remaining four categories in relation to the hospital’s combined 2010 ratios, HPDS notes, “the only ratio poorer than average is the current asset to current liabilities ratio. The hospital

has great leeway in how it will hold its assets between current and board designated. The Board Designated funds for this size hospital are appropriate”. Table 5 details the results. [HPDS analysis, p2]

The A means it is better if the number is above the State number and B means it is better if the number is below the state number. Bold numbers indicate a score that is outside the preferred ratio.

**Table 5
Sacred Heart Hospital’s Current and Projected Financial Ratios**

Ratio Category	Trend	State09	Sacred Ht 10	2012 CONy1	2013 CONy2	2014 CONy3
Long Term Debt to Equity	B	0.550	0.297			
Current Assets/Current Liabilities	A	2.221	1.477			
Assets Funded by Liabilities	B	0.433	0.365			
Operating Expense/Operating Rev.	B	0.942	0.943	0.461	0.461	0.461
Debt Service Coverage	A	5.935	11.132			
Definitions						
Long Term Debt to Equity	Long Term Debt/Equity					
Current Assets/Current Liabilities	Current Assets/Current Liabilities					
Assets Funded by Liabilities	Current Liabilities + Long term Debt/Assets					
Operating Exp./Operating Rev.	Operating Expense/Operating Revenue					
Debt Service Coverage	Net Profit + Depr and Interest Exp/Current Mat. LTD and Int. Exp					

Based on the information above, the department concludes that the project will not negatively affect these ratios and the immediate and long-range operating costs of the project can be met. **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.

Sacred Heart proposes to begin performing pancreatic transplants. There are no estimated capital expenditures reported for this service expansion. [Application, p38; March 4, 2011 Supplemental Information, p3]

To assist the department in its evaluation of this sub-criterion, HPDS provides a summary of the reasonableness of the project in relation to the potential impact on revenue and charges. The review notes that, “in the 2009 Comprehensive Hospital Abstract Reporting System (CHARS) there is some variation among hospitals in the billed charges. The volume statewide is also very low. The average charges of this project are on the whole well within the average. Table 6 supplies summary of the HPDS review. [HPDS analysis, p4, March 4, 2011 Supplemental Information, p11]

Table 6
HPDS Analysis of Forecasted Rates at Sacred Heart Hospital
Adult Pancreas transplant volume only

Sacred Heart Adult Pancreas			
Rate per Various Items	CONyr1	CONyr2	CONyr3
Units of Measure (Transplants)	12	12	12
Units of Measure (Patient Day)	107	107	107
Gross Revenue	1,453,704	1,453,704	1,453,704
Deductions From Revenue	883,546	883,546	883,546
Net Patient Billing	570,158	570,158	570,158
Net Operating Revenue	1,641,081	1,641,081	1,641,081
Operating Expense	1,156,754	1,156,754	1,156,754
Operating Profit	484,327	484,327	484,327
Net Profit	484,327	484,327	484,327
Operating Revenue per Transplant	\$ 136,757	\$ 136,757	\$ 136,757
Operating Expense per Transplant	\$ 96,396	\$ 96,396	\$ 96,396
Net Profit per Transplant	\$ 40,361	\$ 40,361	\$ 40,361
Operating Revenue per Patient Day	\$ 15,337	\$ 15,337	\$ 15,337
Operating Expense per Patient Day	\$ 10,811	\$ 10,811	\$ 10,811
Net Profit per Patient Day	\$ 4,526	\$ 4,526	\$ 4,526

Due to the focus on a particular program within the hospital, the net profit by adjusted patient day ranges is high in comparison to a tradition review of a hospital's profit per patient day. On this topic, HPDS concludes, "the project costs to the patient and community appears to be similar to current providers". Additional project costs are limited to staffing and support, which will only grow as demand for services increase. The Department concludes that costs of the project to add an adult pancreatic transplant program is not likely to have an unreasonable impact upon the costs and charges for health services. **This sub-criterion is met.**

(3) *The project can be appropriately financed.*

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

There are no costs associated with this project which require financing. **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 application is consistent with the applicable structure and process 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.

If this project is approved, Sacred Heart anticipates adding FTEs (full time equivalents) to Sacred Heart's current staff in only a few specialized areas. Table 7 shows the breakdown of Sacred Heart's proposed incremental FTEs if proposed pancreatic transplant program is approved. [March 4, 2011 Supplemental Information, p14]

Table 7
Sacred Heart Hospital Projected Incremental FTE Totals

Project FTEs	2011	2012	Total
Social Worker	0.5	0.0	0.5
Surgeon	0.0	0.5	0.5
Nephrologists	0.0	0.5	0.5
Total Program Additions	0.5	1.0	1.5

By the end of 2012, Sacred Heart expects to have hired the additional specialists and support staff necessary for the adult pancreas transplant program. Sacred Heart has an active adult kidney transplant program. These additional FTEs will supplement the staff currently supporting the kidney transplant program. This includes the recent addition of Okechukwu Ojogho, M.D., who provides the hospital with an experienced surgeon to perform the pancreatic transplants. [Application, p 46 & Exhibit 6]

Based on the information provided in the application, the department concludes that Sacred Heart provided a comprehensive approach to recruit and retain staff necessary to perform pancreatic transplants at Sacred Heart. As a result, the department concludes that qualified staff can be recruited and retained. **This sub-criterion is met.**

- (2) The proposed service(s) will have an appropriate relationship, including organizational relationship, to ancillary and support services, and ancillary and support services will be sufficient to support any health services included in the proposed project.

WAC 246-310 does not contain specific WAC 246-310-230(2) criteria as identified in WAC 246-310-200(2)(a)(i). There are no 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.

Sacred Heart currently provides health care services to the residents of Spokane and the surrounding areas. The applicant currently maintains contracts to facilitate the operation of the hospital and there is no indication that these relationships would not be able to expand related services to accommodate the proposed service expansion.

Sacred Heart also supplied a breakdown of how various internal components of the hospital's operations would be affected by or would contribute to the proposed adult pancreas transplant program. In each instance, the various clinics, intensive care departments, patient services, and staff training are considered and the potential impact is commiserate with the modest increase in transplants that the need methodology forecasts.

Therefore, the department concludes that there is reasonable assurance that Sacred Heart will continue its relationships with ancillary and support services within and associated with the hospital and this project would not negatively affect those relationships. **This sub-criterion is met.**

- (3) There is reasonable assurance that the project will be in conformance with applicable state licensing requirements and, if the applicant is or plans to be certified under the Medicaid or Medicare program, with the applicable conditions of participation related to those programs.

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 no 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.

Sacred Heart will continue to provide Medicare and Medicaid services at the hospital to the residents of Spokane County and the surrounding communities. Sacred Heart contracts with the Joint Commission to survey and accredit the quality of service provided. The Joint Commission lists Sacred Heart Hospital in full compliance with all applicable standards following the most recent on-site survey in September 2010.¹¹ The Joint Commission also lists certification of advanced programs in care for Stroke and Ventricular Assist devices. [Joint Commission website]

Complementing reviews performed by the Joint Commission, are the surveys conducted by the Department's Investigation and Inspection's Office. Records indicate that the department has completed two compliance surveys for Sacred Heart¹² between 2008 and 2010. Each compliance survey revealed minor deficiencies which are typical for the type of facility and Sacred Heart submitted a plan of corrections and implemented the required corrections. [Compliance survey data provided by Investigation and Inspection's Office]

As stated above, Okechukwu Ojogho, M.D. will perform the pancreas transplants for the proposed program. A review of the compliance history of Dr. Ojogho has shown that his credentials are up to date and reveal no recorded sanctions. [Application, p46Compliance history provided by Medical Quality Assurance Commission]

¹¹ <http://www.qualitycheck.org>

¹² Surveys of complete hospital completed January, 2008 and a transplant program Medicare survey (heart & kidney) in August, 2010

Based on Sacred Heart compliance history, the department concludes that there is reasonable assurance that the hospital would continue to operate in conformance with state and federal regulations with the additional pancreatic transplant beds. **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 the need section of this evaluation, the department concluded that there is a need for the additional transplant capacity beyond that currently available and accessible to residents of the planning area. The promotion of continuity of care and unwarranted fragmentation of services does not require nor is it intended to have a single facility provide each and every service a patient might require. If that was the intent, there would be no concern about unnecessary duplication of services. The application guidelines provide guidance regarding the intent of this criterion. These guidelines ask for identification of existing and proposed formal working relationships with hospitals, nursing homes, and other health services and resources serving the applicant's primary service area. This description should include recent, current, and pending cooperative planning activities, shared services agreement, and transfer agreements.

Sacred Heart reasons that the proposed transplant program will assist in the continuity of care provided by the hospital to the community. Specifically, the applicant considered the follow-up necessary for a transplant recipient and states, "this care includes an anti-rejection regimen to ensure the body accepts the new organ. Fragmented care results when the patient receives a transplant on one side of the state and post-operative care on the other". [Application, p49]

Expansion of a hospital's tertiary transplant services in the planning area, supported by the projected need, minimizes the potential to increase the cost of care for all providers and can provide services closer to the patient's residence. Therefore, the department concludes that approval of an adult pancreas transplant program is not likely to lead to a fragmentation of care. **This sub-criterion is met.**

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

This sub-criterion is addressed in sub-section (3) above and is **determined to be met.**

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

Based on the source information reviewed, the department determines that the application is consistent with the applicable 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 (tie-breaker) criteria contained in WAC 246-310. The tie-breaker 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, Sacred Heart's project met the review criteria under WAC 246-310-210, 220, and 230. Therefore, the department moves to step two below.

Step Two

Within the application, Sacred Heart discussed the considerations within the organization before submitting this application. The primary factors cited by the applicant consider access and costs of service, and include: [Application, p53]

- A desire from local referring physicians to have a more locally accessible program
- The ability to begin the program with no capital costs
- By associating the pancreas transplants with the existing kidney program, costs can be spread over more transplant procedures

Sacred Heart stated that it could not identify any disadvantages to the proposed program and the department cannot identify any additional options for consideration. With the numeric need portion of this evaluation resulted in need, the proposed addition of an adult pancreas transplant program can be supported and has been shown to be financially feasible. Given the options available, the department concludes that the project described is the best available alternative for the community. **This sub-criterion is met.**

Step Three

Sacred Heart was the only entity who submitted an application to begin performing adult pancreas transplants. As a result, step three is not evaluated under this sub-criterion.