

STATE AGENCY ACTION REPORT
ON APPLICATION FOR CERTIFICATE OF NEED

A. PROJECT IDENTIFICATION

1. Applicant/CON Action Number

Sacred Heart Health System, Inc.
d/b/a Sacred Heart Hospital/CON #10229
5375 North Ninth Avenue
Pensacola, Florida 32504

Authorized Representative: M. Denise Barton
Chief Business Development Officer
(727) 588-5200

2. Service District/Subdistrict

Organ Transplantation Service Area (TSA) 1 which includes: District 1 (Escambia, Okaloosa, Santa Rosa and Walton Counties), District 2 (Bay, Calhoun, Franklin, Gadsden, Gulf, Holmes, Jackson, Jefferson, Leon, Liberty, Madison, Taylor, Wakulla and Washington Counties), District 3 (excluding Lake County), Alachua, Bradford, Citrus, Columbia, Dixie, Gilchrist, Hamilton, Hernando, Lafayette, Levy, Marion, Putnam, Sumter, Suwannee and Union Counties and District 4 (excluding Volusia County), Baker, Clay, Duval, Flagler, Nassau and St. Johns Counties.

B. PUBLIC HEARING

A public hearing was not held or requested.

Letters of Support

The applicant submitted 73 unduplicated and individually composed letters of support (with a total of 164 signatures) dated during May 20 through June 19, 2014. All letters and signatures indicated residence within TSA 1 or the delivery or receipt of medical services within TSA 1.

Recurring themes among these letters include:

- excessive distance and travel time to the nearest kidney transplantation provider
- financial challenges that accompany the distance and travel for the procedure, including the corresponding cost of the many pre and post procedure follow-up visits
- work and family hardships due to distance and travel time
- limited or reduced access due to the above reasons.

The support letters are briefly described below.

State Representatives Clay Ingram (Florida House of Representatives District 1), Mike Hill (District 2) and Doug Broxson (District 3), state that residents of their districts must travel at least six hours to the nearest transplant facility: Birmingham, Atlanta, Jacksonville or Gainesville and “by contrast, other Florida residents are within two hours of the nearest transplant center”. They comment that the proposed project service area includes 13 counties in northwest Florida that currently have more than 3,000 residents with ESRD and 22 residents on UF Health Shands Hospital’s kidney transplant waiting list. The representatives also state that the proposed project “would be a great benefit not only to our community but for patients in the region and outside the State of Florida”.

Ashton J. Hayward, Mayor, City of Pensacola, states that the proposal “will undoubtedly provide a great benefit to our community in the form of increased access to care for our residents”. He also states that available data, including the Partnership for a Healthy Community’s 2012 Assessment, indicates “a clear need for additional health care services in Pensacola and Escambia County”.¹

John J. Lanza, MD, PhD, MPH, FAAP, Director, Florida Department of Health (DOH) in Escambia County, states that “at the current time, over half of the residents in northwest Florida travel out of state to access kidney transplant services”. Dr. Lanza also states that his organization works in partnership with Sacred Heart Health System to address health and health care issues in the area and that over the years, the applicant “has shown a strong commitment to address gaps in health care access”.

¹ Per the website at <http://www.sacred-heart.org/news/article/?NID=1570>, the ‘Partnership for a Healthy Community 2012 Health Assessment’ for Escambia and Santa Rosa Counties dated December 5, 2012, compared results on more than 230 indicators such as deaths, incidences of disease and behavioral risk factors.

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Jeffery H. Fair, MD, Professor & Chief, Department of Surgery, Division of Transplantation & Hepatobiliary Surgery and Kenneth A. Andreoni, MD, Associate Professor, Surgery, Director of Kidney and Pancreas Transplant, College of Medicine, University of Florida Health (UF Health), offer their support. Dr. Fair states that he has over 20 years of abdominal transplant experience and Dr. Andreoni states he has over 15 years of kidney transplant experience. Both physicians state they will be a key part of the recruitment of the surgeon to the UF Department of Surgery to serve as the Program Director for the proposed project. Dr. Fair indicates he will serve as the Sacred Heart Primary Transplant Surgeon during its primary implementation phases. Both physicians indicate that they “will support the Pensacola-based UF transplant surgeon for on-call backup, continued program development, program quality oversight and vacation coverage”. They conclude that the proposed program will “ensure that the citizens in the Pensacola area receive increased access to this needed service in a manner that provides the best possible clinical outcomes”.

Kevin E. Behrns, MD, Chairman of Surgery, Edward R. Woodward Professor, College of Medicine, University of Florida, states that he oversees the physicians caring for transplantation patients within both the University of Florida clinics and UF Health Shands Hospital. Steven Goldstein, MD, Associate Medical Director, UF Health Shands Transplant Laboratory (UF Health Medical Lab-Rocky Point), states that “our extensive experience as a long standing transplant lab” will allow for the provision of guidance in the interpretation and clinical implication of test results.

Edward Jimenez, Senior Vice President and Chief Operating Officer, UF Health Shands Hospital, UF Health, states his hospital has “a long history of successful solid organ transplantation, including kidney transplant”. Mr. Jimenez indicates that the project goal is “to create a collaborative (UF Health and Sacred Heart Hospital) kidney transplant program to ensure that the citizens of the Pensacola area receive increased access to this needed service”. He also states that “both UF Health Shands and Sacred Heart have agreed that the UF Health Transplant Administrator will oversee both programs in order to ensure consistency of quality and operations between programs and facilitate ready access to any additional needed expertise as the Sacred Heart program evolves”.

Phillip L. Wright, FACHE, Chief Executive Officer, Santa Rosa Medical Center, states that the applicant is recognized for its compassionate and high quality care, with “a history of being the first to provide life-saving services, such as adult and pediatric trauma, high risk maternity and baby care and stroke”. He also indicates that the applicant “is the area’s largest safety net provider, as our community has more than 22 percent

of residents without insurance”. The reviewer notes that Sacred Heart Hospital is a certified Level II Trauma Center and a Pediatric Trauma Center.

Barry Keel, President/CEO, Bay Medical Center Sacred Heart Health System, states that “there is great need (for the project), not only in Panama City but also in the surrounding service area, with county health rankings that are among the worst in the state. We have a high incidence of diabetes, high blood pressure, heart disease, smoking and other risk factors that contribute to kidney disease. Because of the high incidence of kidney disease, Bay Medical has a six-bed dialysis unit on-site, which has historically provided in excess of 2,400 treatments per year.” He further states that his area has “a large population of uninsured and underinsured residents” and “Sacred Heart Hospital has a long history of serving as the safety net provider for poor and vulnerable patients”.

Don Turner, Executive Director, Escambia Community Clinics, Inc., a federally qualified health center (FQHC), states that his FQHC is the medical home to more the 32,000 individuals, with the majority of them being low income and the working poor who are at higher risk for kidney disease due to hypertension and diabetes. He also states that “almost 15 percent of our patient population has a primary or secondary diagnosis of kidney disease”.

William J. Whibbs, MD, Medical Director, Health First Network, Inc.², states that the applicant has been and continues to be “at the forefront of health care in the Panhandle of Florida and the surrounding area”. He also states that he has been on the medical staff at Sacred Heart Health System for over 37 years and has seen the positive impact of this provider, indicating the applicant has “the roots” to provide an excellent program.

Humam Humeda, MD, Co-Founder, Renalus Center for Kidney Care, Inc., indicates support for the proposed project on behalf of his team of nephrologists who treat patients with common and rare kidney disorders, many of whom he states are patients with ESRD and are viable candidates for kidney transplantation. Shadi Oweis, MD, PhD, Nephrology Associates of the Gulf Coast (a five physician nephrology group) makes comments similar to Dr. Humeda. The Nephrology Associates of the Gulf Coast website indicates that the practice has locations in Escambia, Okaloosa, Santa Rosa, Walton and Washington

² Per the website at <http://www.hfni.com>, Health First Network, Inc., is a comprehensive network of 650+ physicians dedicated to improving the health care experience and quality of life of people in northwest Florida.

Counties, three locations in Alabama, affiliation with 11 (eight Florida) hospitals and works closely with DaVita Dialysis³.

Michael Foulk, Northwest Florida Regional Operations Director for DaVita Dialysis and nine others representing DaVita Dialysis centers located in Bay, Escambia and Okaloosa Counties submitted letters indicating that many of their patients would benefit from the proposed project⁴. Angela Knight, RN, BSN, Facility Administrator, DiVita's Coastal Kidney Center (Panama City, Bay County) states that she currently has 84 ESRD patients but only two are on a transplant list. Per Ms. Knight, many patients would be excellent candidates for transplantation but do not pursue this option due to the travel that is required.

Six licensed clinical social workers (LCSWs) and one LCSW/ACSW⁵, provided letters of support. Alison Vinson, Fresenius Medical Care's Lead Social Worker for the Florida Panhandle/South Alabama, indicates she is familiar with stories of viable candidates for kidney transplantation that decline the opportunity due to distance and travel costs. Kelly Meadows, RD, LD, and the other social worker letters contain comments similar to Ms. Vinson's. Fresenius Medical Care-West Pensacola provided a declaration of support that has 26 staff and 64 patient signatures.

Matt Herron, DO, President, Panhandle Anesthesiology, PA, states that his group "has been interested in this project for some time and we have been looking forward to being part of it".

Stuart A. Harlin, MD, FACS, President, Coastal Vascular & Interventional, PLLC, and Managing Partner, Innovative MRI Partners, states that "the entire community is committed to this daunting project which will forever change the scope of health care within the Florida panhandle". This physician group includes eight physicians and one ARNP-C.

Kurt Stockamp, MD, FACS, McMahon & Ricketson, MD, PA, states the proposed project has been in discussion "over the past several months, and indeed years, as plans were developed to make the step to provide a

³ Source: <http://www.kidney-docs.com/about-kidney-doctors.html>.

⁴ DaVita Dialysis centers are operated by DaVita Kidney Care, a division of DaVita HealthCare Partners Inc., a Fortune 500® company that is a leading provider of dialysis services in the U.S. per the website at <http://www.davita.com/about>.

⁵ ACSW stands for Academy of Certified Social Workers and the ACSW is a credential issued by the National Association of Social Workers to members who have met education and experience requirements and pass the ACSW examination.

more complete and comprehensive care package for nephrology patients in northwest Florida and the surrounding communities”.

R. Scott Benson, MD, Creekside Psychiatric Center, states the proposed project is “a natural extension of the commitment of Sacred Heart Health System to the healthcare needs of our region”. He also states that the applicant “has a team of physicians who have a history of collaborative care for complex health problems”.

Physicians on staff at Sacred Heart Hospital stating support for the proposed project include:

- Jill M. Prafke, MD, President, Medical Executive Committee
- Charles E. Farmer, MD, Pathology and Medical Executive Committee, Pensacola Pathologists, PA
- Susan J. G. Laenger, MD, FACP, Credentials Committee and President, Escambia County Medical Society
- James W. Ward, Jr., MD, Chief Medical Officer
- Donald W. Farmer, MD, Chairman, Radiology Department and President, Pensacola Radiology Associates, PA
- John E. Retzloff, DO, Program Director, Internal Medicine Residency Program
- Paul Tamburro, MD, Director, Cardiovascular Services
- Thomas J. Dennie, MD, PA, Chief of Surgery
- Frank J. Greskovich, III, MD, Chief of Urology, Woodlands Medical Specialists
- Barbara H. Wade, MD, Epidemiology (board-certified in infectious diseases)
- Michael J. Caluda, III, MD, FACS, (previously part of the medical leadership at Sacred Heart Hospital), The Surgery Group
- James W. Smith, MD, Long Range Planning Committee and Physician Performance Committee, Gastroenterology Associates of Pensacola/Endoscopy Center of Pensacola
- John M. Bray, MD, President, Pensacola Lung Group, PA (a six physician group that serves as primary pulmonary and critical care physicians for Sacred Heart Hospital).

Matthew C. Pauli, DO, Department of Physical Medicine and Rehabilitation, Pensacola Ice Flyers Medical Staff, Sacred Heart Medical Group states that he sees multiple admissions “to LTACH and IPR facilities for ESRD” and these admissions could be reduced if transplants were available locally.

Robert J. George, DO, FACOFP, dist., Associate Dean of Academic Affairs, College of Osteopathic Medicine, Lake Erie College of Osteopathic Medicine (LECOM) Bradenton, states that SHHS has “been involved with the education of LECOM medical students for quite a while” and has been “a highly sought after rotation”. He also states that “many of our students have continued their studies at Sacred Heart Health System facilities as residents and fellows and have gone on to practice in the area”.

Paige Collier, MS, Executive Director, West Florida Area Health Education Center, Inc., (West Florida AHEC)⁶ states that her organization “strives to be innovative in addressing needs and developing primary health care strategies to assist populations who are most at risk”. She states that “one of the ways we do this is through our partnership and support of community-based training opportunities for student health professions from the University of Florida College of Medicine throughout the four county area (Escambia, Santa Rosa, Okaloosa and Walton)”. Ms. Collier concludes that the proposed project “would provide additional training opportunities and exposure for the health professional students in our community-based programs”.

Bonita Stephens-Warnke, Director of Nutrition Services, TouchPoint Support Services (TSS), states that TSS agrees to provide responsible oversight for the provision of services, functions and performances of both the food and clinical nutrition services to include the management of registered dieticians in general and specialty areas.

Sister Mary Jean Doyle, DC, LCSW, Sacred Heart Health System Board Member and Sacred Heart Hospital medical social worker, states experiencing firsthand “the agony of patients and families needing services but requiring limited and expensive referrals”. She also comments on “the frequent need for air transport” and that “one can imagine the toll that such stress places on the healing process”.

Eleven area residents who have ESRD or other nephrology conditions are highly complementary of the services they received at Sacred Heart. Letters from four area residents who received transplants express the financial, emotional and transportation challenges of being five to six hours from home to receive the procedure and pre and post follow-up care. The writers all contend that the proposed project will better accommodate transplant donors, recipients and their families.

⁶ West Florida AHEC is a member of The Florida AHEC Network, an extensive, statewide system (10 regional AHECs supported by four state medical schools) for health professional education and support. This organizational structure enables the AHECs to draw upon the resources of the academic health centers in addressing local health care issues. Source: <http://flahec.org/locations.asp>.

C. PROJECT SUMMARY

Sacred Heart Health System, Inc. d/b/a Sacred Heart Hospital (CON application #10229), a Florida not-for-profit corporation and subsidiary of Ascension Health, seeks approval to establish an adult kidney transplantation program at Sacred Heart Hospital (SHHP), in Pensacola (Escambia County, Florida), TSA 1. Specifically, the proposed project plans to serve the residents of District 1 and District 2 (see Item A. 2. of this report). Sacred Heart Health System, Inc. (SHHS) states that UF Health will form a clinical integration affiliation with the applicant and that UF Health will develop, implement and provide oversight for the proposed project.

Stated goals are to:

- Improve geographic access to transplantation services
- Significantly reduce out-migration of kidney transplant patients to surrounding states
- Reduce long waiting times for kidney transplantation
- Address health disparities within northwest Florida.

SHHS operates four general hospitals – Sacred Heart Hospital and Sacred Heart Hospital on the Emerald Coast (District 1) and Sacred Heart Hospital on the Gulf and Bay Medical Center Sacred Heart Health System (District 2).

Sacred Heart Hospital is a 466-bed general hospital, licensed for 411 acute care, 22 Level II neonatal intensive care unit (NICU) and 27 Level III NICU beds. SHHP has two acute care bed notifications—N1100003 to delete five and N1100024 to add 115 acute care beds. Sacred Heart Hospital offers Level II adult cardiovascular services and is a primary stroke center. Also, Sacred Heart Hospital is a certified Level II Trauma Center and a pediatric trauma center.

The applicant indicates that adult kidney transplant program, if approved, is to be operational by January 2015. However, the first procedure is not projected to occur until CY 2016. There is no new construction or renovation associated with the project. Total project costs are \$121,650 and include equipment, project development and start-up costs.

Schedule C includes the following conditions:

Condition #1: Education/Training

SHHP will provide clinical education and training opportunities for medical staff, clinical staff, and post-graduate physician residents to inform professionals about the kidney transplantation program, organ donation, and caring for the patient with renal disease. The purpose of the education and training is to promote and improve understanding of treatment options for patients with permanent kidney failure. SHHP is committed to perform the following education/training activities on an annual basis:

- Continuing Education: Offer to all health care professionals at two accredited CEU sessions on kidney transplant and related topics, with specific education units awarded by MECOP.⁷ The sessions could include Grand Rounds, lectures or presentations for physicians, nurses, and allied health professionals. *This will be measured by an annual report by SHHP certifying the educational session topic, speaker, date and CEU credits provided by MECOP.*
- Nurse Orientation: As part of new hire orientation, include specific modules on caring for the patient with renal disease and competency/skills checks for staff assigned to the proposed kidney transplant program. *This will be measured by an annual report by SHHP certifying the content and dates of the new hire orientation sessions, and competency skills checks completed by staff assigned to the proposed kidney transplant program.*
- Internal Medicine Residency Rotations: All Internal Medicine Residents will complete a nephrology rotation that includes the transplant program. *This will be measured by an annual report by SHHP to AHCA certifying this rotation is in place, and the number of residents who have completed the rotation in the prior 12 months.*

Condition #2: Organ Donor Plan

SHHP understands that organ donation is important to the provision of kidney transplantation for all wait list patients, not just those that will receive services at SHHP. SHHP commits to participating in an annual organ donor development plan with the organ procurement agency for this transplant service area. The plan outlines SHHP's performance with respect to appropriate and timely referral of potential donors, effective request rate, and the average number of organs transplanted per donor, which are organ donation goals supported by CMS and The Joint Commission.

⁷ **MECOP** is a nationally accredited provider of continuing medical education for physicians in Northwest Florida and surrounding areas per their website at <https://www.mecop.org/>.

- SHHP will complete an annual organ donor development plan with the designated organ procurement agency. The plan will be reviewed by senior leadership and specific performance goals and associated tactics will be delineated for the calendar year. The plan will be mutually agreed upon by SHHP and the organ procurement agency, with appropriate signatures acknowledging the plan. *This will be measured by submission of SHHP's annual organ donor development plan to AHCA.*

Should the project be approved, the applicant's conditions would be reported in the annual condition compliance report as required by Rule 59C-1.013 (3) Florida Administrative Code. The Agency will not condition annual reporting requirements that are mandated by Rule.

D. REVIEW PROCEDURE

The evaluation process is structured by the certificate of need review criteria found in Section 408.035, Florida Statutes. These criteria form the basis for the goals of the review process. The goals represent desirable outcomes to be attained by successful applicants who demonstrate an overall compliance with the criteria. Analysis of an applicant's capability to undertake the proposed project successfully is conducted by assessing the responses provided in the application, and independent information gathered by the reviewer.

Applications are analyzed to identify strengths and weaknesses in each proposal. If more than one application is submitted for the same type of project in the same district (subdistrict), applications are comparatively reviewed to determine which applicant best meet the review criteria.

Section 59C-1.010(3)(b), Florida Administrative Code, allows no application amendment information subsequent to the application being deemed complete. The burden of proof to entitlement of a certificate rests with the applicant. As such, the applicant is responsible for the representations in the application. This is attested to as part of the application in the Certification of the Applicant.

As part of the fact-finding, the consultant Steve Love analyzed the applications in its entirety with consultation from the financial analyst Eric West, Bureau of Central Services, who evaluated the financial data. Architectural criteria conformance was not part of this review, as the applicant reported no construction or renovation.

E. CONFORMITY OF PROJECT WITH REVIEW CRITERIA

The following indicate the level of conformity of the proposed project with the criteria and application content requirements found in Florida Statutes, sections 408.035, and 408.037; applicable rules of the State of Florida, Chapter 59C-1 and 59C-2, Florida Administrative Code.

1. Fixed Need Pool

a. Does the project proposed respond to need as published by a fixed need pool? Or does the project proposed seek beds or services in excess of the fixed need pool? Rule 59C-1.008(2), Florida Administrative Code.

There is no fixed need pool publication for adult kidney transplant programs. Therefore, it is the applicant's responsibility to demonstrate the need for the project, including a projection of the expected number of adult kidney transplants that will be performed in the first years of operation.

TSA 1 currently has two operational adult kidney transplant programs—Mayo Clinic in District 4 (Duval County) and UF Health Shands Hospital in District 3 (Alachua County).

There are eight operational adult kidney transplantation programs in Florida, two in each of the four service areas. There are two approved not yet operational programs—Largo Medical Center (CON #10205) in Service Area 2 and Broward Health Medical Center (CON #10152) in Service Area 4.

Cleveland Clinic Hospital's (Service Area 4) program was not operational until July 29, 2013. The utilization chart below accounts for all adult kidney transplantations performed in Florida during the five-year period that ended on December 31, 2013.

Florida Adult Kidney Transplantation Utilization Calendar Years 2009—2013								
Service Area	County	Facility	2009	2010	2011	2012	2013	Total
1	Alachua	UF Health Shands Hospital	143	146	154	86	90	619
1	Duval	Mayo Clinic	100	117	139	161	160	677
1	Duval	UF Health Jacksonville*	34	29	1			64
2	Hillsborough	Tampa General Hospital	198	197	223	191	206	1,015
2	Lee	Gulf Coast Medical Center Lee Memorial Health System	40	35	28	29	37	169
3	Orange	Florida Hospital	152	176	148	171	161	808
3	Volusia	Halifax Health Medical Center	7	14	14	19	13	67
4	Broward	Cleveland Clinic Hospital					7	7
4	Miami-Dade	Jackson Memorial Hospital	249	238	280	286	299	1,352
		Total	923	952	987	943	973	4,778

Source: Florida Need Utilization Data for Adult & Pediatric Transplant Programs issued April 2010—April 2014.

Notes: * UF Health Jacksonville's program was terminated effective 1/12/11.

The above chart indicates that over the five-year period, statewide, the mean number of procedures was 955.6, with a median of 952. The fewest number of procedures was 923 (CY 2009) and the most was 987 (CY 2011). During the five-year period, Jackson Memorial Hospital in Miami-Dade County (Service Area 4) performed the most adult kidney transplants in Florida at 28.30 percent (1,352/4,778), followed by Tampa General Hospital (Service Area 2) with 21.24 percent (1,015/4,778). Service Area 1 facilities averaged 272 annual procedures during the period. However, Service Area 1 transplant volume was 247 in 2012 and 250 in 2013, mostly driven by UF Health Shands decreasing from 143 to 154 during CY 2009-2011 to 86 in 2012 and 90 in CY 2013.

Unlike other hospital programs, transplant services are reliant upon donors, and patients are often placed on waiting lists. Utilization data, whether current or historic, is primarily an indication of the number of donors. Although wait lists are an indicator of need, without available donors, they are not by themselves a predictor of utilization.

The reviewer notes that according to the Organ Procurement and Transplantation Network (OPTN), the national database of patient waiting lists for organ transplantation in the United States, there are 4,417 adults currently registered in Florida on the kidney transplantation waiting list⁸.

Geographic Accessibility

SHHS states that travel distance to a transplant center is a barrier to accessible care for patients living in northwest Florida. Further, the applicant states that “Northwest Florida is the only area within Florida

⁸ As of July 4, 2014 per the OPTN website @ <http://optn.transplant.hrsa.gov>.

and surrounding states that lies outside of a reasonable travel distance to a kidney transplant center” and therefore, northwest Florida is geographically underserved. The applicant further states and the reviewer confirms SHHS’s support letters bolster its contention that geographic accessibility is a factor in patient selection of transplant as a treatment option.

Out-Migration for Transplant Services

SHHS states that TSA 1 transplant centers have the highest in-migration of any kidney transplant program in Florida. The reviewer notes this would be consistent with the fact that TSA 1 borders Georgia and Alabama, with all remaining Florida TSAs being geographically more distant for residents from those two states. The applicant also states that for similar reasons, TSA 1 is a net exporter of Florida residents to out-of-state transplant centers.

SHHS indicates that in 2013, TSA 1 facilities experienced 51 kidney transplant in-migration cases and 29 TSA 1 residents received their transplants out of state. The applicant indicates that a total of 54 Floridians left the state to obtain kidney transplants and half of these or 27 of TSA 1’s 29 total were residents of District 1 or District 2, which includes Escambia County in the west through Madison and Taylor Counties in the eastern portion of TSA 1. SHHS indicates that during CY 2013, TSA 1 residents out-migrated at a rate of 14.3 percent and Florida residents out-migrated at a rate of 6.1 percent, which is similar to the rates for CY 2010 through 2012.

Long Wait List Presents Barrier to Timely Care

SHHS states that timely access to transplantation is critically important to patients on ESRD. Further, the applicant indicates that “long waiting times and elevated exposure to dialysis have a deleterious effect on outcomes after the procedure”. The applicant states that the majority of the 27 kidney transplant surgeries for District 1 and District 2 residents are performed at the University of Alabama in Birmingham (UAB). SHHS provides the following table to indicate as of July 2013, adult kidney transplant wait list statistics for District 1 and District 2 residents.

Kidney Transplant Wait List Statistics

Wait List Data	UAB	UF Health Shands	Mayo Clinic
Kidney Transplant Wait List	3,287	302	631
Median Time to Transplant	>72 months	11.7 months	37.4 months

Source: CON application #10229, page 15, Table 3 and the Scientific Registry of Transplant Recipients.

SHHS cites UAB's wait list of 3,287 above and states this indicates that northwest Florida patients on UAB's wait list are not getting timely transplants. The chart above indicates that kidney transplant candidates have over a six-year wait at UAB compared to less than a year at UF Health Shands and slightly over three years at Mayo Clinic. The reviewer notes that the Scientific Registry of Transplant Recipients (SRTR) offers one year patient survival rate data regarding adult kidney transplant providers nationwide. See the chart below.

**Adult Kidney Transplant CY 2013 Volume
& One Year Post Transplant Survival Rates
For January 1, 2011 – June 30, 2013**

State	Facility	Recipients Age 18 and Over 1/1/13-12/31/13	After Transplant Patient Survival Rate-One Year 1/1/11-6/30/13
Alabama	UAB	228	98%
Florida	Mayo Clinic	153	96%
Florida	UF Health Shands Hospital	84	97%

Source: SRTR at <http://www.srtr.org/csr/current/Centers/TransplantCenters.aspx?organcode=KI>.

The reviewer notes that the one year survival rate among the three adult kidney transplantation providers that serve northwest Florida residents is within one to two percent of each other, per the data. However, SRTR data indicates UAB had a higher than expected wait list mortality rate during CY 2013, while UF Health Shands and Mayo Clinic were within the expected mortality rate.⁹

Health Disparities

SHHS contends that health disparities among area residents adversely impact access to kidney transplantation, as follows:

- Diabetes and hypertension are frequent precursors to nephritis, renal failure and kidney transplantation
- African-Americans have a higher rate of diabetes and hypertension and lower rates of transplantation
- Poverty is linked to higher rates of diabetes and hypertension and lower rates of transplantation.

SHHS indicates that per the US Census, 2008-2012, American Community Survey, District 1 and District 2, jointly, have the highest rate (19.0 percent) of African-Americans and the highest rate (77.8 percent) of counties with median household income below the Florida median, compared to TSA 1 overall and TSAs 2 through 4.

⁹ Source: Specific to facility @ [http://www.srtr.org/csr/current/Centers/centerdetail.aspx?facility=.](http://www.srtr.org/csr/current/Centers/centerdetail.aspx?facility=)

SHHS references health status indicators of District 1 and District 2 residents, as determined by the Robert Wood Johnson's 2014 *County Health Rankings and Roadmap*. The applicant states and the reviewer confirms, that eight of the 18 counties ranked in Florida's worse quartile are in District 1 or 2.

SHHS indicates that 44.4 percent of the counties ranked in the worst quartile of Florida counties for health outcomes and 33.3 percent of the counties in the worst quartile for health factors were District 1 or 2 counties. Further, 66.7 percent of the counties ranked in the bottom half for both health outcomes and health factors were District 1 or 2 counties. SHHS also provides maps that indicate that northwest Florida counties have high death rates from diabetes and kidney disease. The applicant contends that it follows that these counties also have high mortality rates due to nephritis or renal failure.

b. Determination of Need.

Applications for the establishment of new adult kidney transplantation programs shall not normally be approved in a service planning area unless the following criteria are met:

- 1. Each existing kidney transplantation provider in the applicable service area performed a minimum of 30 transplants in the most recent calendar year preceding the application deadline, and no additional program has been approved for the same service planning area.**

UF Health Shands Hospital and Mayo Clinic are the existing adult kidney transplantation providers in TSA 1. UF Health Shands Hospital performed 90 and Mayo Clinic performed 160 adult kidney transplants during the 12-month period ending December 31, 2013.

There are no additional adult kidney transplant programs approved for TSA 1.

2. **The application shall include documentation that a minimum of 15 kidney transplants per year will be performed within two years of program operation. Such documentation shall include, at a minimum, the number of kidneys procured in the state during the most recent calendar year, and an estimate of the number of patients who would meet commonly-accepted criteria identifying potential kidney transplant recipients. This estimate shall be based on the number of patients on dialysis within the same service planning area.**

SHHS expects to draw its adult kidney transplant candidates from Districts 1 and 2, along with some contiguous/surrounding counties in southern Alabama. SHHS states that between 2009 and 2013, adult kidney procurement increased by 17 percent, while transplantation increased by 15 percent, among the four Organ Procurement Organizations (OPOs) in Florida. The applicant states that SRTS data for the 12-month period ending June 30, 2013, indicates that 192 kidneys were procured by UF Health’s LifeQuest Organ Recovery Service (LifeQuest), the OPO in the applicant’s service area.

SHHS reports a kidney donation rate of 80.0 percent, stated to exceed the average rate of all hospitals in TSA 1 that make such organ donations. See the table below.

Top Organ Donation Facilities in TSA 1

TSA 1 Facility	Donors Meeting Eligible Death Definition	Eligible Deaths	Observed Donation Rate	Expected Donation	Additional Donors
UF Health Shands Hospital	24	33	72.2%	75.3%	10
UF Health Jacksonville	12	19	63.2%	70.6%	6
Sacred Heart Hospital	8	10	80.0%	69.8%	3
Tallahassee Memorial Hospital	8	11	72.7%	75.4%	2

Source: CON application #10229, page 23, Table 9.

SHHS states that it is committed to maintaining its high performance with respect to organ donation. The applicant states and the reviewer confirms that SHHS commits to an organ donor plan in Condition #2 (see Item C of this report for the entire condition). SHHS contends that kidney procurement at service area hospitals is sufficient to support the proposed program.

The reviewer notes that considering the applicant’s estimate of no procedures in year (ending December 31, 2015) and seven procedures in year two (ending December 31, 2016), the requirement of a minimum of 15 kidney transplants per year within two years of program operation is not met. However, SHHS

projects the first kidney transplant to occur in ‘year two’—CY 2016, and the date of the first procedure is the starting point for a project. SHHS projects to perform 15 adult kidney transplants in CY 2017 (year two of operation) and 29 during CY 2018 (year three of operation). The applicant meets this criterion.

ESRD Cases

For CY 2009-2013, SHHS indicates a District 1 adult ESRD growth rate of 162 ESRD cases, an increase of 17.7 percent (an annual growth rate (AGR) of 3.5 percent), and a District 4 growth rate of 273 cases, an increase of 13.8 percent (or 2.8 percent AGR). The applicant also points out that TSA 1’s total ESRD growth rate was 515 cases, a 9.6 percent growth rate (a 1.9 percent AGR), compared to the state growth rate of 14.1 percent (2.8 percent AGR). See the table below.

Growth Rate of ESRD in TSA 1

	Adult ESRD: Prevalence					Growth	Percent Change	Annual Rate of Growth
	2009*	2010*	2011*	2012**	2013**			
District 1	916	934	984	1,055	1,078	162	17.7%	3.5%
District 2	814	815	859	837	874	60	7.3%	1.5%
District 3	1,646	1,691	1,695	1,635	1,667	21	1.3%	0.3%
District 4	1,978	2,103	2,164	2,216	2,251	273	13.8%	2.8%
TSA 1	5,354	5,543	5,702	5,743	5,869	515	9.6%	1.9%
Florida	23,044	24,007	24,875	25,216	26,283	3,239	14.1%	2.8%

* 2009-2011 United States Renal Data System (USRDS) Renal Extraction & Referencing (RenDER) FL Data, Age 18+: Prevalence

** 2012-2013 FMQAI: The Florida ESRD Network 7: Prevalence

Source: CON application #10229, Table 10, page 23.

SHHS contends that ESRD rates in TSA 1 are growing at three times the rate of population growth and that for District 1 and District 2, the ESRD growth rates are over four times the population growth rate. SHHS asserts that this likely reflects “the poor health status of residents” which the applicant discussed earlier.

From July 1, 2010 to July 1, 2013, District 1’s population increased from 533,660 to 550,137 (16,477 residents), an increase of 3.09 percent (a 0.76 percent AGR). TSA 1’s total population increased from 3,280,993 to 3,361,213 or by 80,220 residents (by 2.45 percent or a 0.61 percent AGR). SHHS states that its projections are based on the historical 2009-2013 ESRD growth rate. See the table below.

Projected ESRD Cases CY 2014-2019

		Projected ESRD Case Prevalence: 18+					
Area	Annual Rate of Growth	2014	2015	2016	2017	2018	2019
District 1	3.5%	1,116	1,155	1,195	1,237	1,280	1,325
District 2	1.5%	887	900	914	927	941	955
District 3	0.3%	1,672	1,677	1,682	1,687	1,692	1,697
District 4	2.8%	2,314	2,378	2,445	2,513	2,584	2,656
TSA 1		5,988	6,110	6,235	6,364	6,497	6,633
Florida	1.9%	23,964	24,463	24,463	25,512	26,063	26,632

Source: CON application #10229, page 24, Table 12.

As shown in the table above, SHHS expects an ESRD annual rate of growth of 3.5 percent for District 1 and 2.8 percent for District 2, for the five-year period ending in 2019. This is compared to a projected 1.9 percent annual growth rate, statewide, for the same period. The applicant notes that the ESRD growth rate in TSA 1 is growing at three times the population growth rate and in Districts 1 and 2, the ESRD growth rate is over four times the population growth rate.

Transplant Projection

SHHS expects TSA 1 residents in Districts 1 and 2 will account for 48 adult kidney transplants in 2015 (year one) and 49 in 2016 (year two). The reviewer notes that Schedule 7A indicates zero procedures in year one and seven in year two. By year five (2019), the applicant expects 53 District 1 and District 2 residents (SHHS's planned service area) will have kidney transplants. For TSA 1 overall, SHHS expects a total of 173 procedures in 2015 (year one) and 177 by 2016 (year two). By 2019, SHHS projects 189 procedures for TSA 1, in total. See the table below.

Projected Adult Kidney Transplants in TSA 1

Area	2012 Transplants per ESRD Cases	2015	2016	2017	2018	2019
District 1	0.025	29	30	31	32	33
District 2	0.021	19	19	19	20	20
SHHP Service Area Total		48	49	50	52	53
District 3	0.022	37	37	37	37	37
District 4	0.037	88	90	93	96	98
TSA 1	0.028	173	177	181	185	189

Source: CON application #10229, page 25, Table 13.

In determining the 2012 transplants per ESRD cases percentage calculations for each district (in the table above), SHHS indicates that the ratio of transplants to ESRD cases was calculated. Per SHHS, the last full year for which both ESRD and transplant data

were available by county was 2012. The applicant indicates that the county data was summarized at the district level and that this was applied to Agency population projections for each district within TSA 1.

SHHS asserts that it will meet the 15 case minimum volume standard by the second year of operation of performing transplant surgery (2017) based on the following factors:

- SHHS hospitals are the most preferred providers of tertiary care in northwest Florida and that the proposed program will attract a significant number of service area residents.
- SHHP's clinical integration with UF Health will give patients confidence that the new program at SHHP will achieve the same quality outcomes.
- Over 78 percent of all kidney transplants from District 1 leave Florida for transplantation and the proposed program will offer a local, high quality program closer to home, capturing cases that are out-of-state migrations.
- In the past, lower income patients have declined transplantation due to the costs and hardships of travel and the proposed program will help patients reconsider their decision.
- Four nephrology physician groups in northwest Florida and south Alabama are the primary sources of referral for kidney transplant surgery in the service area.
- Physicians in all four physician groups have privileges at Sacred Heart facilities and are anticipated to refer and participate in the evaluation of their patients in the proposed program.

The reviewer provides a chart below showing TSA 1 resident adult kidney transplantation patient service patterns within Florida for calendar year 2013. The chart is arranged from licensed providers where adult kidney transplantation procedures were performed on District 1 and District 2 residents.

**TSA 1 Resident Facility Selection
Adult Kidney Transplantation Procedures
Calendar Year 2013**

Facility (TSA)	Total Procedures	TSA 1 Resident Patients	TSA 1 Resident Patient Percent	District 1 Resident Patients	District 2 Resident Patients	Districts 1 and 2 Resident Patients Combined	Districts 1 and 2 Resident Patients Percent
UF Health Shands Hospital (TSA 1)	83	46	55.42%	1	13	14	16.87%
Mayo Clinic (TSA 1)	138	82	59.42%	6	6	12	8.70%
Halifax Health Medical Center (TSA 3)	13	2	15.38%	0	1	1	7.69%
Tampa General Hospital (TSA 2)	187	3	0.02%	0	0	0	0.00%
Florida Hospital (TSA 3)	154	2	0.01%	0	0	0	0.00%
Total	575	135	23.48%	7	20	27	20.00%

Source: Florida Center for Health Information and Policy Analysis CY 2011 database.

The above chart verifies that UF Health Shands Hospital and Mayo Clinic realized in-migration (patients originating outside of TSA 1) at rates of 44.58 percent and 40.58 percent, respectively. This confirms the prior assertion that these providers have high rates of in-migration for this procedure. Seven District 1 residents and 20 District 2 residents received adult kidney transplantation in Florida in CY 2013. Of these 27 residents, 26 received the procedure in a TSA 1 facility (14 at UF Health Shands Hospital and 12 at Mayo Clinic). The Agency confirms that in CY 2013, 16.87 percent of UF Health Shands Hospital's and 8.70 percent of Mayo Clinic's total adult kidney transplants were residents of District 1 or District 2. Forty-six and 82 TSA 1 residents received the procedure at UF Health Shands Hospital and Mayo Clinic, respectively. SHHS stresses that District 1 and District 2 residents find distance and travel time as a geographic barrier and a hardship in seeking adult kidney transplants within TSA 1.

SHHS contends that 50 kidney transplants were performed at UAB in 2013 on patients living in south Alabama. The applicant includes south Alabama residents in its utilization forecast as SHHS contends the project will also serve these patients. SHHS states that its projected volume assumes a modest ramp up for the first three years, with seven cases by 2016 and 48 cases by 2019. SHHS estimates the projected market share and volume in the table below.

SHHP Projected Adult Kidney Transplant Surgeries

	2016			2017		
	Projected Kidney Transplants	Market Share	SHHP Transplant Volume	Projected Kidney Transplants	Market Share	SHHP Transplant Volume
District 1	30	15%	4	31	30%	9.0
District 2	19	10%	2	19	15%	3.0
Total Florida Transplants	49	12%	6	50	24%	12
South Alabama	47	2%	1	47	7%	3
Total Transplants			7			15
	2018			2019		
	Projected Kidney Transplants	Market Share	SHHP Transplant Volume	Projected Kidney Transplants	Market Share	SHHP Transplant Volume
District 1	32	50%	16.0	33	75%	25
District 2	20	30%	6.0	20	45%	9
Total Florida Transplants	52	42%	22	53	64%	34
South Alabama	47	15%	7	47	30%	14
Total Transplants			29			48

Source: CON application #10229, page 27, Table 14.

Impact on Existing Providers

SHHS states that during the fourth quarter of 2012 through the third quarter of 2013, District 1 and 2 residents accounted for nine kidney transplants at Mayo Clinic and 10 at UF Health Shands Hospital. The applicant notes that this is “a small portion” of these facilities total transplant volumes. Based on this, SHHS states the proposed program “will have a nominal, if any, impact on current TSA transplant centers”. The reviewer previously verified the relatively low percentage of District 1 and District 2 resident adult kidney transplants by TSA 1 providers.

2. Agency Rule Criteria

Does the project respond to preferences stated in agency rules? Please indicate how each applicable preference for the type of service proposed is met. Chapter 59C-1.031-044, Florida Administrative Code.

Chapter 59C-1.044, Florida Administrative Code, contains criteria and standards by which the department is to review the establishment of organ transplantation services under the certificate of need program regardless of the type of organ. These criteria and standards also specifically address additional requirements for kidney transplant programs. The appropriate areas addressed by the rule and the applicant’s responses to these criteria are as follows:

a. **Coordination of Services. Chapter 59C-1.044(3), Florida Administrative Code. Applicants for transplantation programs, regardless of the type of transplantation program, shall have:**

1. **Staff and other resources necessary to care for the patient's chronic illness prior to transplantation, during transplantation, and in the post-operative period. Services and facilities for inpatient and outpatient care shall be available on a 24-hour basis.**

The applicant indicates that it has the staff and resources necessary, either directly or through contract, to care for a kidney transplant patient's chronic illness prior to transplantation, surgical needs during transplantation and medical care in the post-operative period.

CON application #10229, Tab 3 includes an organizational chart for the proposed program, including senior staff from Sacred Heart Hospital and UF Health. The applicant indicates that clinical oversight will be provided by the transplant surgeon, working as a team leader with the transplant coordinator and transplant physician (nephrologist).

SHHS states plans to collaborate with UF Health and area nephrologists to determine the best approach for management of patients during and after the transplantation process. SHHS also states that SHHP maintains hospitalists, critical care, emergency medicine, and trauma surgery coverage 24 hours a day, 365 days a year. The applicant provides a description for each of the following medical and related staff (CON application #10229, pages 29-31):

- Program Transplant Administrator
- Transplant Surgeon/Medical Director
- Transplant Physician
- Transplant Coordinator (Advanced Registered Nurse Practitioner)
- Social Worker
- Financial Counselor
- Medical Assistant/Data Analyst.

- 2. If cadaveric transplantation will be part of the transplantation program, a written agreement with an organ acquisition center for organ procurement is required. A system by which 24-hour call can be maintained for assessment, management and retrieval of all referred donors, cadaver donors or organs shared by other transplant or organ procurement agencies is mandatory.**

The applicant states that LifeQuest Organ Recovery Services, located at 720 SW Second Avenue, Suite 570 North, Gainesville, Florida 32601, is the federally assigned designated OPO for TSA 1 and will provide donor kidneys to SHHP in accordance with donor allocation policies established by UNOS and CMS. CON application #10229, Tab 5 includes a signed and dated memorandum of agreement between Sacred Heart Health System and Shands Teaching Hospital and Clinics, Inc. d/b/a LifeQuest Organ Recovery Services.

- 3. An age-appropriate (adult or pediatric) intensive care unit which includes facilities for prolonged reverse isolation when required.**

SHHP indicates it has a 20-bed adult surgical intensive care unit located on the fourth floor of its Bayou Tower. Per the applicant, the unit is equipped for prolonged reverse isolation, if required.

- 4. A clinical review committee for evaluation and decision-making regarding the suitability of a transplant candidate.**

Per SHHS, an interdisciplinary team of health care professionals participating in and supporting the kidney transplantation program will function as the Kidney Transplant Patient Review Committee. The review committee will evaluate each candidate for kidney transplant, with respect to clinical suitability, psycho-social suitability, financial support and completeness of evaluation. The reviewer notes that the review committee composition is similar to those identified in Item E. 2. a. 1. above.

SHHS states that the protocols for kidney transplant patient selection utilized at UF Health will provide the framework for

the patient selection process. CON application #10229, Tab 6 includes the UF Health's Guidelines for Evaluation and Treatment of Candidates for Renal, Simultaneous Kidney and Pancreas, and Isolated Pancreas Transplantation.

5. Written protocols for patient care for each type of organ transplantation program including, at a minimum, patient selection criteria for patient management and evaluation during the pre-hospital, in-hospital, and immediate post-discharge phases of the program.

SHHS indicates that it will use UF Health protocols for selection and pre-transplant management of kidney transplant patients. UF Health Shands Hospital/Transplant Center's June 2014 kidney/pancreas transplant protocols are included in CON application #10229, Tab 7. Titles include:

- Hospital Admission Guidelines for Kidney and/or Pancreas Transplant
- Post Kidney/Pancreas Transplant Acute Rejection Treatment Guidelines
- Post Kidney Transplant Biopsy Guidelines
- Post Kidney/Pancreas Social Services Guidelines
- Post Kidney/Pancreas Transplant Parathyroid Hormone (PTH) Monitoring and Treatment Guidelines
- Post-Transplant Education, Kidney and/or Pancreas Transplant
- Post-Transplant Hyperlipidemia Management
- Nutritional Services
- Post Kidney/Pancreas Transplant Anemia Guidelines.

6. Detailed therapeutic and evaluative procedures for the acute and long-term management of each transplant program patient, including the management of commonly encountered complications.

The applicant refers the reviewer to its responses in CON application #10229 Tabs 6 and 7, previously described in Item E. 2. a. 4 and 5, respectively, immediately above.

- 7. Equipment for cooling, flushing, and transporting organs. If cadaveric transplants are performed, equipment for organ preservation through mechanical perfusion is necessary. This requirement may be met through an agreement with an organ procurement agency.**

SHHS cites its agreement with LifeQuest and states that LifeQuest operates according to UNOS policies regarding preservation, packaging and transportation of cadaveric organs consistent with the requirement. The applicant indicates that the project includes the acquisition of a kidney pump that can provide mechanical perfusion of cadaveric kidneys, if clinically indicated, that are accepted by SHHS for potential transplantation. Per SHHS, appropriate staff will be identified and trained in the operation of the kidney pump based upon guidelines and protocols consistent with those at UF Health.

- 8. An on-site tissue-typing laboratory or a contractual arrangement with an outside laboratory within the State of Florida, which meets the requirements of the American Society of Histocompatibility.**

SHHP plans to contract with the UF Health Histology and Immunology Laboratory for tissue-typing services.

- 9. Pathology services with the capability of studying and promptly reporting the patient's response to the organ transplantation surgery.**

SHHP states it has pathology services with the capability of studying and promptly reporting the patient's response to the kidney transplant surgery, and analyzing appropriate kidney biopsy material through the SHHP Clinical Laboratory and by contractual agreement with Pensacola Pathologists, P.A.

SHHS further indicates that the clinical laboratory is operational 24 hours a day, 365 days a year and is fully accredited by the College of American Pathologists and the American Association of Blood Banks, meets Joint Commission standards and is in compliance with state and federal regulations. The applicant includes an Agency

clinical laboratory license and a CMS certificate of accreditation for Sacred Heart Hospital (CON application #10229, Tab 11).

10. Blood banking facilities.

SHHS indicates that it has appropriate blood banking facilities and transfusion services to support the proposed kidney transplant program. Per the applicant, in the unlikely event that additional blood supply is needed, SHHS has an agreement with OneBlood for blood and blood products, which are supplied locally. Further, should more complex needs be required, the OneBlood reference laboratory located in St. Petersburg, Florida, is available.

11. A program for the education and training of staff regarding the special care of transplantation patients.

SHHS reiterates its clinical integration agreement with UF Health, including the education and training of staff to acquire the knowledge and maintain competencies regarding the special care of kidney transplant patients. SHHS indicates this assures a comparable and high-quality proposed project.

SHHS states that based on preliminary discussion with UF Health, there are five training priority areas for the proposed program's implementation and operations, as follows:

- Staff understanding how to create a program flow for communication for kidney transplantation
- The Patient Review Committee and "QAPI" process
- An understanding of transplant financial processes because most kidney transplants are funded under the organ acquisition component of Medicare
- Operating room, intensive care and medical/surgical nursing and support department competencies
- Specific psychosocial/family needs of the kidney transplant patient.

SHHS states clinical competencies will be documented by its human resource system and will include the following initial and on-going educational methods:

- Written and video education materials
- UF Health protocol access and orientation

- Rotation to UF Health Shands Hospital in Gainesville to participate in kidney transplant care to allow return demonstration of skills and understanding
- In-service education by the transplant surgeon, coordinator, social work/financial, and clinical service educators on key topics and issues during program implementation.

12. Education programs for patients, their families and the patient's primary care physician regarding after-care for transplantation patients.

SHHS plans to adopt UF Health education practices and modify these as necessary, to accommodate the literacy and language needs of SHHP patients. Examples of these materials are included in CON application #10229, Tab 9. The applicant indicates that during proposed program development, SHHP and UF Health will jointly develop an outreach and ongoing communication plan to ensure coordination of care and information with dialysis centers and primary care physicians.

b. Staffing Requirements.

Applicants for transplantation programs, regardless of the type of transplantation program, shall meet the following staffing requirements. Chapter 59C-1.044(4), Florida Administrative Code.

- 1. A staff of physicians with expertise in caring for patients with end-stage disease requiring transplantation. The staff shall have medical specialties or sub-specialties appropriate for the type of transplantation program to be established. The program shall employ a transplant physician, and a transplant surgeon, if applicable, as defined by the United Network for Organ Sharing (UNOS) June 1994. A physician with one year experience in the management of infectious diseases in the transplant patient shall be a member of the transplant team.**

SHHS states that UF Health will assist in the selection and recruitment of all necessary program staff to meet UNOS requirements. SHHS provides curriculum vitae (CVs) for the primary transplant surgeon (Jeffrey H. Fair, M.D.), on-call transplant surgeon (Kenneth Andreoni, M.D.), two area nephrologists who have completed post-graduate fellowship

training in the treatment and management of transplant patients (Haitham Qadar, M.D. and Katharina Meyer, M.D.) and SHHS's Epidemiologist (Barbara Wade, M.D.) in CON application #10229's, Tabs 2 and 4. Many of these physicians wrote letters of support for the proposed project.

- 2. A program director who shall have a minimum one year formal training and one year of experience at a transplantation program for the same type of organ transplantation program proposed.**

SHHS states that Jeffrey H. Fair, M.D., Transplant Surgeon, will serve as the program director. His letter of support and CV were discussed previously.

- 3. A staff of nurses and nurse practitioners with experience in the care of chronically ill patients and their families.**

SHHS indicates it currently employs over 1,500 registered nurses and has extensive capability to care for related chronic conditions which may impact kidney transplant patients during the course of their care. SHHP provides specialized nursing care in 10 medical disciplines, including critical care and nephrology, among others.

SHHS states that in addition to inpatient and outpatient nursing care, an ARNP with a minimum of five years clinical experience in the management of chronically ill patients, nephrology patients, or solid organ transplant patients will be recruited to serve as the transplant coordinator.

- 4. Contractual agreements with consultants who have expertise in blood banking and are capable of meeting the unique needs of transplant patients on a long-term basis.**

SHHS reiterates that it has appropriate blood banking facilities and transfusion services, staff and other services in place to support a kidney transplant program and the long-term needs of transplant patients. The applicant indicates that it also has access to consultants with additional expertise through its agreement with OneBlood, which has eight reference consultation laboratories in Florida (see Item E. 2. a. 10 of this report).

5. Nutritionists with expertise in the nutritional needs of transplant patients.

SHHS states that nutritional services are provided at SHHP through a contract with Touchpoint Support Services. The applicant indicates that SHHP's Food and Nutrition Services Department has six registered dieticians with expertise in the nutritional needs of acute and chronic care patients, including those with specialized needs. The role of a renal dietician is also discussed. The CV of the lead nutritionist for the proposed program is included in CON application #10229, Tab 10.

6. Respiratory therapists with expertise in the needs of transplant patients.

SHHP states it has policies, procedures and staff available for the diagnostic evaluation, management, and care of patients with deficiencies and abnormalities of the cardiovascular system. Current respiratory therapy capabilities are discussed. SHHS names an on-site board-certified pulmonologist, with CV (CON application #10229, Tab 4). SHHP indicates that any additional competency standards and training necessary to care for patients undergoing kidney transplantation will be added into the skills review process.

7. Social workers, psychologists, psychiatrists, and other individuals skilled in performing comprehensive psychological assessments, counseling patients, and families of patients, providing assistance with financial arrangements, and making arrangements for use of community resources.

SHHP states and the reviewer confirms it will have 1.0 FTE social worker (MSW) for the proposed project. Specific duties of this social worker are discussed. SHHP indicates it will contract with Creekside Psychiatric Center for emergency behavioral health services and outpatient referral. SHHP indicates plans to develop a kidney transplant support group as well.

8. Data Reporting Requirements. Facilities with organ transplantation programs shall submit data regarding each transplantation program to the Agency or its designee, within 45 days after the end of each calendar quarter. Facilities with organ transplantation programs shall report to the Agency or its designee, the total number of transplants by organ type which occurred in each month of the quarter.

The applicant anticipates no difficulties in meeting data reporting requirements of the Agency.

- 9. Kidney Transplantation Programs. In addition to meeting the requirements specified in subsections (3) – (5), a certificate of need for a new kidney transplantation program shall not normally be approved unless the following additional criteria are met:**

(a) Coordination of Services.

- 1. Inpatient services shall be available which shall include renal dialysis and pre- and post-operative care. There shall be 24-hour availability of on-site dialysis under the supervision of a board-certified or board-eligible nephrologist.**

SHHP states it operates a seven station dialysis unit and can provide bedside dialysis, as needed. SHHP indicates its dialysis and apheresis services are provided through a contractual relationship with Renal Care Group of the Southeast, an affiliate of Fresenius Medical Care. These services are stated to be under the direction of Humam Humeda, MD, a board-certified nephrologist with active medical staff privileges at SHHP (CON application #10229, Tab 4).

- 2. Outpatient services shall be available which shall include renal dialysis services and ambulatory renal clinic services.**

Per the applicant, outpatient services are currently provided by referral to DaVita, Fresenius, and other area dialysis centers. DaVita and Fresenius also offer home dialysis services. Prior to implementation of the proposed project, the referral protocol will be revised to include providers of renal clinic services.

- 3. Ancillary services shall include pre-dialysis, dialysis and post transplantation nutritional services; bacteriologic, biochemical and pathological services; radiologic services; and nursing services with the capability of monitoring and support during dialysis and assisting in home care including vascular access and home dialysis management, when applicable.**

SHHS states having a broad array of ancillary services available to meet the needs of kidney transplant candidates throughout the evaluation, transplantation, and post-transplant phase of the process. The applicant discusses SHHPs Food and Nutrition Services Department, Clinical Laboratory, Radiology Department and provision of acute dialysis and apheresis services in a dedicated unit and at bedside. SHHS indicates that it refers patients to Fresenius (through a contractual agreement) for home dialysis.

(b) Staffing Requirements for Adult Kidney Transplantation Programs.

- 1. The kidney transplantation program shall be under the direction of a physician with experience in physiology, immunology and immune-suppressive therapy relevant to kidney transplantation.**

SHHP previously discussed plans to contract with UF Health for the services of Jeffery H. Fair, MD, as the primary transplant surgeon and medical director. Dr. Fair is knowledgeable in the physiology, immunology, and immune-suppressive therapy relevant to kidney transplantation.

- 2. The transplant surgeon shall be board-certified in surgery or a surgical subspecialty, and shall have a minimum of 18 months training in a transplant center.**

The reviewer notes that Dr. Fair, the primary transplant surgeon and Dr. Andreoni, the backup surgeon for the proposed project, meet this criterion.

- 3. The transplant team performing kidney transplantation shall include physicians who are board-certified or board-eligible in the areas of anesthesiology, nephrology, psychiatry, vascular surgery and urology.**

SHHP provides physician names and CVs to show compliance with this criterion in CON application #10229, Tab 4.

4. **Additional support personnel which shall be available include a nephrology nurse with experience in nursing care of patients with permanent kidney failure and a renal dietician.**

SHHP states plans to have a nephrology nurse to meet this proposed project and already has nursing staff caring for patients with kidney disease and renal failure in its intensive care and medical/surgical units.

5. **A laboratory with the capability of performing and promptly reporting bacteriologic, biochemical and pathologic analysis.**

SHHS previously presented the qualifications of hospital laboratory capabilities in response to this criterion.

6. **An anesthesiologist experienced in kidney transplantation.**

Per SHHS, Panhandle Anesthesiology Associates, P.A., provides full service anesthesiology services for inpatient, outpatient and procedural cases at SHHP. SHHS names four physicians in the group stated to have completed specialized training and have been on transplant surgical teams.

3. **Statutory Review Criteria**

- a. **Is need for the project evidenced by the availability, quality of care, accessibility and extent of utilization of existing health care facilities and health services in the applicant's service area? ss. 408.035(1)(a) and (b), Florida Statutes.**

SHHS references its Item E. 1. discussion of need for the proposed project as evidenced by availability, accessibility and utilization of existing health care facilities providing adult kidney transplantation services. The applicant further reiterates letters of support (see Item B of this report) and that poor geographic accessibility produces economic barriers and hardships for patients who would benefit from kidney transplant.

SHHS offers four bulleted factors, stated to quantifiably document the need for the proposed project:

- Twenty-eight residents of District 1 and 2 received kidney transplant services at out-of-state centers in 2013 and that these constituted the highest outmigration rate and number of residents leaving Florida.
- Of those leaving Florida for care, the majority received transplant services at the UAB, with the median wait list time to transplant being greater than 72 months at UAB compared to 11.7 months at UF Health Shands Hospital.
- The proposed project is clinically integrated with UF Health, stated to be a known quality provider for transplant services within TSA 1.
- As of April 2014, UF Health's internal data indicate 107 adults on the kidney transplant wait list are residents of the District 1/District 2 area.
- District 1 and 2 residents currently on the wait list for kidney transplant at out-of-state centers would have the option to dual wait list at SHHP, increasing their chance of receiving a transplant.

The reviewer notes that utilization over the five year period ending December 31, 2013, was previously charted in Item E. 1. a of this report.

b. Does the applicant have a history of providing quality of care? Has the applicant demonstrated the ability to provide quality care? ss. 408.035 (1)(c), Florida Statutes.

SHHS provides a copy of Sacred Heart Hospital's license (CON application #10229, Tab 11) and Joint Commission accreditation certificate (CON application #10229, Tab 12). The applicant notes that its Joint Commission certification bears the Gold Seal of Approval and Medal of Honor for Organ Donation. Sacred Heart Hospital's clinical laboratory and CMS certificate of accreditation were discussed previously in this report. SHHP participates in the Medicare and Medicaid programs. SHHS notes that other notable-designations include:

- Regional Perinatal Intensive Care Center for high risk maternity and baby care and the Western Panhandle Early Steps Program for developmental evaluation of infants and toddlers, both designations issued by the Florida DOH, Children's Medical Services
- Community Cancer Center approved by the American College of Surgeons and an affiliate of the MD Anderson Cancer Network™
- Chest Pain Center accredited by the Society of Cardiovascular Patient Care
- Bariatric Surgical Center of Excellence recognized by the American Society of Metabolic and Bariatric Surgery and Surgical Review Corporation
- Level 2 Wound Care and Hyperbaric Medicine accredited by the Undersea and Hyperbaric Medical Society
- LifeQuest-Standards of Excellence for Organ Donation (2013)

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- American Stroke Association and American Heart Association-Gold Plus Stroke Award (2014)
- HealthGrades
 - Distinguished Hospital for Clinical Excellence (2012)
 - Emergency Medicine Excellence (2010-2012)
 - Critical Care Excellence (2012, 2013)
 - Women's Health Excellence (2011)
 - Gynecologic Surgery Excellence (2011-2013)
 - Bariatric Surgery Excellence (2011-2013)
- National Research Corporation
 - Consumer Choice Award for Northwest Florida (last 16 years)
 - Best Overall Quality
 - Best Doctors and Nurses
 - Most Preferred for All Health Needs
 - Highest Patient Safety.

SHHS states that as a (planned) clinically integrated program, SHHP intends to adopt and adapt, as necessary, the UF Health Quality Assessment and Performance Improvement (QAPI) Plan for organ transplantation, and includes UF Health Shands Transplant Center 2013-2014 written materials on solid organ transplant (CON application #10229, Tab 13). Per SHHS, this QAPI Plan provides a comprehensive, consistent, coordinated and multidisciplinary framework for performance improvement to enhance patient safety and outcomes at all stages of the transplant process.

SHHS states that in summary, transplant patients treated at UF Health spend less time waiting for a transplant as compared to the nation as a whole, and experienced higher survival rates consistent with national norms. Further, SHHS indicates that residents of TSA 1 who are African-American and need kidney transplant services are more likely to be evaluated, wait listed, and receive transplant services compared to other programs nationally. The applicant offers these as quality factors in requesting project approval.

Agency complaint records indicate, for the three-year period ending July 8, 2014, Sacred Heart Hospital had one substantiated complaint. A single complaint can encompass multiple complaint categories. The substantiated complaint category was—quality of care/treatment.

SHHS, the parent corporation of Sacred Heart Hospital, operates four general hospitals in the northwest Florida area, with an aggregate of 866 licensed beds. Agency complaint records indicate, for the three-year period ending July 8, 2014, SHHS had six substantiated complaints in the following complaint categories:

Sacred Heart Health System, Inc. Substantiated Complaint Categories for the 36 Months Ending July 8, 2014	
Nursing Services	2
Quality of Care/Treatment	2
Admission/Transfer/Discharge Rights	1
Life Safety Code	1
Resident/Patient/Client Assessment	1
Resident/Patient/Client Rights	1

Source: Agency licensure records.

c. What resources, including health personnel, management personnel and funds for capital and operating expenditures are available for project accomplishment and operation? ss. 408.035(1)(d), Florida Statutes.

The financial impact of the project will include the project cost of \$121,650 and year two operating costs of \$1,256,813. The applicant is a medium urban hospital and a wholly owned subsidiary of SHHS (parent).

The applicant provided a copy of the June 30, 2013 and 2012, audited financial statements for the parent, SHHS. A letter of support was provided and signed by the senior vice president and chief financial officer of SHHS.

Short-Term Position

The parent's current ratio of 2.3 is above average and indicates current assets are approximately 2.3 times current liabilities, an adequate position. The working capital (current assets less current liabilities) of \$98,152,000 is a measure of excess liquidity that could be used to fund capital projects. The ratio of cash flow to current liabilities of 0.7 is average and an adequate position. Overall, the parent has an adequate short-term position (see Table 1 below).

Long-Term Position

The ratio of long-term debt to net assets of 0.4 is average and indicates that equity exceeds long-term debt. The ratio of cash flow to assets of 7.0 percent is below average and a moderately weak position. The most recent year had a net loss of \$2,988,000 which resulted in a negative 0.4 percent operating margin. Overall, the parent has a moderately weak long-term position (see Table 1 below).

Capital Requirements

The applicant indicates on Schedule 2 capital projects totaling \$25.4 million which includes this project, a bed tower construction project, ICU renovation and routine capital expenditures. In addition, the applicant is projecting a year one operating loss of \$950,840. The applicant will have to fund this loss until profitability can be achieved.

Available Capital

The applicant indicates that funding for the project will be provided by the parent. A letter from the parent's chief financial officer in support of the related company financing was included. The parent's 2013 audited financial statements show \$19,380,000 in cash and cash equivalents, \$98,152,000 in working capital and \$50,638,000 in cash flow from operations.

Other Issues

The parent is named in a civil lawsuit by the Florida Attorney General (Medicaid Fraud Control Unit), DOJ, OIG, and DOD related to improper payments for radiation therapy services provided at a partially owned subsidiary—Gulf Region Radiation Oncology Centers. Tentative settlements have been reached on all claims save for a whistle-blower's wrongful termination/retaliation claim. The owner of the parent, Ascension Health, is currently under investigation from the U.S. Department of Justice to determine if implantable cardioverter defibrillators (ICDs) were provided to certain Medicare recipients. Further details can be found in Note 9 of the audited financial statements.

Staffing

The table below shows the applicant's projected staffing for years one – three (CY 2015 – CY 2017) for the project. SHHS provides staffing tables through CY 2019. Notes to Schedule 6A indicate that adult kidney transplantation programs at Ascension Health facilities and recommended assumptions by UF Health were used to project patient flow and staffing requirements.

Sacred Heart Health System, Inc. d/b/a Sacred Heart Hospital Adult Kidney Transplantation Program Staffing Patterns			
	Year One CY 2015	Year Two CY 2016	Year Three CY 2017
Administration			
Transplant Coordinator (ARNP)	1.00	1.00	1.00
Financial Counselor	0.50	0.50	0.50
MOS/MA	1.00	1.00	1.00
Nursing			
OR/PACU RN	0.00	0.07	0.16
ICU RN	0.00	0.07	0.14
Telemetry	0.00	0.00	0.01
Ancillary			
Social Worker MSW	1.00	1.00	1.00
Total	3.50	3.64	3.81

Source: CON application #10229, Schedule 6A.

The applicant's notes to Schedule 6A indicate that SHHS is contracting with UF Health for the kidney transplant surgeon and the kidney program administrator and the FTE impact on other ancillary services is negligible so these and the existing FTEs for ancillary services are not included. SHHS indicates that it accounts for the costs associated with these positions in its Schedule 8A assumptions.

Conclusion:

Funding for this project and the entire capital budget should be available as needed.

TABLE 1		
CON application #10229 / Sacred Heart Health Systems, Inc. d/b/a		
Sacred Heart Hospital		
	SHHS (Parent)	SHHS (Parent)
	06/30/13	06/30/12
Current Assets (CA)	\$175,654,000	\$187,701,000
Cash and Current Investment	\$19,380,000	\$13,275,000
Total Assets (TA)	\$724,861,000	\$716,020,000
Current Liabilities (CL)	\$77,502,000	\$70,981,000
Goodwill	\$0	\$0
Total Liabilities (TL)	\$256,754,000	\$246,381,000
Net Assets (NA)	\$468,107,000	\$469,639,000
Total Revenues (TR)	\$671,716,000	\$673,172,000
Interest Expense (Int)	\$5,319,000	\$6,048,000
Excess of Revenues Over Expenses (ER)	(\$2,988,000)	\$46,412,000
Cash Flow from Operations (CFO)	\$50,638,000	\$45,484,000
Working Capital	\$98,152,000	\$116,720,000
FINANCIAL RATIOS		
	06/30/13	06/30/12
Current Ratio (CA/CL)	2.3	2.6
Cash Flow to Current Liabilities (CFO/CL)	0.7	0.6
Long-Term Debt to Net Assets (TL-CL/NA)	0.4	0.4
Times Interest Earned (ER+Int/Int)	0.4	8.7
Net Assets to Total Assets (NA/TA)	64.6%	65.6%
Operating Margin (ER/TR)	-0.4%	6.9%
Return on Assets (ER/TA)	-0.4%	6.5%
Operating Cash Flow to Assets (CFO/TA)	7.0%	6.4%

d. What is the immediate and long-term financial feasibility of the proposal? ss. 408.035(1)(f), Florida Statutes.

A comparison of the applicant's estimates to the control group values provides for an objective evaluation of financial feasibility, (the likelihood that the services can be provided under the parameters and conditions contained in Schedules 7 and 8), and efficiency, (the degree of economies achievable through the skill and management of the applicant). In general, projections that approximate the median are the most desirable, and balance the opposing forces of feasibility and efficiency. In other words, as estimates approach the highest in the group, it is more likely that the project is feasible, because fewer economies must be realized to achieve the desired outcome. Conversely, as estimates approach the lowest in the group, it is less likely that the project is feasible, because a

much higher level of economies must be realized to achieve the desired outcome. These relationships hold true for a constant intensity of service through the relevant range of outcomes. As these relationships go beyond the relevant range of outcomes, revenues and expenses may either go beyond what the market will tolerate, or may decrease to levels where activities are no longer sustainable.

The applicant was compared to hospitals in the Medium Urban Hospital Group (Group 5). The applicant did not provide hospital-wide data for projected patient days. Without this data, the Agency was not able to calculate net revenue per adjusted patient day and cost per adjusted patient day. Because of this, the Agency used actual hospital results from 2012 for the purpose of comparing the applicant to the rest of the hospital group. In the first year, the total projected incremental increase cost from the proposed project is \$950,840, or 0.25 percent of total expenses. As such, the projected increases in costs from this project are immaterial and were not included when performing this review.

Net revenues, total expenses and patient days were obtained from the applicant's 2012 Florida Hospital Uniform Reporting System (FHURS) report.

The 2012 data was standardized to account for case mix index, fiscal year end and geographic location. Standardized net revenue per adjusted patient day (NRAPD) of \$1,180 in 2012 is between the control group median and lowest values of \$1,315 and \$1,023. With net revenues falling between the median and lowest level in 2012, the facility consumed health care resources in proportion to the services provided (see Table 2 below).

Standardized cost per adjusted patient day (CAPD) of \$1,078 in 2012 is between the median and lowest values of \$1,220 and \$976. With costs falling between the median and lowest level in 2012, the costs appear to be reasonable (see Table 2 below).

Conclusion: The project appears to be financially feasible.

TABLE 2

**Sacred Heart Health System, Inc. d/b/a Sacred Heart Hospital
CON application #10229**

2012 DATA Med Urban Hospital Group

	2012 ACTIVITY	2012 STDZD ACTIVITY PER DAY	<u>Highest</u>	<u>Median</u>	<u>Lowest</u>
NET REVENUES	385,761,150	1,180	1,963	1,315	1,023
EXPENSES					
TOTAL EXPENSES	352,196,167	1,078	1,873	1,220	976
OPERATING INCOME	33,564,983	102 8.6%	422	106	-288
PERCENT OCCUPANCY	69.98%		<u>Highest</u> 77.4%	<u>Median</u> 57.8%	<u>Lowest</u> 23.3%
TOTAL BED DAYS AVAILABLE	170,090				
TOTAL NUMBER OF BEDS	466				
PAYER TYPE	<u>PATIENT DAYS</u>	<u>% TOTAL</u>			
SELF PAY	2,985	2.5%			
MEDICAID	34,963	29.4%	29.4%	7.3%	1.6%
MEDICAID HMO	1,882	1.6%			
MEDICARE	35,706	30.0%	66.0%	47.7%	30.0%
MEDICARE HMO	6,507	5.5%			
INSURANCE	0	0.0%			
HMO/PPO	33,092	27.8%	42.5%	14.5%	7.8%
OTHER	3,896	3.3%			
TOTAL	119,031	100%			

- e. Will the proposed project foster competition to promote quality and cost-effectiveness? ss. 408.035(1)(g), Florida Statutes.**

Given the limited size and focus of this project, this project will not likely have a material impact to foster the type of competition generally expected to promote quality and cost-effectiveness.

- f. Are the proposed costs and methods of construction reasonable? Do they comply with statutory and rule requirements? ss. 408.035(1)(h), Florida Statutes; Chapter 59A-3, Florida Administrative Code.**

SHHS indicates that the proposed project does not involve construction or renovation.

- g. Does the applicant have a history of providing health services to Medicaid patients and the medically indigent? Does the applicant propose to provide health services to Medicaid patients and the medically indigent? ss. 408.035(1)(i), Florida Statutes.**

Below is a chart to account for Sacred Heart Hospital’s and District 1’s Medicaid and charity care percentages for FY 2012.

**Medicaid and Charity Care for
Sacred Heart Hospital (CON application #10229)
Compared to District 1 for FY 2012**

Applicant	Medicaid & Medicaid HMO Days	Charity Percentage Service	Combined Medicaid & Charity Care
Sacred Heart Hospital	30.95%	3.20%	34.16%
District 1 Average	18.50%	2.12%	20.61%

Source: Fiscal Year 2012 Agency for Health Care Administration Actual Hospital Budget Data.
NOTE: The combined Medicaid and charity care percentage discrepancy of 0.01 percent is likely due to rounding.

The reviewer notes that the District 1 hospital with the next highest combined Medicaid and charity care patient day percentage was Baptist Hospital, Inc. at 20.62 percent.

The table below illustrates Sacred Heart Hospital’s FY 2013-2014 low-income pool (LIP) and disproportionate share hospital (DSH) program participation, as of March 20, 2014.

Sacred Heart Health System, Inc. d/b/a Sacred Heart Hospital LIP and DSH Program Participation FY 2013-2014		
Program	Annual Total Allocation	Year-to-Date Total Allocation As of March 20, 2014
LIP	\$4,373,915	\$2,747,671
DSH	\$494,068	\$13,480

Source: Agency Division of Medicaid, Office of Program Finance.

SHHS indicates the provision of services to all patients in need, regardless of the ability to pay or source of payment. In CON application #10229, Table 15, Sacred Heart Hospital provides the gross revenues and patient days by payer for fiscal years ending June 30, 2011-2013.

According to Schedule 7A, six of the proposed project’s year two (CY 2016) transplants will be provided to Medicare patients and one patient will be covered by commercial insurance. As previously stated, the applicant’s year two (CY 2016) is the first year in which a transplant is to be performed. The applicant proposes to perform 15 procedures in CY 2017, SHHS projects 12 of these will be Medicare and three commercial insurance patients.

Schedule 7A shows no Medicaid/Medicaid HMO or charity care cases or patient days for the proposed project. Notes to Schedule 7A indicate that the majority (80 percent) of Florida adult kidney transplantation cases are Medicare and the balance commercial. The notes further indicate that the precipitating condition of ESRD prior to transplant qualifies these patients for Medicare Disability coverage. In addition, SHHS states that should a self-pay/charity transplant patient present, SHHP “will accept the patient as consistent with our mission”. The reviewer notes that statewide during CY 2013, of the 877 adult kidney transplant procedures performed, 21 (or 2.39 percent) were compensated through Medicaid/Medicaid HMO, per the Agency’s Florida Center for Health Information and Policy Analysis database.

F. SUMMARY

Sacred Heart Health System, Inc. d/b/a Sacred Heart Hospital (CON application #10229) seeks approval to establish an adult kidney transplantation program at Sacred Heart Hospital, in Pensacola (Escambia County, Florida), TSA 1. Specifically, the proposed project plans to serve the residents of District 1 and District 2. SHHS states that UF Health will form a clinical integration affiliation with the applicant and that UF Health will develop, implement and provide oversight for the proposed project.

The adult kidney transplant program, if approved, is to be operational by January 2015, with its first transplant taking place in CY 2016. There is no reported new construction or renovation associated with the project. Total project costs are \$121,650 and include equipment, project development and start-up costs.

The Schedule C proposed conditions are found on pages 9-10 of this report.

Need:

Need is not published by the Agency for kidney transplants. It is the applicant's responsibility to demonstrate need. The planning for organ transplantation programs in Florida is done on a regionalized basis covering four regions defined by Rule.

TSA 1 currently has two operational adult kidney transplant programs—UF Health Shands Hospital in District 3 (Alachua County) and Mayo Clinic in District 4 (Duval County). The reviewer notes a driving distance/driving time of 340.92 miles/five hours and four minutes from Sacred Heart Hospital to the nearest operational Florida adult kidney transplantation provider (also located in TSA 1).

During calendar year 2013 UF Health Shands Hospital performed 90 and Mayo Clinic performed 160 adult kidney transplants.

Sacred Heart Hospital projects it will perform seven adult kidney transplants in year one (CY 2016), 15 in CY 2017 and 48 in CY 2019.

SHHS plans to capture a combined District 1 and District 2 service area, and draw applicable patients from south Alabama. The applicant contends that travel creates geographic barriers and hardships for patients seeking these procedures and that the proposed project will address this issue.

Quality of Care:

SHHS has Joint Commission accreditation including the Gold Seal of Approval and Medal of Honor for Organ Donation.

SHHS lists numerous recognition awards and plans to have a clinically integrated program (with UF Health), to adopt and adapt, as necessary, the QAPI Plan for organ transplantation.

Agency complaint records indicate, for the three-year period ending July 8, 2014, Sacred Heart Hospital had one substantiated complaint and Sacred Heart Health System, Inc. (four acute care hospitals with 866 licensed beds) had six substantiated complaints.

The applicant demonstrates the ability to provide quality care and presents a good description of the quality of care it proposes for the proposed project.

Financial/Cost:

Funding for this project and the entire capital budget should be available as needed.

The project appears to be financially feasible.

Given the limited size and focus of this project, the proposed program will not likely have a material impact to foster the type of competition generally expected to promote quality and cost-effectiveness.

Medicaid/Indigent Care:

Sacred Heart Hospital has a history of providing care to Medicaid and Indigent patients. The applicant is a safety net provider and participates in both the state's low income pool program and disproportionate share hospital program.

The precipitating condition of ESRD prior to transplant qualifies most patients for Medicare Disability coverage.

The applicant projects zero Medicaid or charity care patient transplants during all five years presented in its Schedule 7A. The applicant does not propose to condition project approval to serve Medicaid or charity care patients.

G. RECOMMENDATION

Approve CON #10229 to establish an adult kidney transplantation program in Escambia County, Transplantation Service Area 1. The total project cost is \$121,650. There is no new construction or renovation associated with this project.

CONDITIONS:

Condition #1: Education/Training

SHHP will provide clinical education and training opportunities for medical staff, clinical staff, and post-graduate physician residents to inform professionals about the kidney transplantation program, organ donation, and caring for the patient with renal disease. The purpose of the education and training is to promote and improve understanding of treatment options for patients with permanent kidney failure. SHHP is committed to perform the following education/training activities on an annual basis:

- Continuing Education: Offer to all health care professionals at two accredited CEU sessions on kidney transplant and related topics, with specific education units awarded by MECOP. The sessions could include Grand Rounds, lectures or presentations for physicians, nurses, and allied health professionals. *SHHP will include the educational session topic, speaker, date, and CEU credits provided by MECOP in its annual condition compliance report.*
- Nurse Orientation: As part of new hire orientation, include specific modules on caring for the patient with renal disease and competency/skills checks for staff assigned to the proposed kidney transplant program. *SHHP's condition compliance report will include the content and dates of the new hire orientation sessions, and competency skills checks completed by staff assigned to the proposed kidney transplant program.*
- Internal Medicine Residency Rotations: All Internal Medicine Residents will complete a nephrology rotation that includes the transplant program. *SHHP's report will certify this rotation is in place and include the number of residents who have completed the rotation.*

Condition #2: Organ Donor Plan

SHHP understands that organ donation is important to the provision of kidney transplantation for all wait list patients, not just those that will receive services at SHHP. SHHP commits to participating in an annual organ donor development plan with the organ procurement agency for this transplant service area. The plan outlines SHHP's performance with respect to appropriate and timely referral of potential donors, effective request rate, and the average number of organs transplanted per donor, which are organ donation goals supported by CMS and The Joint Commission.

- SHHP will complete an annual organ donor development plan with the designated organ procurement agency. The plan will be reviewed by senior leadership and specific performance goals and associated tactics will be delineated for the calendar year. The plan will be mutually agreed upon by SHHP and the organ procurement agency, with appropriate signatures acknowledging the plan. *This will be measured by submission of SHHP's annual organ donor development plan to AHCA.*

AUTHORIZATION FOR AGENCY ACTION

Authorized representatives of the Agency for Health Care Administration adopted the recommendation contained herein and released the State Agency Action Report.

DATE: _____

James B. McLemore
Health Services and Facilities Consultant Supervisor
Certificate of Need