A. PROJECT IDENTIFICATION

1. Applicant/CON Action Number

South Broward Hospital District
d/b/a Memorial Regional Hospital/CON #10044
3501 Johnson Street
Hollywood, Florida 33021

Authorized Representatives: Mr. Jon D. Bandes
(954) 265-3452

2. Service District/Subdistrict

Organ Transplant Service Area 4: Districts 10 (Broward County), District 11 (Miami-Dade and Monroe Counties); Collier County only (in District 8) and Palm Beach County only (in District 9).

B. PUBLIC HEARING

A public hearing was not held or requested. However, letters of support were received by the Agency for Health Care Administration (the Agency) and were submitted by the applicant proposing to establish a pediatric heart transplantation program at Memorial Regional Hospital/Joe DiMaggio Children’s Hospital, as discussed below.

Letters of Support

The applicant submitted 24 unduplicated letters of support (Attachment Q-Letters of Support) and an additional 25th support letter (a memorandum of understanding [MOU]) regarding the procurement of suitable donor hearts (Attachment D-Life Alliance Organ Recovery Agency [LAORA]). The letters are signed and timely (most having a December 2008 date). The support letters are summarized below.
The Honorable Debbie Wasserman Schultz, U.S. House of Representatives offered her support. The Honorable Eleanor Sobel (District 31) and the Honorable Nan Rich (District 34), Florida Senate, offered their support. The Honorable Ellyn Bogdanoff (District 91) and the Honorable Elaine Schwartz (District 99), Florida House of Representatives, lent their support. A former state senator, Steve Geller, also offered his support. These elected officials’ letters emphasize that the applicant is a tax assisted hospital district and is the only provider of pediatric open heart surgery in Broward, Palm Beach and Collier Counties. Senator Geller stated he consistently fought to help set up and fund the Joe DiMaggio Children’s Hospital (within Memorial Regional Hospital) and that project approval would be a “natural and important fit” to deal with those in need of pediatric heart transplantation.

The Honorable Stacy Ritter, Broward County Mayor, the Honorable Ken Keechl, Broward County Vice-Mayor and the Honorable Sue Gunzburger, Commissioner, Broward County Commission all lent their support in a form letter variety, stating generally that Transplant Service Area 4 has only one pediatric heart transplantation provider yet the largest population of the transplant service areas statewide.

Seven City of Hollywood elected officials also submitted a form letter of support, advising generally that the applicant is a tax assisted hospital district, providing care regardless of ability to pay and operates state-of-the-art, safe, quality care, particularly noting the applicant’s cardiac program is the only provider of pediatric open heart surgery in Broward, Palm Beach and Collier Counties. These seven City of Hollywood officials are as follows: the Honorable Peter Bober, Mayor and the Honorable Richard Blattner, Vice-Mayor, and the following five City of Hollywood Commissioners – the Honorable Fran Russo; the Honorable Linda Sherwood; the Honorable Beam Furr; the Honorable Patricia Asseff and the Honorable Heidi O’Sheehan.

Mr. John Johnson, President and CEO, Holy Cross Hospital (one of the largest acute care hospitals in Broward County), offered his support, stating the applicant is in an excellent position to make the project a success and that his hospital has had a good referral relationship with Memorial Regional Hospital/Joe DiMaggio Children’s Hospital for many years. Mr. Johnson further stated the project would relieve families from having to travel to receive applicable care.

Two local area physicians wrote support letters – Jeffrey Skimming, MD, Pediatric and Adolescent Cardiologist with Pediatrix Medical Group (part of a national group practice of neonatal, maternal-fetal and pediatric subspecialists and locally a five-member physician group located
primarily in Broward but also Palm Beach County) states that in his three years in South Florida, he has worked with three patients that were in need of heart transplants. Dr. Skimming also stated great faith in existing pediatric heart physicians at Memorial Regional Hospital/Joe DiMaggio Children’s Hospital. Dr. Vicente Lemes, Pediatric Cardiologist, with Pediatric Heart Associates, PA. (a two-member physician group in the area) simply states that there is a need for this service in Broward and Palm Beach Counties.

Five parents of former or current patients in need of heart transplantation at Memorial Regional Hospital/Joe DiMaggio Children’s Hospital provide their support. These letters are highly complimentary of pediatric heart care for their children by Memorial Regional Hospital/Joe DiMaggio Children’s Hospital staff and cite the challenges and pitfalls of having to travel outside the Broward County area to receive applicable care. They generally state that pediatric heart transplantation at Memorial Regional Hospital/Joe DiMaggio Children’s Hospital would alleviate many of the challenges families face when their children are in need of heart transplantation.

C. PROJECT SUMMARY

South Broward Hospital District d/b/a Memorial Regional Hospital (CON #10044) proposes the establishment of a pediatric heart transplantation program in Organ Transplant Service Area 4. The applicant is also a provider of tertiary care services. The project is planned to be located within the applicant’s Memorial Regional Hospital/Joe DiMaggio Children’s Hospital. The applicant, South Broward Hospital District operates Memorial Regional Hospital, Memorial Regional Hospital South, Memorial Hospital West, Memorial Hospital Miramar, and Memorial Hospital Pembroke, all Class 1 acute care hospitals. Memorial Regional Hospital is licensed for 515 acute care beds, 22 Level II Neonatal Intensive Care Unit (NICU) beds, 19 Level III NICU beds, 45 adult and 10 child adolescent inpatient psychiatric beds, 11 adult substance abuse beds, 26 skilled nursing unit beds and 42 comprehensive medical rehabilitation (CMR) beds. The applicant advises six of the 42 CMR beds are pediatric beds. Memorial Regional is also a Level II adult cardiovascular services center, a primary stroke center, a Level I state-certified trauma center and the only provider of pediatric cardiac catheterizations and pediatric open heart surgery in Broward County. The applicant has no transplantation services at this time. According to the applicant, the proposed project, if approved, would complement the other pediatric programs already operational at Memorial Regional Hospital.
The pediatric heart transplant program, if approved, is to be operational within six months or less of final CON approval (year one ending April 30, 2010). Project costs total $147,025. These costs include equipment and project development costs. There are no construction or renovation costs associated with the project.

The applicant conditions CON approval to:

The specific site is 3501 Johnson Street, Hollywood, Florida 33021, and to accept and provide care to any and all pediatric heart transplant patients (ages 0-14) from Organ Transplant Service Area 4 (Monroe, Miami-Dade, Broward, Palm Beach and Collier Counties) regardless of their ability to pay. The applicant’s Schedule 7B specific to the project indicates that 23.7 percent of the year one and year two project days will be provided to Medicaid patients. Self-pay is shown as 40.9 percent for each year but charity care is not provided.

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(2) (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 application in its entirety with consultation from the financial analyst Derron Hillman, who evaluated the financial data.
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 pediatric heart transplant programs. Therefore, it is the applicant’s responsibility to demonstrate the need for the project, including a projection of the expected number of pediatric heart transplants that will be performed in the first years of operation.

There is presently one operational pediatric heart transplant program in Organ Transplant Service Area 4 at Jackson Memorial Hospital in Miami-Dade County. As noted at the beginning of this review, Organ Transplant Service Area 4 includes the following service areas: Districts 10 (Broward County), District 11 (Miami-Dade and Monroe Counties); Collier County only (in District 8) and Palm Beach County only (in District 9).

Data reported to the Agency for the most recent reporting period, July 1, 2007 through June 30, 2008 show the following pediatric heart transplant utilization data:

<table>
<thead>
<tr>
<th>Hospital</th>
<th>OTSA*</th>
<th>District</th>
<th>Total Procedures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Shands at the Univ. of FL</td>
<td>1</td>
<td>3</td>
<td>6</td>
</tr>
<tr>
<td>All Children’s Hospital</td>
<td>2</td>
<td>5</td>
<td>11</td>
</tr>
<tr>
<td>Jackson Memorial Hospital</td>
<td>4</td>
<td>11</td>
<td>8</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>25</strong></td>
<td><strong>25</strong></td>
<td><strong>25</strong></td>
</tr>
</tbody>
</table>


Note: *OTSA is Organ Transplant Service Area as defined in Rule 59C-1.044(2) (f) F.A.C.
Data reported to the Agency show that of the seven pediatric transplant services regulated by the Agency (liver, lung, heart, intestines, kidney, pancreas and bone marrow), heart transplantation was the fourth most frequently performed, for the period (25 procedures). Intestines transplantation (zero procedures) was the least performed and bone marrow transplantation (88 procedures) was the most performed, of the seven types of pediatric transplantation programs.

Pediatric heart transplantation is performed by only three facilities statewide (named in the table above), one of which is located in Transplant Service Area 4 (that being Jackson Memorial Hospital [Miami-Dade County]). The Agency received no opposition to this project. The greatest single population concentration in Transplant Service Area 4 is Miami-Dade County and the next most is Broward County. This is also true for the 0-14 age population in Transplant Service Area 4, the highest population concentration is in Miami-Dade County and the next most is Broward County. Palm Beach County is the third most populated in the service area, then Collier and Monroe Counties (the least populated with the lowest 0-14 age population being in Monroe County). The current sole pediatric heart transplantation provider in Transplant Service Area 4 (Jackson Memorial Hospital) is approximately 18.81 miles, primarily by interstate highway, to the applicant’s proposed pediatric heart transplantation site – Memorial Regional Hospital. All Children’s Hospital (St. Petersburg/Pinellas County) is the next nearest facility to the applicant at approximately 251.12 miles, again primarily by interstate highway. The most distant pediatric heart transplantation provider from the applicant’s proposed site is Shands Hospital at the University of Florida, approximately 321.77 miles distant.

For the 12-month period ended June 30, 2008, All Children’s Hospital performed 11 procedures (or 44.0 percent of all pediatric heart transplantations statewide), followed by Jackson Memorial Hospital, which performed eight procedures (or 32.0 percent of all pediatric heart transplantations statewide) and followed last by Shands Hospital at the University of Florida, which performed six procedures (or 24.0 percent of all pediatric heart transplantations statewide). Below is a five-year chart to account for pediatric heart transplants over the time period.

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1 All mileage per www.mapquest.com
Pediatric Heart Transplantation Procedures in Florida Hospitals
Fiscal Years Ending June 30

<table>
<thead>
<tr>
<th>Facility/Transplant Service Area (TSA)</th>
<th>2004</th>
<th>2005</th>
<th>2006</th>
<th>2007</th>
<th>2008</th>
<th>TOTAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Shands Hospital at UF (TSA 1)</td>
<td>7</td>
<td>8</td>
<td>10</td>
<td>7</td>
<td>6</td>
<td>38</td>
</tr>
<tr>
<td>All Children’s Hospital (TSA 2)</td>
<td>6</td>
<td>7</td>
<td>7</td>
<td>11</td>
<td>11</td>
<td>42</td>
</tr>
<tr>
<td>Jackson Memorial Hospital (TSA 4)</td>
<td>4</td>
<td>5</td>
<td>1</td>
<td>2</td>
<td>8</td>
<td>20</td>
</tr>
<tr>
<td>State Total</td>
<td>17</td>
<td>20</td>
<td>18</td>
<td>20</td>
<td>25</td>
<td>100</td>
</tr>
</tbody>
</table>


For the five years ending June 30, 2008, All Children’s Hospital maintained the highest volume of pediatric heart transplantations of the three facilities, followed by Shands at the University of Florida, with the lowest volume at Jackson Memorial Hospital. Again for the same period, statewide, pediatric heart transplantations trended upward each year except for the 12-month period ending June 2006, which showed a 10.0 percent decline (from June 2005 to June 2006). For each of the first four of these five years, Jackson Memorial Hospital provided the fewest pediatric heart transplantations, yet this service area has the highest 0-14 age range population.

It is noted that 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.

Organ Procurement and Transplantation Network (OPTN)
Current Florida Wait List Registrants
As of February 2, 2009

<table>
<thead>
<tr>
<th>Category</th>
<th>Pediatric Heart</th>
</tr>
</thead>
<tbody>
<tr>
<td>All Time</td>
<td>14</td>
</tr>
<tr>
<td>&lt; 30 Days</td>
<td>3</td>
</tr>
<tr>
<td>30 to &lt; 90 Days</td>
<td>2</td>
</tr>
<tr>
<td>90 Days to &lt; 6 Months</td>
<td>2</td>
</tr>
<tr>
<td>6 Months to &lt; 1 Year</td>
<td>4</td>
</tr>
<tr>
<td>1 Year to &lt; 2 Years</td>
<td>2</td>
</tr>
<tr>
<td>2 Years to &lt; 3 years</td>
<td>0</td>
</tr>
<tr>
<td>3 Years to &lt; 5 Years</td>
<td>0</td>
</tr>
<tr>
<td>5 or More Years</td>
<td>1</td>
</tr>
</tbody>
</table>

Source: [http://www.optn.org/latestData/rptData.asp](http://www.optn.org/latestData/rptData.asp)

*0-17 age range per the OPTN on-line database.
Florida Pediatric Heart Donors Recovered
January 1, 2003- December 31, 2008

<table>
<thead>
<tr>
<th>Calendar Year</th>
<th>2003</th>
<th>2004</th>
<th>2005</th>
<th>2006</th>
<th>2007</th>
<th>2008</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number</td>
<td>26</td>
<td>25</td>
<td>26</td>
<td>28</td>
<td>38</td>
<td>24</td>
</tr>
</tbody>
</table>

Source: http://www.optn.org/latestData/rptData.asp

The Agency’s Florida Center for Health Information and Policy Analysis hospital utilization data shows that a total of 22 pediatric heart transplants were performed in Florida during the 12 month period ended June 30, 2008. Donor/patient matches are also a factor in transplant services. However, it is noted that there were 24 Florida pediatric heart donors in 2008. As of February 2, 2009, there are 14 Florida patients are on the waiting list. This indicates there are currently about the same number of donors as patients being transplanted.

According to the data reported to the Agency (July 2007 through June 2008), 21 of 22 (or 95.45 percent) of pediatric heart transplants performed in Florida were performed for Florida residents. Organ Transplant Service Area 4 residents accounted for five of the 22 procedures, representing 22.73 percent of all DRG 103 (heart transplant or implant of heart assist system for the third quarter of 2007) and DRGs 001 and 002 (heart transplants or implant of heart assist system for the fourth quarter of 2007 and the first two quarters of 2008) procedures performed in Florida. Pediatric heart transplants for the 12-month period ending June 30, 2008 for Transplant Service Area 4 residents were performed as follows: Shands at the University of Florida in Transplant Service Area 1 (zero patients); All Children’s Hospital in Transplant Service Area 2 (one patient or 20.0 percent) and Jackson Memorial Hospital in Transplant Service Area 4 (four patients or 80.0 percent). Therefore, of this patient population (five Transplant Service Area 4 residents), approximately 20.0 percent (or about one of five patients) traveled an estimated 251 miles, one way, primarily by interstate highways, for the procedure (performed at All Children’s Hospital). This estimate is provided the patient resided in the vicinity of the applicant.

The applicant estimates 12 pediatric heart transplants in the second year of operation, ending April 30, 2011. Memorial Hospital bases its estimate on several factors: that there is a sufficient number of candidates in the planning area; the applicable transplant rate in Transplant Service Area 4 has consistently been lower than the state average and that the number of procedures performed in recent years has been approximately half that of the number of hearts procured (0-17 age range). As Transplant Service Area 4 residents accounted for five of the 22 pediatric heart transplantation procedures performed for the 12-
month period ending June 30, 2008, a second year pediatric heart transplantation count of 12 would seem ambitious, given total statewide demand by Transplant Service Area 4 residents for these procedures for the 12-month period ending June 30, 2008. In summary, for the period, 80.0 percent of Transplant Service Area 4 residents seeking and receiving pediatric heart transplantation services in Transplant Service Area 4, received services approximately 18.81 driving miles from the applicant’s proposed site. The applicant contends that geographic, financial and programmatic access barriers have lead to poorer quality outcomes and less demand than would have been realized and a lower Transplant Service Area 4 pediatric heart transplant count had the project been operational.

2. Applications for the establishment of new pediatric heart transplantation program shall not normally be approved in a service planning area unless the following additional criteria are met:

(a) **Staffing Requirements:** An applicant for a heart transplantation program shall have the following program personnel and services. (Rule 59C-1.044(6)(a), Florida Administrative Code).

(1) A board-certified or board eligible adult cardiologist; or in the case of a pediatric heart transplantation program, a board-certified or board-eligible pediatric cardiologist.

The applicant reports a comprehensive group of physicians on staff who are all board-certified and actively practice at the hospital in the full array of specialties and sub-specialties likely to be called upon to support the project. According to the applicant, the facility has 18 board-certified pediatric cardiologists with active medical staff privileges at Memorial Regional Hospital/ Joe DiMaggio Children’s Hospital and Memorial Healthcare System’s sister hospitals. These 18 physicians are stated to be board-certified in cardiology, pediatric cardiology, cardiovascular disease, and clinical cardiac electrophysiology. The applicant advises intentions of utilizing its current hospital staff physicians - Mark Boucek, MD; Kak-Chen Chan, MD and Lillian Valdes-Cruz, MD. These three physicians are stated to be board-certified cardiologists with extensive experience in pediatric heart transplant and will be directly involved with the proposed project.
(2) **An anesthesiologist experienced in both open heart surgery and heart transplantation.**

The applicant reports three pediatric cardiac anesthesiologists as part of the pediatric cardiac team. The applicant advises that Dr. Richard Berlin is Vice Chief of Anesthesia Services and had experience in pediatric heart transplants during his tenure at Cincinnati Children’s Hospital. Dr. Ed Saade is stated to have been on staff at Memorial Regional Hospital/Joe DiMaggio Children’s Hospital for more than a year, with expertise in pediatric cardiac medicine, including pediatric heart transplantation. Dr. Kristin Royal is stated to have recently joined Memorial Regional Hospital/Joe DiMaggio Children’s Hospital after completing a pediatric anesthesia fellowship at National Children’s Hospital in Washington, D.C. where she also gained experience in pediatric cardiac anesthesia. Per the applicant, all three physicians are board-certified by the American Board of Anesthesiology (Vol. 2, Attachment H-Memorial Regional Hospital/Joe DiMaggio Children’s Hospital Pediatric Physicians and Personnel Curriculum Vitae).

(3) **A one-bed isolation room in an age-appropriate intensive care unit.**

The applicant advises that Memorial Regional Hospital/Joe DiMaggio Children’s Hospital has a dedicated 22-bed pediatric intensive care unit, with 19 rooms being private rooms and three being semi-private. It is also stated that four of the private rooms are suitable for reverse isolation with the appropriate air flow system. The applicant further advises that all post transplant patients will be placed in a single patient room.
(b) **Need Determination:** An application for a certificate of need to establish a new heart transplantation program shall not normally be approved in a service area unless: (Rule 59C-1.004(6)(b), Florida Administrative Code).

(1) **Each existing heart transplantation provider in the applicable service area performed a minimum of 24 heart transplants in the most recent calendar year preceding the application deadline for new programs, and no other heart transplantation program has been approved for the same service planning area.**

The applicant advises this criterion is not met in Transplant Service Area 4 due to geographic, financial and programmatic access barriers to optimal utilization. The applicant further advises that residents in Transplant Service Area 4 do not have adequate access to pediatric heart transplant services and that the project, if approved, would remedy this issue.

As shown earlier in this report, Transplant Service Area 4’s only pediatric heart transplant provider, Jackson Memorial Hospital, has averaged four pediatric heart transplants for the five-year period ending June 30, 2008. Statewide, for the same period, the average has been 20 such procedures. It is also shown the in spite of its sizable population and 0-14 age range population in south Florida, Jackson Memorial Hospital has performed the fewest pediatric heart transplants of the three providers that are currently approved to offer such services.

(2) **The application contains documentation that a minimum of 12 heart transplants per year will be performed within two years of certificate of need approval. Such documentation shall include, at a minimum, the number of hearts procured by Florida hospitals during the most recent calendar year, and an estimate of the number of patients in the service planning area who would meet commonly-accepted criteria identifying potential heart transplant recipients.**

The application advises that Memorial Regional Hospital/Joe DiMaggio Children’s Hospital will satisfy the minimum volume requirements specified in Rule 59C- 1.044(6)(b)(2) by performing 12 pediatric heart transplants in its second year.
of operation. This is affirmed, in part, by the applicant’s attestation that there are sufficient numbers of transplant candidates in the planning area, and because the pediatric heart transplant rate in Transplant Service Area 4 has consistently been well below the transplant rate in Florida. The applicant advises that in 2007, 38 hearts were procured by Florida hospitals. The applicant also states that in 2007, 98 patients in the service area were candidates for heart transplantation. The applicant also advises that Transplant Service Area 4 has the largest pediatric population of any service area in the state.

(3) An application for a pediatric heart transplantation program shall include documentation that the annual duplicated cardiac catheterization patient caseload was at or exceeded 200 for the calendar year preceding the certificate of need application deadline; and that the duplicated cardiac open heart surgery caseload was at or exceeded 125 for the calendar year preceding the certificate of need application deadline.

The applicant is a provider of both pediatric heart catheterization (reporting 178 such procedures for the 12-month period ending June 30, 2008) and a provider of pediatric open heart surgery (reporting 212 such procedures for the same period). For calendar year 2007, Memorial Regional Hospital reported 159 pediatric cardiac catheterization procedures and 167 pediatric open heart surgery procedures. Therefore, while it exceeded the minimum number of required pediatric open heart surgeries, according to Agency records, it did not meet the minimum requirement for pediatric cardiac catheterizations.

2. Agency Rule Criteria

Chapter 59C-1.044, Florida Administrative Code, contains criteria and standards by which the department is to review the establishment of organ transplantation programs under the certificate of need program. Appropriate areas addressed by the rule and the applicant’s responses to these criteria are as follows:

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2 This is confirmed through the Organ Procurement Transplant Network (OPTN), http://www.optn.org/latestData/rptData.asp

3 Florida Need Projections for: Pediatric Cardiac Catheterization Programs and Pediatric Open Heart Surgery Programs, published October 3, 2008.
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 advises Memorial Regional Hospital/Joe DiMaggio Children’s Hospital has staff and resources necessary to care for children with end-stage heart disease. The applicant’s cardiac center is stated to have the existing capability to care for children with acute or chronic heart failure due to either congenital heart disease or dilated cardiomyopathy with end-stage heart failure prior to heart transplant, during the heart transplant process and in the early and late post-transplant period. Per the applicant, this is evidenced by 202 pediatric open heart surgeries in calendar year 2007, 216 diagnostic and interventional catheterizations and approximately 2,500 echocardiograms. The services and personnel required for this care are available 24 hours a day and provide for safe, patient and family centered care, in a unique child friendly environment, per the applicant. The applicant further advises it currently cares for applicable patients up to the point of the heart transplantation and then transports the patient to another center for the actual surgical component and early post-transplant care.

### 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 includes a memorandum of understanding (MOU) between South Broward Hospital District and the applicable organ procurement organization (OPO), Life Alliance Organ Recovery Organization [Vol. 2, Attachment D-4 Life Alliance Organ Recovery Agency (LAORA) Agreement]
Letter]. The MOU is signed by LAORA’s executive director in December 2008. Applicable heart procurement is stated to occur within organ allocation policies and procedures established by the United Network for Organ Sharing (UNOS). The applicant advises it will have a cardiac transplant team, complete with a transplant donor coordinator and a lead transplant coordinator. Applicable data gathering and consultation will occur within the time guidelines of UNOS. The applicant states its cardiac center has a well established 24/7 and 365 day per year call schedule, operational for the past several years and that the call schedule covers the following services: pediatric cardiac surgeon; pediatric CV OR team; perfusion; pediatric anesthesia; pediatric transplant cardiologist and pediatric sonographer. The applicant advises the call schedule will be expanded to include the on call transplant coordinator/donor coordinator, transplant surgeon and transplant cardiologist. It is also stated that there is in place a 24/7 ECMO (heart-lung bypass) call schedule if a patient needs support at that level either pre-operative or post transplant.

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

The applicant advises that Memorial Regional Hospital/Joe DiMaggio Children’s Hospital has a dedicated 22-bed pediatric intensive care unit (PICU) with 19 rooms being private rooms and three being semi-private. It is also stated that four of the private rooms are suitable for reverse isolation with the appropriate air flow system.

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

The applicant states that it will establish a Transplant Selection Committee which will meet weekly. The committee is to be organized under the program director, Mark Boucek, MD and Frank Scholl, MD (cardiac transplant surgeon) and will include a multidisciplinary team. Once a candidate is approved, he/she will be placed on the waiting list and registered with the local organ procurement organization. Depending on the results of the committee’s review and decision, a candidate may be accepted, rejected or tabled.
The transplant coordinator will document these decisions and families will be appropriately notified.

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.**

The applicant includes an applicable 95-page draft protocol (Vol. 2, Attachment F- Memorial Regional Hospital/Joe DiMaggio Children’s Hospital Pediatric Heart Transplant Protocol). The applicant advises these protocols are modeled after similar protocols developed and successfully utilized by Loma Linda Medical Center and Denver Children’s Hospital for pediatric heart transplantation and that they are consistent with those utilized by Drs. Boucek, Scholl and Perryman. These physicians’ experience and background in pediatric heart transplant or related areas is extensively described.

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.**

As previously stated, the applicant includes an applicable 95 page draft protocol (Vol. 2, Attachment F- Memorial Regional Hospital/Joe DiMaggio Children’s Hospital Pediatric Heart Transplant Protocol). These protocols include both acute and long-term management of each pediatric heart transplant patient, including the management of commonly encountered complications.

The applicant advises the therapeutic and evaluative procedures are consistent with those utilized by Drs. Boucek, Scholl and Perryman. These physicians’ experience and background in pediatric heart transplant or related areas is extensively described.
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.

The applicant includes a memorandum of understanding between South Broward Hospital District and the applicable organ procurement organization, Life Alliance Organ Recovery Organization [Vol. 2, Attachment D-Life Alliance Organ Recovery Agency (LAORA) Agreement Letter]. The MOU is signed by LAORA’s executive director in December 2008, but not signed by the South Broward Hospital District. A like previous agreement was signed by all parties in May 2006. As previously stated in this report, the applicant is a Level I state-certified trauma center\(^4\) and is familiar with and experienced in the process of cooling, flushing and transporting organs.

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.**

The applicant meets this requirement by providing a signed December 2008 letter of commitment in the provision of laboratory and blood product support (Vol. 2, Attachment J-Community Blood Centers of South Florida, Inc. Agreement). The applicant states the applicable laboratory meets the requirements of the American Society of Histocompatibility.

9. **Pathology services with the capability of studying and promptly reporting the patient’s response to the organ transplantation surgery, and analyzing appropriate biopsy material.**

The applicant advises that Memorial Regional Hospital/Joe DiMaggio Children’s Hospital laboratory operates 24 hours a day, seven days a week, has high-level pathology and laboratory capabilities and maintains responsibility for the state-certified Level 1 adult and pediatric trauma center, neonatal intensive care unit, open heart surgery unit, 

\(^4\) [http://www.doh.state.fl.us/DEMO/Trauma/MapofFloridaCertifiedTraumaCenters.pdf](http://www.doh.state.fl.us/DEMO/Trauma/MapofFloridaCertifiedTraumaCenters.pdf)
pediatric specialty center, breast cancer center and Memorial’s oncology center. The applicant reports the main laboratory, located on the fifth floor of the hospital, is under the direction of Sallie Anne Wright, Manager of Clinical Laboratories. The applicant reports four pathologists: Paul Malek, MD; Rita Reik, MD; FCAP; Lawrence Wong, MD and Frederick Kiechle, MD, PhD. The applicant includes extensive resumes of these physicians and other pathology department staff (Vol. 2, Attachment K-Memorial Regional Hospital/Joe DiMaggio Children’s Hospital Laboratory and Blood Bank Personnel Curriculum Vitae).

The applicant indicates that Memorial Regional Hospital/Joe DiMaggio Children’s Hospital laboratory has state licensure and is Joint Commission accredited (Vol. 2, Attachment P-Joint Commission Accreditation for Memorial Regional Hospital).

10. **Blood banking facilities.**

The applicant meets this requirement by providing a signed December 2008 letter of commitment in the provision of laboratory and blood component supply (Vol. 2, Attachment J-Community Blood Centers of South Florida, Inc. Agreement). The applicant states the applicable laboratory meets the requirements of the American Society of Histocompatibility and that it has had a relationship for these services since 2004.

The applicant also provides a six-page scope of service description (Vol. 2, Attachment L-Scope of Service for Memorial Regional Hospital/Joe DiMaggio Children’s Hospital Laboratory Transfusion Services).

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

Per the applicant, Chris Mashburn, RN, BSN, Director of Clinical Programs for the pediatric cardiac center and Eileen Watkins, RN, BSN, Cardiac Clinical Specialist, PICU, will be responsible for all education and training of staff regarding the special care of transplantation patients. Ms. Mashburn will be the lead transplant coordinator for the proposed pediatric heart transplant program at Memorial Regional Hospital/Joe DiMaggio Children’s Hospital.
The applicant also advises that upon project approval, comprehensive training will be provided to the staff on all aspects of heart transplant including: transplant evaluation, diagnosis suitable for transplant, psychosocial evaluation and support for the transplant patient and family, pre-transplant management strategies, anticipated wait list times by listing status and blood type, management of elevated PRA, surgical transplant procedure and organ procurement, post-op care of the transplant recipient, transplant medications (all aspects), immunology, infectious disease as it relates to the transplant patient, rejection (signs, symptoms, treatment, monitoring), long-term management and potential long-term complications.

It is further advised that education will be done collectively by the very experienced transplant team members: transplant cardiologist, transplant surgeon, transplant coordinator and by the cardiac clinical specialist in the PICU who has extensive transplant experience. Education will occur on an ongoing basis as well as built into the orientation curriculum for staff in the units mentioned above. Selected staff from the PICU will attend national conferences on heart transplant and transplant in general to gain further information regarding the field of transplant. It is also stated that the cardiac center team members, Julissa Jimenez, ARNP and Katie Smiley, PA will visit the pediatric transplant team at The Children’s Hospital, Aurora, CO to obtain in-depth, hands on experience on the management of transplant recipients.

The applicant advises that in 2007, there were over 238,892 hours of training and education provided to more than 11,661 employees at Memorial Health System. The applicant indicates that at Memorial Regional Hospital/Joe DiMaggio Children’s Hospital there were a total of 1,344 Memorial Academy Classes and 3,784 clinical classes with over 25,000 participants.

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

The applicant provides a pediatric heart transplant draft parent handbook (Vol. 2, Attachment M- Memorial Regional
Hospital/Joe DiMaggio Children’s Hospital Pediatric Heart Transplant Program Parent Manual). The manual has four primary categories: welcome/history/the team; evaluation/procedure/after transplant; medication/glossary/resources; appointments/contacts/journal and personal stories. The manual will be given to each patient/family at the time they are referred to the pediatric heart transplant team, per the applicant.

The applicant advises that once CON approved, heart transplant will be formally added to the scope of service and will be announced to community pediatricians, primary care physicians, pediatric cardiologists and staff 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.

The applicant reports a comprehensive group of physicians on staff who are all board-certified and actively practice at the hospital in the full array of specialties and sub-specialties likely to be called upon to support the project. According to the applicant, the facility has 18 board-certified pediatric cardiologists with active medical staff privileges at Memorial Regional Hospital/Joe DiMaggio Children’s Hospital and Memorial Healthcare System’s sister hospitals. These 18 physicians are stated to be board-certified in cardiology, pediatric cardiology, cardiovascular disease, and clinical cardiac electrophysiology.

The applicant advises the following three Memorial Regional Hospital/Joe DiMaggio Children’s Hospital transplant physicians will participate in the project: Dr. Kak-Chen
CON Action Number: 10044

Chan, Director, Inpatient Pediatric Cardiology Services; Dr. Lilliam Valdes-Cruz, Director, Non-Invasive Cardiology Services and Dr. Mark Boucek, Program Director. The applicant reports the following two Memorial Regional Hospital/Joe DiMaggio Children’s Hospital transplant surgeons: Dr. Frank Scholl and Dr. Richard Perryman. These two physicians are reported to be pediatric cardiovascular surgeons with extensive experience performing pediatric heart transplantation and are board certified in pediatric cardiac surgery and meet all requirements established by the United Network for Organ Sharing.

The applicant reports other relevant physicians that will be integral to the project (Vol. 1, page #81).

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.**

The pediatric heart transplant project program director will be Mark Boucek, MD., presently the Director of Pediatric Cardiovascular Services for Memorial Regional Hospital/Joe DiMaggio Children’s Hospital and internationally known for his work in pediatric transplant and interventional cardiology. The applicant also advises that Dr. Boucek has served as Assistant Professor of Pediatrics at the University of Utah College of Medicine, Director of Pediatric Cardiology and Pediatric Heart Transplant Program at The Children’s Hospital/University of Colorado School of Medicine, and Director of Pediatric Cardiology and Professor of Pediatric Cardiology at Loma Linda University School of Medicine. Dr. Boucek is reported to have managed more than 450 heart transplant patients (Loma Linda - 200 and Denver Children’s - 250 transplants), having performed extensive research in interventional cardiology and heart transplant.

3. **A staff with experience in the special needs of children if pediatric transplantations are performed.**

The applicant reports that Anna Jedlinska-Reyes, MSW, will provide ongoing support to the children and families who are referred for transplant and that she already serves a key role in Memorial Regional Hospital/Joe DiMaggio Children’s
Hospital’s cardiac center where she assists patients and their families with financial and insurance issues, helps connect to community agencies and provides emotional and anticipatory support. In addition, the applicant advises it employs a “humor therapist” (Lotsy Dotsy) and that this is part of the child life program.

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

The applicant reports three nurses or practitioners who will serve integrally in the project – Julissa Jimenez, ARNP, Elaine Watkins, BSN, RN and Kathryn Smiley, PA. Ms. Jimenez is the cardiac coordinator for cardiac service at Memorial Regional Hospital/Joe DiMaggio Children’s Hospital, Ms. Watkins is clinical manager of Memorial Regional Hospital/Joe DiMaggio Children’s Hospital’s PICU and co-ECMO coordinator and Ms. Smiley is a part of the PICU staff.

5. **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.**

The applicant includes a signed December 2008 letter of commitment in the provision of laboratory and blood product support (Vol. 2, Attachment J-Community Blood Centers of South Florida, Inc. Agreement). The applicant states the applicable laboratory meets the requirements of the American Society of Histocompatibility.

The applicant reports the existing hospital’s transfusion services laboratory is located on the second floor, adjacent to surgical services and anatomic pathology. The applicant further advises that Paul Malek, MD is the laboratory medical director and serves with associate Rita Reik, MD. The applicant also indicates that the transfusion service provides all routine and stat immunohematology testing, including blood type and screen, crossmatch, antibody identification and transfusion reaction workup.
6. **Nutritionists with expertise in the nutritional needs of transplant patients.**

The applicant advises of a wide variety of clinical dietitians with experience and expertise in the nutritional needs of transplant patients and those in need of cardiac care. This includes pediatric clinical dietitians that specialize in nutritional support of parenteral and enteral nutrition (tube feedings). The applicant further advises this pertains directly to the nutritional status of pre-transplant patients, food and drug interactions of immunosuppressants, hypertension issues, gastrointestinal disturbances, electrolyte imbalance, fluid balance and healing promotion. Karen Rubin, MS, RD, LD is specifically referenced (Vol. 2, Attachment O-Nutrition, Respiratory Therapy and Social Work Curriculum Vitae).

7. **Respiratory therapists with expertise in the needs of transplant patients.**

The applicant advises it currently employs 50 respiratory therapists, with 22 of them having training in critically ill PICU patients. The applicant states that Lucille Fasone, MPH, RRT is the manager of the Memorial Regional Hospital/Joe DiMaggio Children’s Hospital Respiratory Department (Vol. 2, Attachment O- Nutrition, Respiratory Therapy and Social Work Curriculum Vitae), reporting that she has 23 years of respiratory care experience at Jackson Memorial Hospital where her respiratory team managed the ventilatory support for cardiac, multi-visceral and transplant patients. Ms. De’Ann Laufenberg, RRT is also stated to have 23 years of experience. Other respiratory therapists on staff at Memorial Regional Hospital/Joe DiMaggio Children’s Hospital are stated to have experience with post-operative pediatric heart transplant patients.

8. **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.**
The applicant identifies Anna J. Jedlinska-Reyes, MSW, as the social worker for the Memorial Regional Hospital/Joe DiMaggio Children’s Hospital Pediatric Heart Transplant team (Ms. Jedlinska-Reyes Curriculum Vitae is included in Volume 2, Attachment O of the application). Ms. Jedlinska-Reyes has worked at Memorial Regional Hospital/Joe DiMaggio Children’s Hospital more than seven years, with the last three years dedicated directly to working with pediatric patients and families with cardiac issues. Stated responsibilities include arranging all discharges, including home health, medications and follow-up care coordination, clinical assessment and referral as needed, arranging for educational and support groups for patients and their families and working with patients, families, community resources and insurance companies to ensure that client needs are met in a complete and timely manner. As social worker for the transplant team, her responsibilities will include all the above and in addition, she will assist with timely financial referrals for Medicaid and coordination of services (transplant) through patients’ insurance, per the applicant. The applicant further states that when a formal psychiatric/psychology evaluation is necessary as part of the pre-transplant evaluation or if psychiatric/psychology services are needed for the patient or family at anytime during the transplant process, they will be referred to a pediatric psychiatrist or psychologist on staff at Memorial Regional Hospital/Joe DiMaggio Children’s Hospital.

c. **Data Reporting Requirements.** Facilities with organ transplantation programs shall submit data regarding each transplantation program to the agency or its designee twice a year. The first submission shall be by August 1 of each year, and shall cover the period between January 1 through June 30 of the same calendar year. The second submission shall be by February 1 of each year, and shall cover the period between July 1 through December 31 of the preceding year. The following data shall be provided for each type of organ transplanted. Chapter 59C-1.004(5), Florida Administrative Code.

1. The number of patients by county origin and zip code
2. The average gross revenue per admission.
3. The average length of stay.
4. Mortality rates
The applicant indicates that as an existing provider of hospital services in Florida, Memorial Regional Hospital/Joe DiMaggio Children’s Hospital will incorporate applicable data reporting into existing data management and reporting capabilities without difficulty. The applicant indicates it will report registry data to UNOS and the Organ Procurement and Transplant Network. The applicant indicates intentions to select, purchase and install an array of applicable software applications to support the project and to this end, if CON approved, the applicant advises it will finalize negotiations for the purchase of a customized pediatric heart transplant/heart failure database. The applicant states that the Program Director, Dr. Mark Boucek and Chris Mashburn played key roles in the development of this database system while at The Children’s Hospital of Denver.

3. Statutory Review Criteria

a. Is need for the project evidenced by the availability, quality of care, efficiency, 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.

Access

There is currently one pediatric heart transplant service provider in Organ Transplant Service Area 4 which is comprised of the following five counties: Broward; Collier; Miami-Dade; Monroe and Palm Beach. The three existing Florida pediatric heart transplant providers are located as follows: Transplant Service Area 1 (Shands at the University of Florida); Transplant Service Area 2 (All Children’s Hospital), and Transplant Service Area 4 (Jackson Memorial Hospital).
According to the data reported to the Agency (July 2007 through June 2008), 21 of 22 (or 95.45 percent) of pediatric heart transplants performed in Florida were performed for Florida residents. Organ Transplant Service Area 4 residents accounted for five of the 22 procedures, representing 22.73 percent of all procedures performed in Florida.

**Pediatric Heart Transplants by Patient Residence**  
**Year Ended June 30, 2008**

<table>
<thead>
<tr>
<th>Service Area</th>
<th>Transplants Performed</th>
<th>Percent of Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
<td>9.09%</td>
</tr>
<tr>
<td>2</td>
<td>9</td>
<td>40.91%</td>
</tr>
<tr>
<td>3</td>
<td>5</td>
<td>22.73%</td>
</tr>
<tr>
<td>4</td>
<td>5</td>
<td>22.73%</td>
</tr>
<tr>
<td>Out-of-State</td>
<td>1</td>
<td>4.54%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>22</strong></td>
<td><strong>100.00%</strong></td>
</tr>
</tbody>
</table>

Source: Florida Center for Health Information and Policy Analysis database, DRG 103, 001 and 002 (Heart Transplant or Implant of Heart Assist System) for applicable time frames July 2007-June 2008.

Memorial Regional Hospital/Joe DiMaggio Children’s Hospital is estimating 12 pediatric heart transplantation procedures in year two of the project (ending April 30, 2011). This is a relatively ambitious estimate, considering that for the 12-month period ending June 30, 2008, a total of five such procedures were performed for Transplant
Service Area 4 residents. However, it is noted that the Agency received no opposition to this project from the current sole Transplant Service Area 4 pediatric heart transplantation provider - Jackson Memorial Hospital.

Though the applicant advises that the complications and disruption brought on by distant travel to receive these procedures, it is noted that for the 12-month period ending June 30, 2008, four of a total of five Transplant Service Area 4 residents that received pediatric heart transplantation received them at Jackson Memorial Hospital, which is 18.81 driving miles from the proposed project site and is within Transplant Service Area 4.

Need
The applicant contends that poorer quality outcomes and lower volume for pediatric heart transplant in Transplant Service Area 4 is attributable to the following three alleged barrier to access issues – geographic, financial and programmatic. The applicant notes that Jackson Memorial Hospital has low transplant volumes (as shown in section E.1.a. of this report, for the five-year period ending June 30, 2008, Jackson Memorial Hospital had the fewest pediatric heart transplants [an aggregate of 20 procedures] compared to Shands at the University of Florida [38 procedures] and All Children’s Hospital [42 procedures]). Below is a description of the applicant’s need explanation.

The applicant indicates that 304 children were discharged from Florida hospitals in 2007, with 98 of the 304 discharged from Transplant Service Area 4 alone, with what the applicant identifies as a primary diagnosis associated with the need for a heart transplant. The applicant goes on to advise that a disproportionately low number of residents with an applicable diagnosis went on to receive a pediatric heart transplant. The applicant states that Transplant Service Area 4 had the highest number of children of any service area with an applicable pediatric heart transplant diagnosis in both 2007 and 2005 and that this is consistent with Transplant Service Area 4 having the highest 0-14 resident population in the state (2005-2007). The applicant also points to a generally upward trend in pediatric heart transplants statewide and that continued 0-14 resident age population growth will keep up demand.

The applicant advises that Transplant Service Area 4 residents 0-14 resident age population totaled 1,136,156 in 2007. The applicant then calculates a pediatric heart transplant rate (expressed as the number of pediatric heart transplants per million population) by age cohort by organ transplant service area. Transplant Service Area 4 has the lowest such rate, at 2.6 per million, compared to 2.7 per million in Transplant
Service Area 1, 5.7 per million in Transplant Service Area 3 and 10.5 per million in Transplant Service Area 2. The applicant also reports a 5.5 per million rate for the statewide population age 0-14.

In summary, the applicant justifies that the 0-14 resident age population in Transplant Service Area 4 is higher than any other service area in the state with the most children (0-14) with a discharge diagnosis consistent with pediatric heart transplant candidacy and yet Transplant Service Area 4 has the lowest per million rate of pediatric heart transplants performed.

The applicant presents 14 reported case histories, stated to be from September 2006 to the time of application submittal. These 14 patients are reported to be Memorial Regional Hospital patients who were in need of pediatric heart transplantation services (the nearest being at Jackson Memorial Hospital in Miami-Dade County) but experiencing challenges due to a lack of pediatric heart transplant opportunity at Memorial Regional Hospital, under the current arrangement. A brief review of these indicates access barriers were of a geographic, financial or programmatic nature. One case history (Patient #3) is of a patient over 14 years of age (16 years of age) so beyond the applicable 0-14 age range and another (Patient #9) begins in 1996, so not timely as stated by the applicant (from September 2006 to the time of the application submittal). These cases generally report access barriers at Jackson Memorial Hospital’s pediatric heart transplant program.

The applicant indicates that it is reasonable to expect that all applicable transplants needed by residents of Transplant Service Area 4 should be transplanted within the service area, either at the applicant’s proposed site or at Jackson Memorial Hospital. The applicant also identifies where all applicable transplants were performed for the first six months of 2008, by transplant service area, facility and four different age brackets from 0-14 years of age. This table indicates that Jackson Memorial Hospital performed just two such procedures for the six-month period. In the next table, the applicant extrapolates a 12-month estimate by doubling the reported procedures for the six months ending June 30, 2008. Based on this extrapolation, the applicant estimates 33 applicable transplants for calendar year 2010, as follows: six from Transplant Service Area 1; 10 from Transplant Service Area 2 and five from Transplant Service Area 3 and 12 from Transplant Service Area 4.²

² This could be reasonable considering that this is only slightly greater than the two year increase in the number of transplants between 2006 and 2008 from 11 to 22 transplants while Jackson’s program has averaged only four procedures over that last five year reporting periods.
The applicant’s Table 8, shows it has the lowest pediatric heart transplant rate (2.6 per million resident population) with the highest pediatric population of any transplant service area, so the applicant uses extrapolated data to show a 3.5 per million resident population for CY 2008. This calculation shifts the estimated pediatric heart transplant rate (expressed as the number of pediatric heart transplants per million population) by age cohort by transplant service area such that the new rate for Transplant Service Area 4 becomes 3.5 and Transplant Service Area 1 becomes 2.6, Transplant Service Area 2 becomes 9.3 and Transplant Service Area 3 becomes 11.4. The statewide average rate becomes 6.4. Per the applicant, Transplant Service Area 4 has the lowest such rate, at 2.6 per million, compared to 2.7 per million in Transplant Service Area 1, 5.7 per million in Transplant Service Area 3 and 10.5 per million in Transplant Service Area 2.

The applicant continues to estimate further applicable rates such that by 2011, the applicant projects an Transplant Service Area 4 rate of 11.2, expecting the increase due to eliminating the geographic, financial and programmatic barriers stated by the applicant earlier. In this table, the applicant expects a statewide applicable procedures per million residents of 9.9. By calendar year 2011, the applicant estimates 35 applicable procedures statewide, with Transplant Service Area 4 having the largest number of them (13), followed by Transplant Service Area 2 (10), Transplant Service Areas 1 and 3 (six each). The applicant expects that none of the existing applicable programs will experience a measurable decline in transplant activity as a consequence of the proposed project. In its last need analysis table, the applicant estimates six applicable procedures in year one and 12 in year two (ending April 30, 2011).

**Quality of Care**

The applicant provides no transplantation services, neither adult nor pediatric, and is seeking approval for a first-time pediatric transplantation service – pediatric heart transplantation. As a non-provider of any transplantation services at this time, the applicant has no direct history of on-site transplants but would be augmenting and enhancing existing pediatric cardiovascular services and reports staff experienced with and trained in pediatric heart transplantation and related pediatric services.

Need for the project is evidenced by the availability, quality of care, efficiency, accessibility and extent of utilization of existing health care facilities and health services in the applicants’ service area.
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.

The applicant states receipt of numerous accreditations and awards, such as the Foster G. McGaw Award (stated to be for innovative programs that significantly improve the health and well being of a community), the Sapphire Award: Recognizing Community Health Excellence from the Blue Foundation (affiliate of Blue Cross and Blue Shield of Florida). The applicant also reports accreditation by the Joint Commission (Vol. 2, Attachment P-Joint Commission Accreditation for Memorial Regional Hospital).

Memorial Regional Hospital/Joe DiMaggio Children’s Hospital also states numerous other awards recognizing its high quality of care. These awards or recognitions trace from the present back to 2000. Some examples are as follows:

**Memorial Regional Hospital:**

- 100 Top Hospitals®: Cardiovascular Benchmarks for Success, Thomson Reuters, 2008.
- Consumer Choice Award — Most Preferred Hospital for Overall Quality, Image, Doctors & Nurses.
- Best Run Hospital, *Florida Medical Business*, 2002.

**Joe DiMaggio Children’s Hospital:**

- Best Nursing Team - Pediatric Emergency Department, *ADVANCE for Nurses*, 2008.
Other characteristics reported by the applicant regarding the Joe DiMaggio Children’s Hospital include the following:

- One of seven hospitals in the state and the only one in Broward and Palm Beach counties to be granted membership in the National Association of Children’s Hospitals and Related Institutions, a non-profit association concerned with children’s needs and the institutions that provide care.

- One of 11 facilities in the State of Florida to be designated as a Regional Perinatal Intensive Care Center by the Florida Department of Health Children’s Medical Services.

- Designated as a Department of Health/Children’s Medical Services provider in hematology/oncology, cardiac care and craniofacial program and dialysis center (The Comprehensive Children’s Kidney Failure Center).

In addition to the above recognitions, the applicant reports that regarding quality of care and patient satisfaction, South Broward Hospital District is the third-ranked health care system in the United States, and first in Florida. It is also stated to be the fifth-largest public health care system in the country, recognized as a safety-net provider and particularly strives to reach the medical needs of the poor, underinsured and uninsured.

Memorial Regional Hospital is a Level I state-certified trauma center and it is also a primary stroke center.

The applicant advises that upon project approval and after the appropriate waiting period, Memorial Regional Hospital/Joe DiMaggio Children’s Hospital will submit application to the Centers for Medicare
and Medicaid Services conditions for participation regarding the pediatric heart transplant program. However, this is not conditioned in Schedule C, by the applicant.

Agency complaint data indicates that the applicant experienced four confirmed complaints and no confirmed without deficiency complaints for the three year period ending February 2, 2009. The applicant’s complaint history is itemized below.

South Broward Hospital District
d/b/a Memorial Regional Hospital (CON #10044)
February 2, 2006 through February 2, 2009

<table>
<thead>
<tr>
<th>Complaint Category</th>
<th>Memorial Regional Hospital</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Confirmed Total = 4</td>
</tr>
<tr>
<td>Emergency Access</td>
<td>2</td>
</tr>
<tr>
<td>Medicine Problem/Error/Formulary</td>
<td>1</td>
</tr>
<tr>
<td>Nursing Service</td>
<td>1</td>
</tr>
</tbody>
</table>

Source: Agency for Health Care Administration Complaint Review Records

The applicant demonstrates the ability to provide quality care.

c. What resources, including health manpower, 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 $147,025 and year two incremental operating costs of $2,884,000.

The audited financial statements of the applicant, for the periods ending April 30, 2007 and 2008 were analyzed for the purpose of evaluating the applicant’s ability to provide the capital and operational funding necessary to implement the project.

**Short-Term Position:**
The applicant’s current ratio of 3.9 is well above average and indicates current assets are almost four times current liabilities, a strong position. The ratio of cash flows to current liabilities of 0.4 is below average and a slightly weak position. The working capital (current assets less current liabilities) of $586.5 million is a measure of excess liquidity that could be used to fund capital projects. Overall, the applicant has a good short-term position. (See Table below).
**Long-Term Position:**
The ratio of long-term debt to net assets of 0.6 indicates long-term debt is less than equity. This is consistent with the Florida acute care hospital average and an adequate position. The ratio of cash flow to assets of 4.6 percent is well below average and a weak position. The most recent year had revenue in excess of expenses of $90.6 million, which includes $45.0 million in ad-valorem tax revenue and $50.6 million investment income and resulted in a margin of 7.5 percent. Overall, the applicant has an adequate long-term position. (See Table below).

**Capital Requirements:**
Schedule 2 indicates the applicant currently has $311.4 million in total capital projects.

**Available Capital:**
The applicant indicates that funding for this project and the entire capital budget will come from a combination of cash, cash equivalents, and investments. Operating cash flows for the most recent year was $74.5 million. As discussed above working capital is $586.5 million. In addition, of the $151.3 million of assets limited as to use (see Table below), $83.4 million is designated as capital improvement funds.

**Staffing:**
Currently, the applicant does not provide any transplant services and approval would result in a new product line. However, ORHS facilities have staff on-hand with expertise and experience regarding pediatric heart transplantation and related cardiovascular skill and know-how. According to Schedule 6A, the applicant predicts an incremental 2.0 FTEs (administrative support) for this project for year one (ending April 30, 2010) and 3.0 FTEs (administrative support) for year two (ending April 30, 2011).
### CON #10044

#### Memorial Regional Hospital

<table>
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<tr>
<th></th>
<th>4/30/08</th>
<th>4/30/07</th>
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<tbody>
<tr>
<td>Current Assets</td>
<td>$791,953,000</td>
<td>$744,506,000</td>
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<tr>
<td>Cash and Current Investment</td>
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<td>Assets limited to use</td>
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<td>Total Assets</td>
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<tr>
<td>Current Liabilities</td>
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<td>Total Liabilities</td>
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<tr>
<td>Net Assets</td>
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<td>Total Revenues</td>
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<td>Interest Expense</td>
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<td>Excess of Revenues Over Expenses</td>
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<td>$130,427,000</td>
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<tr>
<td>Cash Flow from Operations</td>
<td>$74,532,000</td>
<td>$137,311,000</td>
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<tr>
<td>Working Capital</td>
<td>$586,454,000</td>
<td>$545,066,000</td>
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</tbody>
</table>

#### FINANCIAL RATIOS

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<th>4/30/08</th>
<th>4/30/07</th>
</tr>
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<tbody>
<tr>
<td>Current Ratio (CA/CL)</td>
<td>3.9</td>
<td>3.7</td>
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<tr>
<td>Cash Flow to Current Liabilities (CFO/CL)</td>
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<td>0.7</td>
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<tr>
<td>Long-Term Debt to Net Assets (TL-CL/NA)</td>
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<td>0.7</td>
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<tr>
<td>Times Interest Earned (NPO+Int/Int)</td>
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<td>7.6</td>
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<td>Net Assets to Total Assets (TE/TA)</td>
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<td>52.0%</td>
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<tr>
<td>Operating Margin (ER/TR)</td>
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<td>11.5%</td>
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<tr>
<td>Return on Assets (ER/TA)</td>
<td>5.6%</td>
<td>8.5%</td>
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<tr>
<td>Operating Cash Flow to Assets (CFO/TA)</td>
<td>4.6%</td>
<td>9.0%</td>
</tr>
</tbody>
</table>

### Conclusion:

The applicant appears to have the financial resources necessary to fund this project and all capital projects listed on Schedule 2.

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 management skills 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.

Comparative data were derived from hospitals in peer groups that reported data in 2007; the applicant will be compared to the hospitals in Peer Group 7 (Large Urban Hospital Group). The Agency also evaluated the projected cost of the pediatric heart transplant program on a stand alone basis. Comparative data for the heart transplant program on a stand alone basis were derived from hospitals with approved and operational heart transplant programs in 2007. Peer Group 7 has a total of 19 facilities including the applicant. Per diem rates are projected to increase by an average of 3.6 percent per year. Inflation adjustments were based on the new CMS Market Basket, 3rd Quarter, 2008.

Gross revenues, net revenues, and costs were obtained from Schedules 7 and 8 in the financial portion of the application. These were compared to the control group as a calculated amount per adjusted patient day.

Projected net revenue per adjusted patient day (NRAPD) of $1,982 in year one and $2,048 in year two is between the control group median and highest values of $1,925 and $2,897 in year one, and $1,979 and $2,978 in year two. With net revenues per adjusted patient day falling between the median and highest values, the facility is expected to consume health care resources in proportion to the services provided. (See Table below). The applicant’s NRAPD in fiscal year 2007 was reported as $1,732. The difference in the NRAPD reported in 2007 and the year two projected NRAPD of $2,048 results in an average compound annual increase of approximately 4.3 percent. This level of increase is greater than the inflation percentage outlined in the CMS Market Basket, 3rd Quarter, 2008, index. Net revenues appear to be slightly overstated.

Projected cost per adjusted patient day (CAPD) of $1,975 in year one and $2,040 in year two is between the control group median and highest values of $1,874 and $2,725 in year one, and $1,926 and $2,801 in year two. With CAPD approaching the median in the peer group, costs are balanced between efficiency and feasibility. (See Table 2 immediately below). The applicant’s CAPD in year 2007 was reported as $1,802. The difference in the CAPD reported in 2007 and the year two projected CAPD of $2,040 results in an average compound annual increase of
approximately 3.3 percent. This level of increase is slightly below the inflation percentage outlined in the CMS Market Basket 3rd Quarter, 2008 index. CAPD appear to be reasonable.

The projections for the transplant program include only the incremental cost of the program. Therefore, the Agency added $1,100 in cost per patient day (CPD) to fully allocate overhead and property to this project. The year two projected fully allocated CPD for the heart transplant patients is $5,105. The fully allocated CPD falls between the control group median and highest values of $4,798 and $6,680. The projected cost appears to be reasonable when compared to the group. It should be noted that the control group included all approved heart transplant programs (adult and pediatric). According to Agency records, in 2007, only 19 pediatric heart transplants were performed in Florida.

The year two operating profit for the hospital of $2.7 million computes to an operating margin per adjusted patient day of $8 which is above the applicant’s 2007 operating margin of negative $70. It should be noted that the applicant receives a substantial amount of funds from the local taxing district that is considered non-operating revenue. The applicant’s total margin, including non-operational revenue, is projected as $17.5 million or $53 per adjusted patient day. This is below the applicant’s 2007 total margin per adjusted patient day of $137. Although the operating margin appears overstated, the total margin appears conservative compared to the 2007 margin and therefore is reasonable. This project is immaterial to the overall operations of the applicant and will not likely have a material financial impact on the applicant’s existing operations.

**Conclusion:**

This project appears to be financially feasible as part of the overall hospital operations and is not likely to have a material impact on the existing operations of the applicant.
# South Broward Hospital District d/b/a Memorial Regional Hospital

## CON #10044

### 2007 DATA  Peer Group 7

<table>
<thead>
<tr>
<th>Activity</th>
<th>Year 2 Activity</th>
<th>Year 2 Per Day</th>
<th>Highest</th>
<th>Median</th>
<th>Lowest</th>
</tr>
</thead>
<tbody>
<tr>
<td>Routine Services</td>
<td>2,000,875,000</td>
<td>6,051</td>
<td>1,631</td>
<td>937</td>
<td>535</td>
</tr>
<tr>
<td>Inpatient Ambulatory</td>
<td>0</td>
<td>0</td>
<td>338</td>
<td>152</td>
<td>16</td>
</tr>
<tr>
<td>Inpatient Surgery</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Inpatient Ancillary Services (N)</td>
<td>0</td>
<td>0</td>
<td>6,991</td>
<td>4,287</td>
<td>2,632</td>
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<tr>
<td>Outpatient Services (O)</td>
<td>1,190,992,000</td>
<td>3,602</td>
<td>3,549</td>
<td>2,348</td>
<td>1,431</td>
</tr>
<tr>
<td>Total Patient Services Rev. (P)</td>
<td>3,191,867,000</td>
<td>9,652</td>
<td>10,559</td>
<td>7,514</td>
<td>5,906</td>
</tr>
<tr>
<td>Other Operating Revenue</td>
<td>27,824,000</td>
<td>84</td>
<td>156</td>
<td>31</td>
<td>3</td>
</tr>
<tr>
<td><strong>Total Revenue</strong></td>
<td>3,219,691,000</td>
<td>9,737</td>
<td>10,570</td>
<td>7,543</td>
<td>5,958</td>
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<tr>
<td>Deductions From Revenue</td>
<td>2,542,577,000</td>
<td>7,689</td>
<td>0</td>
<td>0</td>
<td>0</td>
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<tr>
<td><strong>Net Revenues</strong></td>
<td>677,114,000</td>
<td>2,048</td>
<td>2,978</td>
<td>1,979</td>
<td>1,605</td>
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</table>

## Expenses

<table>
<thead>
<tr>
<th>Expense</th>
<th>Cost</th>
<th>Year 2 Activity</th>
<th>Year 2 Per Day</th>
<th>Highest</th>
<th>Median</th>
<th>Lowest</th>
</tr>
</thead>
<tbody>
<tr>
<td>Routine</td>
<td>185,018,000</td>
<td>560</td>
<td>442</td>
<td>351</td>
<td>238</td>
<td></td>
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<tr>
<td>Ancillary</td>
<td>246,644,000</td>
<td>746</td>
<td>998</td>
<td>698</td>
<td>561</td>
<td></td>
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<tr>
<td>Ambulatory</td>
<td>6,633,000</td>
<td>20</td>
<td>0</td>
<td>0</td>
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<tr>
<td>Total Patient Care Cost</td>
<td>438,295,000</td>
<td>1,325</td>
<td>0</td>
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</tr>
<tr>
<td>Admin. and Overhead</td>
<td>189,580,000</td>
<td>573</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td></td>
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<tr>
<td>Property</td>
<td>34,831,000</td>
<td>105</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Total Overhead Expense (T)</td>
<td>224,411,000</td>
<td>679</td>
<td>1,332</td>
<td>801</td>
<td>692</td>
<td></td>
</tr>
<tr>
<td>Other Operating Expense</td>
<td>11,744,000</td>
<td>36</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td><strong>Total Expenses</strong></td>
<td>674,450,000</td>
<td>2,040</td>
<td>2,801</td>
<td>1,926</td>
<td>1,718</td>
<td></td>
</tr>
</tbody>
</table>

**Operating Income** 2,664,000 8 225 -20 -218

### Patient Days

- Total 205,502
- Adjusted 330,682

### Total Bed Days Available

- 260,245

### Percent Occupancy

- 78.96%

### Patient Type

<table>
<thead>
<tr>
<th>Payer Type</th>
<th>Days</th>
<th>% Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Self Pay</td>
<td>31,182</td>
<td>15.2%</td>
</tr>
<tr>
<td>Medicaid (AY)</td>
<td>27,651</td>
<td>13.5%</td>
</tr>
<tr>
<td>Medicare HMO</td>
<td>0</td>
<td>0.0%</td>
</tr>
<tr>
<td>Medicare (AU)</td>
<td>51,530</td>
<td>25.1%</td>
</tr>
<tr>
<td>Medicaid HMO</td>
<td>0</td>
<td>0.0%</td>
</tr>
<tr>
<td>Insurance</td>
<td>0</td>
<td>0.0%</td>
</tr>
<tr>
<td>HMO/PPO (BD)</td>
<td>94,268</td>
<td>45.9%</td>
</tr>
<tr>
<td>Other</td>
<td>871</td>
<td>0.4%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>205,502</td>
<td>100%</td>
</tr>
</tbody>
</table>
e. **Will the proposed project foster competition to promote quality and cost-effectiveness? ss. 408.035(1)(g), Florida Statutes.**

Competition to promote quality and cost-effectiveness is driven primarily by the best combination of high quality and fair price. Competition forces health care facilities to increase quality and reduce charges/cost in order to remain viable in the market.

Organ transplant programs are unique to most other hospital procedures in that the demand for organ transplants exceeds the supply in available organs as demonstrated by the wait list. A transplant program would need to maintain a minimum level of procedures to remain proficient and ensure quality of outcomes.

Since not all patients will receive a needed organ on a timely basis, a hospital would need to attract a sufficient number of patients to its wait list in order to ensure a minimum number of procedures. This need to attract patients provides the potential for increased quality through increasing access, establishing programs to assist patients before, during, and after the transplant procedure, and maintaining a high one and two-year survival rate relative to other transplant providers.

Cost-effectiveness (as a result of competition) for organ transplant programs is limited on two fronts. First, from the payment perspective, the impact of competition on the price of services is limited to the payer type. Most consumers do not pay directly for hospital services rather they are covered by a third-party payer. The impact of price competition would be limited to third-party payers that negotiate price for services, namely managed care organizations. Therefore, price competition is limited to the share of patient days that are under managed care plans. In 2007, 48.4 percent of the heart transplant recipients were under managed care plans. From the facility’s perspective, incentive for cost-effectiveness is driven by the reimbursement rate. Currently, the fixed price payers’ (the majority payer) reimbursement does not cover the cost of providing the service. The difference is material and ensures that only large facilities with sufficient resources and economies of scale are able to absorb the losses generated by a transplant program over the long-term. Therefore, from the facility perspective, although cost-effectiveness may be impacted by this project, it is more likely to be driven by the facility’s need to reduce the gap between cost of service and the reimbursement rates rather than by competition.
Conclusion:
Although this project may improve quality and cost-effectiveness, these improvements will primarily be driven by the existing regulatory environment and payment structure rather than competition.

f. Are the proposed costs and methods of construction reasonable? Do they comply with statutory and rule requirements? ss. 408.035(1)(h), Florida Statues and Ch. 59A-3 or 59A-4, Florida Administrative Code.

The applicant proposes no construction or renovation costs.

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

The applicant is a Medicaid and disproportionate share facility and is also the safety-net provider for charity care patients in Broward County, serving all patients regardless of ability to pay. South Broward Hospital District operates primary care centers for indigent patients throughout Broward County. The applicant reports that for its fiscal year ending April 30, 2008, the South Broward Hospital District and Memorial Regional Hospital generated 37,341 discharges, with 4,679 of those discharges (or 12.5 percent) being Medicaid and 6,513 discharges (or 17.4 percent) being self-pay/charity. For the past five fiscal years (ending April 30, 2008) South Broward Hospital District states that in 2008 it experienced its highest percent of charity care, at 7.5 percent of gross revenue. South Broward Hospital District also indicates, for the same period, its highest uncompensated care percentages was in 2008 at 13.7 percent and its Medicaid percentage was highest in 2006, at 12.7 percent (with 9.9 percent in 2008).

Strictly from the pediatric heart transplantation proposal, projected revenues on the applicant’s Schedule 7B indicate that operating year one would provide a payer mix of 40.9 percent self-pay and 23.7 percent combined Medicaid and Medicaid HMO (Medicaid HMO at 0.0 percent). “Other managed care” is stated at 35.4 percent for year one and 0.0 percent is “other payers”. A total of 100 percent is reached when self-pay, Medicaid, Medicaid HMO, other managed care and other payers are combined. These percentages remain the same into and through year two of operations. Charity care specific to the project is not provided.

As previously stated, this applicant conditions that it will accept and provide care to any and all pediatric heart transplant patients (ages 0-14) from Transplant Service Area 4, regardless of their ability to pay.
F. SUMMARY

South Broward Hospital District d/b/a Memorial Regional Hospital (CON #10044) proposes to establish of a pediatric heart transplantation program in the Organ Transplant Service Area 4 at Memorial Regional Hospital. Project costs total $147,025, which includes moveable equipment and project development costs. There are no construction or renovation costs. The addition of pediatric heart transplantation would complement the existing and extensive multiple pediatric services that are already provided by the applicant.

The applicant conditions CON approval to:

The specific site is 3501 Johnson Street, Hollywood, Florida 33021.

That it will accept and provide care to any and all pediatric heart transplant patients (ages 0-14) from Organ Transplant Service Area 4 (Monroe, Miami-Dade, Broward, Palm Beach and Collier Counties) regardless of their ability to pay. The applicant’s Schedule 7B specific to the project indicates that 23.7 percent of the year one and year two project days will be provided to Medicaid patients. Self-pay is shown as 40.9 percent for each year but charity care is not provided.

In weighing and balancing the review criteria, the following relevant factors are noted:

Fixed Need Pool

There is no fixed need pool publication for pediatric heart transplantation programs. It is the applicant’s responsibility to demonstrate the need for the project.

There is presently one pediatric heart transplantation provider in Transplant Service Area 4, at Jackson Memorial Hospital. The Agency received no opposition regarding the project. 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. Life Alliance Organ Recovery Agency, the organ procurement organization that serves Transplant Service Area 4, supports the project.
Need

The applicant estimates that the program will perform six pediatric heart transplants in year one and 12 pediatric heart transplants in year two. The applicant is already a provider of extensive pediatric cardiovascular services and approval would augment and enhance existing pediatric services. The applicant offers 14 case histories in which geographic, financial and programmatic barriers to pediatric heart transplantation services are experienced by those in need of pediatric heart transplantation at the applicant’s facility. Therefore, it is shown that patients in need of pediatric heart transplantation could be better served by the applicant, as compared to the current situation. The applicant is a safety-net provider and disproportionate share hospital. The applicant also demonstrates that the pediatric population in Transplant Service Area 4 is growing at a rate that should provide volume sufficient to justify the project. The applicant also demonstrates that Transplant Service Area 4 has the highest pediatric patient population that are prime candidates for heart transplantation and yet has consistently had a low pediatric heart transplant rate compared to other transplant service areas. No evidence or documentation is presented to warrant why so few pediatric heart transplants are performed.

Quality of Care

The applicant has reasonably demonstrated it satisfies the rule requirements per Chapter 59C-1.044, Florida Administrative Code, with regard to the provision of quality of care, though it is not currently a transplant provider. The applicant also has quality of care measures and appropriate policies and protocols in place or ready for implementation to accommodate the proposed project.

Agency complaint data indicates that the applicant experienced four confirmed complaints and no confirmed without deficiency complaints for the three-year period ending February 2, 2009. The applicant’s confirmed complaint history for the period is listed as follows: emergency access (two); medicine problems/errors/formulary (one) and nursing service (one).
Cost/Financial Analysis

The applicant has a good short-term and an adequate long-term position and overall appears to have the financial resources necessary to fund this project and all capital projects listed on Schedule 2.

This project appears to be financially feasible as part of the overall hospital operations and is not likely to have a material impact on the existing operations of the applicant. Regarding the effect of competition, the existing regulatory environment and payment structure will likely have a greater impact than competition.

Medicaid/Charity Care Commitment

The applicant has a history of providing care to Medicaid and charity care patients and has conditioned award of the CON upon accepting and providing care to any and all pediatric heart transplant patients (ages 0-14) from Transplant Service Area 4, regardless of their ability to pay. The applicant also proposes that 23.7 percent of its total pediatric heart transplantation program’s patient days will be provided to Medicaid patients in year one and year two of operation. There are no estimated charity care deductions from revenue for either year.

Architectural Analysis

The project does not require any construction or renovation to be implemented.
G. **RECOMMENDATION**

Approve CON #10044 to establish a pediatric heart transplantation program in Organ Transplant Service Area 4. The proposed total project cost is $147,025. There is no construction or renovation associated with the project.

**CONDITIONS:**

1. The project will be located at 3501 Johnson Street, Hollywood, Florida 33021.

2. Accept and provide care to any and all pediatric heart transplant patients (ages 0-14) from Organ Transplant Service 4 (Monroe, Miami-Dade, Broward, Palm Beach and Collier Counties) regardless of their ability to pay.

3. A minimum of 23.7 percent of the project’s total annual patient days will be provided to Medicaid patients.
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

____________________________
Jeffery N. Gregg
Chief, Bureau of Health Facility Regulation