A. PROJECT IDENTIFICATION

1. Applicant/CON Action Number

Adventist Health System/Sunbelt Inc. d/b/a Florida Hospital (CON #10026)
601 East Rollins Street
Orlando, Florida 32803

Authorized Representatives:  Mr. Richard E. Morrison
Ms. Diane Godfrey
(407) 303-1976

Orlando Regional Healthcare System, Inc. (CON #10027)
1414 Kuhl Avenue, MP-71
Orlando, Florida 32806

Authorized Representative:  Mr. Karl W. Hodges
(321) 841-5124

2. Service District/Subdistrict

Organ Transplant Service Area 3 which includes District 7 (Orange, Osceola, Brevard, and Seminole Counties); District 9, (Indian River, Martin, Okeechobee, and St. Lucie Counties, excluding Palm Beach County); Lake County only in District 3 and Volusia County only in District 4.

B. PUBLIC HEARING

A public hearing was not held or requested. However, letters of support were received by the Agency and submitted by the applicants proposing to establish adult heart transplantation programs, as discussed below.
Adventist Health System/Sunbelt, Inc. (CON #10026): Fifty-three unduplicated letters of support were received through the applicant and 31 support letters received by the Agency directly. Many of the letters jointly support cardio-thoracic transplantation programs - both CON #10026 (adult heart transplantation) and CON #10028 (adult lung transplantation) – submitted in this batching cycle by Adventist. The 84 letters submitted were from state legislators/local community leaders (15 letters); physicians (30 letters) and all other (39 letters). The letters are briefly described and summarized below in state legislator, physician and “all other” order.

Letters of support from state legislators are as follows: the Honorable Carey Baker (District 20), Florida Senate; the Honorable Dr. D. Alan Hays (District 25); two identical letters from the Honorable Pat Patterson (District 26); the Honorable Tony Sasso (District 32); the Honorable Sandy Adams (District 33); the Honorable Dean Cannon (District 35); the Honorable Bryan Nelson (District 38); the Honorable Geraldine Thompson (District 39); the Honorable Stephen Precourt (District 41); the Honorable Darren Soto (District 49); the Honorable Will Weatherford (District 61) and the Honorable Denise Grimsley (District 77). Of these 12 legislators, the last 11 are members of the Florida House of Representatives (the House). House members Cannon, Precourt, Soto and Thompson also support co-batch applicant Orlando Regional Healthcare System’s (ORHS’s) heart transplantation proposal (CON #10027). Orange County Mayor Richard Crotty supports both cardio-thoracic programs submitted by this applicant in this batching cycle (CON #’s 10026 and 10028), similar to the 12 state legislators listed above. City of Orlando Mayor Buddy Dyer supports a CON for heart transplantation services by endorsing both CON #10026 and CON #10027. City of Orlando Commissioner Robert Stuart also supports Adventist’s cardio-thoracic proposals (CON #10026 and CON #10028). Generally, recurring themes stressed include: a lack of heart (and lung) transplant services in the central Florida area; appropriateness to establish a heart/lung program considering the size of the central Florida population; Florida Hospital’s function as a current high volume leader of transplant services in the area and a leader in abdominal transplants statewide; ample existing support, infrastructure and clinical coordination in place to meet applicable need for this project and improved organ distribution locally through the United Network of Organ Sharing (UNOS) local service area. Varying versions of these themes are repeated by the remaining support letters for this application.
The 30 physician support letters vary with some being staff at Florida Hospital, some private practice physicians and others holding positions in academic and educational settings. These include Dr. J. David Vega (Director, Heart and Lung Transplant Program, Emory University); Dr. Leonard Bailey (Surgical Director, Heart Transplant Program, Loma Linda University Medical Center, Loma Linda, California); Dr. George Palmer, III (Director, Cardio-Vascular Surgery at Florida Hospital); Dr. John Guarneri (President, Medical Staff, Florida Hospital); Dr. Andrew Taussig (President, Central Florida Cardiology Group, P.A.); Dr. Mark Milunski (Florida Heart Group, P.A. and Associate Professor of Medicine, University of Central Florida College of Medicine); Dr. Pradip Jamnadas (Chief of Cardiology, Florida Hospital-Orlando) and Dr. Michael Angelis (Surgical Director of Transplant Services, Florida Hospital Transplant Center). Dr. George Palmer, III comments that the applicant amassed over 82,000 cardiac surgical procedures with a less than two percent mortality consistently over the last 40 years. This physician also highlights the applicant’s research infrastructure and journal publications\(^1\). The physician letters cite many of the factors listed by the state legislators and local community leaders, including Florida Hospital’s existing transplantation programs and high quality existing infrastructure.

Some of the 39 “all other” support letters include a hospital, business executives, as well as individuals that are current or former patients at the applicant’s facilities. One letter is from the Tim Jankiewicz, Executive Director, TransLife, in which TransLife states it will allocate deceased donor hearts (and lungs) to Florida Hospital in accordance with donor allocation policies pursuant to UNOS and the Organ Procurement and Transplant Network (OPTN). [Similar support is offered by TransLife to co-batched applicant ORHS]. Some other letters are as follows: Chris McAlpine, Parrish Medical Center’s Senior Vice President for Professional Services and Administration; Barry Friedman, Senior Director, Organ Transplant Services at the University of Minnesota Medical Center; Michael Seely, Executive Director, Oregon Health and Science University and Timothy Koch, Tethys Health Venture’s President. Tethys states it is a reinsurer and provider of transplant services]. Parrish Medical Center is the only hospital that also supports the co-batched applicant (ORHS, CON #10027).

\(^1\) The applicant provides examples of publications and relevant news clippings in two attachments, Attachment O – Medical Staff Authored Papers and Florida Hospital Transplant Center Research Studies and Attachment P – Florida Hospital-Burnham Medical Research Clinical Research Institute and Florida Hospital Diabetes Institute Clinical Trials.
In summary, these letters generally applaud the applicant’s existing transplantation programs, stress the lack of heart transplant services in the area, indicate excessive distance as a factor in ease of care and emphasize that the applicant has a high quality existing infrastructure to meet demand.

**Orlando Regional Healthcare System, Inc. (CON #10027):** Thirty-one unduplicated letters of support were included in the application (Tab 14 - Letters of Support) and nine were received by the Agency directly. The 40 letters submitted were from: state legislators (six letters); senior hospital executives (nine letters); physicians (eight letters) and all other (17 letters). The letters are summarized below in state legislator, senior hospital executive, physician and “all other” order. Letters of support from state legislators are all from members of the Florida House of Representatives (the House) as follows: the Honorable Thad Altman (District 30); the Honorable Chris Dorworth (District 34); the Honorable Dean Cannon (District 35); the Honorable Geraldine Thompson (District 39); the Honorable Stephen Precourt (District 41) and the Honorable Darren Soto (District 49). House members Cannon, Precourt, Soto and Thompson also support co-batch applicant Adventist’s heart transplant proposal (CON #10026). Orange County Mayor Richard Crotty supports both CON #10026 and CON #10027. City of Orlando Mayor Buddy Dyer supports a CON for heart transplantation services by endorsing both CON #10026 and CON #10027. Generally, the recurring theme stressed by legislators is that there are approximately 30 patients from central Florida annually that receive heart transplants performed in either Tampa or Gainesville, Florida and that approval would reduce the need for patients and families to leave the area for this service.

Nine hospital executives support ORMC’s project. They are Timothy Goldfarb, CEO, Shands HealthCare (an existing Service Area 1 (District 3) adult heart transplant provider); Ann M. Barnhart, Sr. Vice President Operations, Health Management Associates, Larry F. Garrison, Executive Vice President/COO, Health First; Richard M. Irwin, President & CEO of Health Central; Steven Harrell, Vice President and COO, Bert Fish Medical Center; Leslie Longacre, CEO, South Lake Hospital; Lee Huntley, President & CEO, Central Florida Health Alliance [Leesburg Regional Medical Center and The Villages Regional Hospital]; Chris McAlpine, Sr. Vice President, Parrish Medical Center and W. Carl Martin, Sr. Vice President and COO, Indian River Medical Center. Overall, these hospital executives state a good existing referral relationship with the applicant. Timothy Goldfarb, CEO, Shands HealthCare states that Shands will
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provide tissue typing laboratory services for the project. Steven Harrell of Bert Fish Medical Center states that Orlando Regional is the only statutory teaching hospital and Level 1 trauma center in the area. Of these facilities, Parrish Medical Center is the only hospital that also supports co-batched applicant Adventist (CON #10026).

The eight physician support letters vary with some being staff at Orlando Regional Medical Center, some private practice physicians and one holding a position at The Methodist Hospital, Baylor College of Medicine, Houston, Texas. Some of these physicians include the following: Dr. William DeCampli (Department of Cardiothoracic Surgery, Arnold Palmer Hospital for Children); Dr. David Nykanen (Director, Arnold Palmer Hospital Cardiology and Cardiac Catheterization); Dr. Joseph Andriole (CEO, Medical Center Radiology Group) and Dr. George Noon (Chief, Division of Transplant and Assist Devices and Executive Director, Multi-Organ Transplant Center, The Methodist Hospital, Baylor College of Medicine). Dr. DeCampli and Dr. Nykanen both generally justify their support by stressing the applicant’s existing congenital heart disease and surgery program and a likely growing need for adult transplantation services for this particular population as it ages. Dr. Andriole represents a 29 physician member group that specializes in diagnostic imaging and radiological intervention. Dr. Noon attests that if CON #10027 is approved, the Methodist DeBakey Heart & Vascular Center/Baylor College of Medicine Transplant Program will enter into an agreement to provide Orlando Health with numerous services, including but not limited to the following: protocols; education and training support and patient selection.

The “all other” support letters include business executives, as well as individuals, including those that are pre or post–heart transplant patients. Two of these letters are from Tim Jankiewicz, Executive Director, TransLife; and Anne K. Chinoda, President and CEO, Florida’s Blood Centers. Mr. Jankiewicz states TransLife will allocate deceased donor hearts to ORMC in accordance with donor allocation policies pursuant to UNOS and the Organ Procurement and Transplant Network (OPTN). [Similar support is offered by TransLife to co-batched applicant Florida Hospital]. Ms. Chinoda states that Florida’s Blood Centers will meet the demands associated with this project.

In summary, these letters generally state that approximately 30 central Florida residents must leave the area annually to receive heart transplants, that approval would eliminate that inconvenience and would support better health care outcomes.
C. PROJECT SUMMARY

Adventist Health System/Sunbelt, Inc. d/b/a Florida Hospital (CON #10026) (also referenced as Adventist, AHS, Florida Hospital, Florida Hospital-Orlando) proposes to develop a cardiothoracic transplant service; this includes adult heart and adult lung transplantation (CON #10028) programs at the main campus, Florida Hospital – Orlando, in Transplant Service Area 3. In this application, Adventist gives focus to heart transplantation. Like co-batched applicant ORHS, the applicant is also a provider of tertiary care services. Adventist operates six other Class 1 acute care hospitals in the greater Orlando area - Florida Hospital-Altamonte, Florida Hospital-Apopka, Florida Hospital-Celebration Health, Florida Hospital-East Orlando, Florida Hospital-Kissimmee and Winter Park Memorial Hospital. The tertiary services offered at Florida Hospital-Orlando’s main campus include: Levels II and III neonatal intensive care unit (NICU), comprehensive medical rehabilitation, adult pancreas transplant, adult liver, adult and pediatric kidney transplant and adult and pediatric bone marrow transplant program. Florida Hospital – Orlando also provides adult open heart surgery. The proposed program, if approved, would compliment the adult open heart program. Unlike co-batched applicant ORMC, Adventist is not a state certified trauma center. Again unlike co-batch applicant Orlando Regional, Florida Hospital-Orlando, the main Adventist campus in Orlando, is not currently a statutory teaching hospital; however, the applicant is designated as a statutory family practice teaching hospital (CON #10026, page #3).

The heart transplant program, if approved, is to be operational by July 1, 2009. Project costs total $532,725. These costs include equipment, project development and start-up costs. There is no construction or renovation associated with the project.

The applicant proposes the following condition: a minimum of 10 percent of heart transplant cases will be provided to Medicaid and charity cases on a combined basis.

Orlando Regional Healthcare System, Inc. (CON #10027) (also referenced as Orlando Regional Medical Center [ORMC], Orlando Regional, Orlando Health or ORHS) proposes to establish an adult heart transplantation program in Organ Transplant Service Area (OTSA) 3. Like co-batched applicant Florida Hospital-Orlando, the applicant is also a provider of tertiary care services. The applicant operates four other Class I acute care hospitals in greater Orlando - Arnold Palmer Hospital.

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2 http://www.doh.state.fl.us/DEMO/Trauma/MapofFloridaCertifiedTraumaCenters.pdf
for Children & Women, Dr. P. Phillips Hospital, Orlando Regional-Lucerne Hospital and Orlando Regional South Seminole Hospital.

Orlando Regional operates an adult open heart surgical service, is a Level 1 state-certified trauma center\(^3\) and is a statutory teaching hospital. Unlike co-batched applicant Adventist which currently provides multiple transplantation services, Orlando Regional currently has no organ transplantation services. If approved, this applicant would be the fifth statutory teaching hospital providing heart transplantation services in Florida (the other four being Jackson Memorial, Mayo Clinic-Jacksonville, Tampa General and Shands at the University of Florida.

The heart transplant program, if approved, is to be operational within six months or less of final CON approval. Project costs total $1,781,632. These costs include building, equipment, project development and start-up costs. The project involves 12,600 gross square feet (GSF) of renovation.

The applicant proposes the following 11 conditions:

1. The ORHS heart transplant program will be operational within six months of final CON award.

2. The ORHS heart transplant program will pursue a Medicare participation agreement as soon as eligible. In conjunction with this effort, ORMC will provide 10 heart transplantation surgeries to Medicare enrollees without charge at an estimated ORHS expense associated with this charity care of $2,038,000.

3. Once certified for Medicare participation, the ORHS heart transplant program will comply at all times with Medicare conditions of participation, including the requirement of providing a minimum average annual volume of 10 heart transplants per year and meeting Medicare specified transplant patient survival standards.

4. ORHS will discontinue operation of the heart transplant program if Medicare certification should lapse. Heart transplant programs can continue to operate following the loss of Medicare certification and some do. ORHS would not.

\(^3\) Ibid
(5) ORHS will provide a combined 12 percent of its heart transplant program discharges to Medicaid and charity patients in each of years one and two of operation and 19 percent in year three and thereafter.

(6) ORHS will enter into a written affiliation agreement with the University of Florida College of Medicine, establishing a cardio-thoracic surgery fellowship fully funded by ORHS beginning within 15 months after initiation of program operations.

(7) ORHS will expand its collaboration with the University of Central Florida in simulation research and training to include heart assist device implantation and heart transplantation surgery.

(8) ORHS will expand its current array of translational research programs to include clinical studies to enhance the design and use of implantable heart assist devices.

(9) ORHS will assist heart transplant candidates who reside outside of Orange, Osceola, Seminole and Lake Counties in obtaining low cost temporary housing for themselves and their families while awaiting surgery and during the intensive post-transplant follow-up period.

(10) ORHS will assure that all heart transplant patients, family caregivers and referring community physicians have timely access to the heart transplant care team via a full range of face-to-face interaction, direct telephone and electronic communication options throughout the course of care and transplant candidates without a personal computer will be provided one without charge and robust security measures will be in place to preserve patient confidentiality at all times in accordance with HIPPA requirements.

(11) ORHS will acquire, install and implement a dedicated suite of software applications dedicated to heart transplantation information management. This support system will be capable of meeting the program’s patient care, quality and outcome measurement, reporting and research requirements.
D. **REVIEW PROCEDURE**

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

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

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

As part of the fact-finding, the consultant, Steve Love analyzed the application in its entirety with consultation from the financial analysts Derron Hillman, who evaluated the financial data for CON #10026 and Butch Brousard, who evaluated the financial data for CON #10027 and consultation from the architect, Scott Waltz, who evaluated the architecturals and the schematic drawings.

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 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 adult heart transplants that will be performed in the first years of operation.

There are presently no operational adult heart transplant programs in Organ Transplant Service Area (OTSA) 3. As noted at the beginning of this review, OTSA 3 includes District 7, District 9 excluding Palm Beach County, Lake County (District 3) and Volusia County (District 4).

Data reported to the Agency for the most recent reporting period, January 1, 2007 through December 31, 2007 show the following 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 Uof F</td>
<td>1</td>
<td>3</td>
<td>32</td>
</tr>
<tr>
<td>Mayo Clinic*</td>
<td>1</td>
<td>4</td>
<td>22</td>
</tr>
<tr>
<td>Tampa General</td>
<td>2</td>
<td>6</td>
<td>51</td>
</tr>
<tr>
<td>Jackson Memorial</td>
<td>4</td>
<td>11</td>
<td>22</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>127</strong></td>
<td><strong>127</strong></td>
<td><strong>127</strong></td>
</tr>
</tbody>
</table>

Source: AHCA Utilization Data for Pediatric and Adult Organ Transplantation Programs published April 4, 2008.

*Formerly known as (f/k/a) St. Luke's Hospital

Data reported to the Agency show that of the seven adult transplant services regulated by the Agency (liver, lung, heart, kidney, intestines, pancreas and bone marrow), heart transplantation was the fourth least frequently performed, for the period. Intestines transplantation (three procedures) was the least performed and kidney transplantation (876 procedures) was the most performed, of the seven types of transplantation programs. Adult heart and adult lung transplantation are both performed by the same four facilities (named in the table above), none of which are located in OTSA 3. The greatest single population concentration in OTSA 3 is Orlando, which is approximately 85.77 miles, primarily by interstate highway, to the nearest heart transplantation facility – Tampa General Hospital\(^4\). Shands at the University of Florida (UF) is the next nearest facility authorized to perform heart transplantation services, at approximately 112.94 miles, again primarily by interstate highway\(^5\). For the 12-month period ending December 31, 2007, Tampa General Hospital had performed 40.16 percent of all heart transplantations statewide, followed by Shands at UF, which had

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\(^4\) [www.Mapquest.com](http://www.Mapquest.com)
\(^5\) Ibid
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performed 25.20 percent. Combined, these two facilities were responsible for the majority (65.36 percent) of all heart transplantations statewide in calendar year 2007. Below is a five-year chart to account for heart transplants over the time period.

### Adult Heart Transplantations Performed
**January, 2003 – December 2007**

<table>
<thead>
<tr>
<th>Facility</th>
<th>Jan 03 Dec 03</th>
<th>Jan 04 Dec 04</th>
<th>Jan 05 Dec 05</th>
<th>Jan 06 Dec 06</th>
<th>Jan 07 Dec 07</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Shands Hospital at UF</td>
<td>29</td>
<td>31</td>
<td>33</td>
<td>29</td>
<td>32</td>
<td>154</td>
</tr>
<tr>
<td>Mayo Clinic</td>
<td>9</td>
<td>12</td>
<td>7</td>
<td>15</td>
<td>22</td>
<td>65</td>
</tr>
<tr>
<td>Tampa General Hospital</td>
<td>55</td>
<td>43</td>
<td>61</td>
<td>59</td>
<td>51</td>
<td>269</td>
</tr>
<tr>
<td>Jackson Memorial Hospital</td>
<td>18</td>
<td>31</td>
<td>20</td>
<td>28</td>
<td>22</td>
<td>119</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>111</td>
<td>117</td>
<td>121</td>
<td>131</td>
<td>127</td>
<td>607</td>
</tr>
</tbody>
</table>

**Source:** Agency for Health Care Administration Adult Organ Transplantation Program Utilization January 2003 – December 2007

For the five years ending December 31, 2007, Tampa General Hospital maintained the highest volume of heart transplantations of the four facilities, followed by Shands at UF. Heart transplants trended upward each year except for calendar year 2007, which showed a 3.15 percent decline from 2006.

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 June 6, 2008**

| All Time | 98 |
| < 30 Days | 19 |
| 30 to < 90 Days | 18 |
| 90 Days to < 6 Months | 15 |
| 6 Months to < 1 Year | 19 |
| 1 Year to < 2 Years | 10 |
| 2 Years to < 3 Years | 3 |
| 3 Years to < 5 Years | 6 |
| 5 or More Years | 8 |

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

### Florida Heart Donors Recovered
**January 1, 2002 - December 31, 2007**

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Deceased Donor</td>
<td>151</td>
<td>130</td>
<td>120</td>
<td>130</td>
<td>129</td>
<td>123</td>
</tr>
</tbody>
</table>

**Source:** http://www.optn.org/latestData/rptData.asp
The most recently reported 12-month heart transplant data shows that a total of 127 heart transplants were performed in Florida as of December 31, 2007. Donor/patient matches are also a factor in transplant services. However, it is noted that there were 151 heart donors in 2007.

According to the data reported to the Agency (calendar year 2007), 176 of 185 (or 95.14 percent) of the patients receiving heart transplants performed in Florida were Florida residents. OTSA 3 residents accounted for 41 of the 185 procedures, representing 22.16 percent of all DRG 103s (heart transplant or implant of heart assist system) for the first three quarters of 2007 and for DRG 001s and 002s (heart transplant or implant of heart assist system) for the fourth quarter of 2007 procedures performed in Florida.

With no current heart transplant provider located in OTSA 3, all heart transplants in 2007 for OTSA 3 residents were performed as follows: Shands in OTSA 1 (21 patients or 51.22 percent of OTSA 3 applicable patients); Tampa General Hospital in OTSA 2 (13 patients or 31.71 percent of OTSA 3 applicable patients); Mayo Clinic in OTSA 1 (four patients or 9.76 percent of applicable OTSA 3 patients) and Jackson Memorial Hospital in OTSA 4 (three patients or 7.32 percent of applicable OTSA 3 patients). Therefore, of this patient population (41 OTSA 3 residents), approximately 82.93 percent (or about 34 of 41 patients) traveled an estimated 83 to 113 miles, one way primarily by interstate highways, for the procedure, with most of these 34 patients likely traveling the longer distance (Shands at UF). This estimate is provided the patients reside in the vicinity of either applicant (CON #’s 10026 or 10027).

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6 DRG 103 (in the first three quarters of 2007) and DRGs 001 and 002 (in the fourth quarter of 2007) includes heart assist device and many of these patients had stays of less than 40.6 days, the average length of stay for these DRGs. Patients with stays of less than 10 days totaled 15 patients or 8.12 percent. Eliminating these patients results in 170 patients remaining, while there were 127 heart transplant procedures reported to the local health councils for CY 2007. OPTN data reveals 129 adult heart transplants in Florida (subtracting the 26 procedures reported as pediatric transplants) by Florida facilities to the LHC. Regardless, some variation in the patient data is to be expected.

7 Of these 41 patients, only one had a stay of less than 10 days (this one stay was reported as a nine-day stay). Twenty-one of these 41 patients were treated at Shands UF which supports the ORMC application and commits to provide tissue typing services to ORMC. Shands provided more OTSA 3 resident heart transplantations than the three remaining heart transplantation providers combined.
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### Adult Heart Transplants by Patient Residence

**Year Ended December 31, 2007**

<table>
<thead>
<tr>
<th>Service Area</th>
<th>Transplants Performed</th>
<th>Percent of Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>40</td>
<td>21.62%</td>
</tr>
<tr>
<td>2</td>
<td>54</td>
<td>29.19%</td>
</tr>
<tr>
<td>3</td>
<td>41</td>
<td>22.16%</td>
</tr>
<tr>
<td>4</td>
<td>41</td>
<td>22.16%</td>
</tr>
<tr>
<td>Out-of-State</td>
<td>9</td>
<td>4.86%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>185</strong></td>
<td><strong>100.00%</strong></td>
</tr>
</tbody>
</table>

Source: Florida Center for Health Information and Policy Analysis database, DRG 103 (Heart Transplant or Implant of Heart Assist System) and DRGs 001 Heart Transplant or Implant of Heart Assist System with MCC (major complications or co-morbidities) and 002 (same diagnosis without MCC) for applicable quarters of 2007.

**Adventist Health System/Sunbelt, Inc. (CON #10026)** estimates 12 heart transplants in the first year of operation and 18 in the second year (CON #10026, page #46). This is slightly more ambitious than co-batched applicant Orlando Regional. Florida Hospital bases its utilization numbers on a number of factors: the absence of a heart transplant provider in the service area; the volume of OTSA 3 residents who sought heart transplants in other areas of the state; the applicant’s transplant expertise and support services available; the large geographic area of the service area; demographic and growth trends and the effect of education and increased awareness about heart transplantation. As stated previously in this section, with OTSA 3 residents accounting for 41 of the 185 heart transplantation procedures performed in calendar year 2007, 21 of these being performed at Shands at UF and 13 at Tampa General Hospital, a first year heart transplantation count of 12 and second year count of 18 would seem reasonable, if not an underestimation of need.

**Orlando Regional Healthcare System, Inc. (CON #10027)** estimates six heart transplants in the first year of operation and 12 in the second year (CON #10027, page #29). It also estimates a ventricular assist device (VAD) count of two by year one and four by year two (CON #10027, page #32). This is slightly more conservative than co-batched applicant Florida Hospital. Orlando Regional bases its utilization numbers and implementation schedule on three factors: the strength and experience of the heart transplant team (to be headed by Dr. Javier Lafuente as program director and primary heart transplant surgeon [curriculum vitae found in CON #10027, Tab 3); the ability to bring the program into operation quickly following CON approval and the ability to build a base of transplant candidates. As stated previously in this section, with OTSA 3 residents accounting for 41 of the 185 heart transplantation procedures performed in calendar year 2007, 21 of these
being performed at Shands at UF and 13 at Tampa General Hospital, a first year heart transplantation count of six (with two VADs) and second year count of 12 (with four VADs) would seem reasonable, if not an underestimation of need.

The applicants’ combined projected volume (18 and 12 respectively) for year two does not exceed the 41 patients from SA 3 in CY 2007 that received the service in other transplant facilities. Both facilities’ projections meet the CMS minimum annual volume requirement for 10 procedures. The existing transplant centers should not be impacted below this level based on CY 2007 volume.

2. Applications for the establishment of new adult 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.

   **Adventist Health System/Sunbelt Inc. d/b/a Florida Hospital (CON #10026):** The applicant will recruit a UNOS-current, board-certified transplant cardiologist, once approved. Two physicians that are stated to have shown interest are Dr. Mark Milunski and Dr. Craig Barnett, both with heart failure patient populations (CON #10026, page #54).

   **Orlando Regional Healthcare System, Inc. (CON #10027):** The applicant claims approximately 100 board-certified cardiologists that have active medical staff privileges with ORHS affiliated hospitals. Dr. Peter D. Tayor, Dr. David Bello and Dr. Paul Sander are highlighted as having training and experience in heart transplantation (CON #10027, page #80).

   (2) **An anesthesiologist experienced in both open heart surgery and heart transplantation.**

   **Adventist Health System/Sunbelt Inc. d/b/a Florida Hospital (CON #10026):** The applicant reports its
anesthesiology group has seven anesthesiologists with experience in open heart surgery and heart transplantation, one being Dr. Mac Axelrod.

**Orlando Regional Healthcare System, Inc. (CON #10027):** The applicant reports two anesthesiologists with active medical privileges at its facilities have experience in both open heart surgery and heart transplantation. These physicians are Dr. Roger Murbach and Dr. Young Oh, both board-certified by the American Board of Anesthesiology.

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

**Adventist Health System/Sunbelt Inc. d/b/a Florida Hospital (CON #10026):** The applicant reports an isolation room in Florida Hospital’s cardiovascular ICU (post-transplant) and cardiac ICU (pre-transplant).

**Orlando Regional Healthcare System, Inc. (CON #10027):** The applicant states that ORMC has a 10-bed cardiovascular recovery room adjacent to applicable operating rooms and that all 10 rooms are equipped as isolation rooms.

(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-1.044(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.**

**Adventist Health System/Sunbelt Inc. d/b/a Florida Hospital (CON #10026):** The applicant notes there are no heart transplant providers in OTSA 3.

**Orlando Regional Healthcare System, Inc. (CON #10027):** The applicant indicates this is not applicable since there is no provider of adult heart transplantation in OTSA 3.
(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.

Adventist Health System/Sunbelt Inc. d/b/a Florida Hospital (CON #10026): The applicant reports residents of OTSA 3 received 30 heart transplants in the 12-month period ending September 2007. It further anticipates 18 heart transplants by the second year of operation. In calendar year 2007, 151 donor hearts were procured statewide. Therefore, the applicant has met this criteria.

Orlando Regional Healthcare System, Inc. (CON #10027): For the 12-month period ending December 31, 2007, 41 OTSA residents received adult heart transplants. The applicant anticipates 12 heart transplants (and four ventricular assist device (VAD) procedures totaling 16 procedures in all) by the second year of operation. In calendar year 2007, 151 donor hearts were procured statewide. Therefore, the applicant has met this criteria. The applicant further attests that ORMC recovers more organs of all types for transplantation than any other hospital located in OTSA 3. This is, at least in part, due to its Level 1 trauma center status, the only hospital with such designation in OTSA 3.

(3) The application includes documentation that the annual duplicated cardiac catheterization patient caseload was at or exceeded 500 for the calendar year preceding the certificate of need application deadline; and that the duplicated patient caseload for open heart surgery was at or exceeded 150 for the calendar year preceding the certificate of need application deadline.

Adventist Health System/Sunbelt Inc. d/b/a Florida Hospital (CON #10026): The applicant states Florida Hospital provided 6,630 cardiac catheterizations and 1,488 open heart surgeries for the 12-month period ending December 31, 2007 (CON #10026, page #56). According to
Agency records\textsuperscript{8} Florida Hospital provided 6,603 cardiac catheterizations for the period. The cardiac catheterizations reported by the applicant is 27 more than verified with Agency records. Even with the discrepancy, the applicant has met this criteria.

**Orlando Regional Healthcare System, Inc. (CON #10027):**
The applicant states ORMC provided 4,990 cardiac catheterizations and 726 open heart surgeries for the 12-month period ending December 31, 2007 (CON #10027, page #14). This is verified through Agency records\textsuperscript{9}. The applicant has met this criteria.

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:

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.

Adventist Health System/Sunbelt Inc. d/b/a Florida Hospital (CON #10026) asserts that Florida Hospital has a significant number of staff and facilities capable of providing the resources necessary to care for the patients’ chronic illness prior to transplantation, during transplantation, and in the post-operative period. Services and facilities for inpatient and outpatient care are currently available to meet these needs on a 24-hour basis for the kidney, liver and pancreas transplant programs.

\textsuperscript{8} Florida Need Projections for: Adult Open Heart Surgery Programs, published April 4, 2008
\textsuperscript{9} Ibid
Florida Hospital also states that the heart transplant program will be integrated with the provider’s existing transplant programs. Both pre-transplant and post-transplant services will be provided in the operating rooms, recovery, cardiovascular ICU and progressive care unit in the Ginsberg Tower (set to open in Fall 2008). The heart transplant program will have the 24-hour availability of transplant nurses and physicians.

**Orlando Regional Healthcare System, Inc. (CON #10027):**
ORMC indicates that it provides 24-hour inpatient and outpatient care to meet chronically ill patient needs as they relate to physical, emotional, spiritual and psychosocial needs (CON #10027, page #34). In addition to having statutory teaching hospital status and being a Level 1 trauma center, among other features, the applicant proposes to optimize continuity of care by having pediatric heart specialists that can track their patients into adult heart transplantation service (if the CON is approved), particularly highlighting its Arnold Palmer Hospital for Children, Miami Children’s Hospital and Congenital Heart Institute affiliations. The applicant also describes itself as a leader in cutting-edge clinical research. According to the applicant, ORMC cardiologists were the first in Florida and only the second in the nation to implement the CardioMEMS HF Pressure Measurement System (CON #10027, page #35), a clinical trial designed to lead to faster treatment analysis and possibly fewer hospital stays. The transplantation services program is planned to exist within the Comprehensive Heart Failure Program (a component of the Orlando Health Heart and Vascular Center [the Center]) already in operation at ORMC. The Center provides heart arrhythmia and coronary artery disease treatment and also a peripheral vascular disease treatment center. The applicant further claims the Center maintains direct linkages with applicable affiliation facilities, along with the ORHS Graduate Medical Education Program, and other affiliations.

The applicant emphasizes the provision of less invasive heart failure preventions and treatments, as precursors before resorting to heart transplantation. Sometimes one of these pre-transplantation options is the ventricular assist device (VAD), another treatment option planned at ORMC (if the CON is approved). The VAD is to serve as a “bridge to transplantation” (CON #10027, page #48) for patients in
need of but too ill to undergo transplantation at the time. When such pre-transplantation options are inapplicable, cease to be effective or otherwise fail, ORMC intends to evaluate options through the ORMC heart transplant multidisciplinary team, also called the Transplant Medical Review Board (TMRB). The applicant includes the ORMC Heart Transplantation Program Policy and Procedures Manual draft (Tab 2 - ORHS Transplant Materials). Members of the core transplant team include the following: cardiologist; surgeon; infectious disease physician, a coordinator (an advanced practice nurse); dietician; psychologist; social worker; financial coordinator and pastoral care provider. Contingency plans are available depending upon the decision of the TMRB. The applicant also has waiting list procedures in place. The applicant provides (Tab 4 – Scope of Services) a list of 13 services applicable to the proposed heart transplantation program.

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.**

**Adventist Health System/Sunbelt Inc. d/b/a Florida Hospital (CON #10026)** provides a letter of commitment from the applicable organ procurement organization (OPO) TransLife (Attachment Q – Agreement with OPO). It is stated that TransLife is part of and a related entity to Florida Hospital and the OPO will respond to calls from hospital personnel within 20 minutes of notification. A 24-hour call system is currently in place for the assessment, management, and retrieval of all referred donors, cadaver donors, or organs shared by other transplant programs or organ procurement agencies. The OPO operates in conformance with OPTN and the Joint Commission on

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10 The letter of commitment from TransLife does not designate a given time frame upon which it will respond, but does state it will meet demand (for both donor hearts and lungs) in accordance with organ allocation policies as established by the Organ Procurement and Transplant Network (OPTN) and the United Network for Organ Sharing (UNOS).
Accreditation of Healthcare Organizations (JCAHO). Florida Hospital states current authorization for kidney, pancreas, bone marrow, and liver transplantation.

**Orlando Regional Healthcare System, Inc. (CON #10027)** provides a written commitment (Tab 8 – Service Agreements) with TransLife, for deceased donor hearts. As the only Level 1 Trauma Center in the area, ORMC claims to be the largest single provider of cadaveric grafts to TransLife. Protocols are in place to respond to donor organ procedures, 24 hours a day, 365 days a year.

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

**Adventist Health System/Sunbelt Inc. d/b/a Florida Hospital (CON #10026)** states that following transplantation, patients will be transferred to the adult cardiovascular intensive care unit, which is the same unit currently utilized by patients in other transplant programs. The applicant states the unit currently has the ability to offer prolonged reverse isolation, if needed.

**Orlando Regional Healthcare System, Inc. (CON #10027)** states ORMC has a 10-bed adult cardiovascular recovery room unit (ICU), all 10 equipped as isolation rooms with four as reverse isolation rooms (positive and negative pressure isolation). It further states operation of an adult 50-bed ICU, this includes the 10-bed adult cardiovascular ICU and the 10-bed cardiovascular recovery room (both previously stated); these two latter 10-bed units are all private, per the applicant.

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

**Adventist Health System/Sunbelt Inc. d/b/a Florida Hospital (CON #10026)** states after thorough evaluation, adult heart transplant candidates will be reviewed at the weekly patient review committee which will include transplant surgeons, cardiologists, a social worker, a financial coordinator, clinical transplant coordinators, and a nurse practitioner. Once approved by the committee,
patients will be placed on the waiting list, registered with the local OPO. Florida Hospital’s pre-transplant coordinators will update medical information on all listed candidates periodically, and the program will re-evaluate listed patients based on OPTN guidelines and the severity of illness.

**Orlando Regional Healthcare System, Inc. (CON #10027)** references the TMRD (see Section 2.a.1 [Agency Rule Criteria]. This clinical review committee will meet weekly. Materials for review and evaluation for decision-making regarding suitability of transplant candidates is described by the applicant in the ORMC Heart Transplantation Program Policy and Procedures Manual draft (Tab 2 - ORHS Transplant Materials). Emergency evaluation can be conducted at patient bedside.

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.**

**Adventist Health System/Sunbelt Inc. d/b/a Florida Hospital (CON #10026)** provides a draft protocol for patient care for heart transplant (Attachment R – Draft Heart Transplant Protocols). The applicant reports these protocols are similar to like protocols developed and utilized by Florida Hospital transplant surgeons for other organs. Protocols include identification of patient selection criteria for patient management and evaluation during pre-hospital, in-hospital, and immediate post-discharge phases of the program.

**Orlando Regional Healthcare System, Inc. (CON #10027)** provides patient selection criteria for patient management and evaluation during the pre-hospital, in-hospital, and post-discharge phases of the program (Tab 2 - ORHS Transplant Materials). This tab includes the ORMC Heart Transplantation Program Policy and Procedures Manual draft. The applicant states these policies and procedures are consistent with those established by the lead program director, Dr. Javier Lafuente who, per the applicant, has performed over 400 transplant surgeries (primarily at The Methodist Hospital and DeBakey Heart Center) in Houston, Texas. This physician is also experienced in VAD implantation surgery (a planned component of the heart
transplantation program if the CON is approved). The applicant states Dr. Lafuente has also performed numerous other solid organ transplantations, including lung and kidney. Dr. Lafuente is set to begin practicing full-time with ORMC in July, 2008.

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.**

**Adventist Health System/Sunbelt Inc. d/b/a Florida Hospital (CON #10026)** provides a draft protocol for patient care for heart transplant (Attachment R – Draft Heart Transplant Protocols); these protocols include therapeutic and evaluative procedures for the acute and long-term management of each adult heart transplant program patient including the management of commonly encountered complications. Also for patients who may require specialized acute or post-acute facilities, either while they wait for their transplant or post-transplant, Florida Hospital reports a “broad variety of facilities to support this population” (CON #10027, page #48).

**Orlando Regional Healthcare System, Inc. (CON #10027)** states that it has developed therapeutic and evaluative procedures for both acute and long-term management of each transplant patient, including management of commonly encountered complications. Review of the ORMC Heart Transplantation Program Policy and Procedures Manual draft (Tab 2 - ORHS Transplant Materials) confirms that the applicant will comply with the above criteria.

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.**

**Adventist Health System/Sunbelt Inc. d/b/a Florida Hospital (CON #10026)** provides a letter of commitment from the applicable organ procurement organization (OPO) TransLife (Attachment Q – Agreement with OPO). The
applicant states TransLife provides the necessary equipment and personnel to recover and maintain solid organs for transplantation.

**Orlando Regional Healthcare System, Inc. (CON #10027)** provides a written commitment (Tab 8 – Service Agreements) with TransLife, for deceased donor hearts. TransLife indicates that fees for equipment for cooling, flushing, and transporting organs will be established at the time of executing a formal contract with ORMC. As the only Level 1 Trauma Center in the area, ORMC claims to be the largest single provider of cadaveric grafts to TransLife. The applicant also states that it has all necessary equipment in place for preservation of organs through mechanical perfusion.

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.**

**Adventist Health System/Sunbelt Inc. d/b/a Florida Hospital (CON #10026)** meets this requirement comprehensively by having its own in-house Agency licensed tissue-typing laboratory (Attachment S – Laboratory, Pathology Tissue-Typing and Blood Bank Certifications). The applicant claims to have the only tissue-typing laboratory in central Florida and one of only seven statewide. Florida Hospital includes in its application an accreditation certificate issued by the American Society for Histocompatibility and Immunogenetics (Attachment S - Laboratory, Pathology Tissue-Typing and Blood Bank Certifications).

**Orlando Regional Healthcare System, Inc. (CON #10027)** meets this requirement by providing a letter of commitment from Shands Healthcare for the provision of tissue typing laboratory services (Tab 8 – Service Agreements). Shands Healthcare states a long and supportive relationship with the applicant and agrees to provide tissue typing laboratory services. The applicant states that patients must have a PRA
(Percent Reactive Antibody) and Tissue Typing done before listing and as such is not time-critical in the actual transplantation. Shands Healthcare’s laboratory meets American Society of Histocompatibility requirements.

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.**

**Adventist Health System/Sunbelt Inc. d/b/a Florida Hospital (CON #10026)** asserts that it is fully qualified to meet the needs of the heart transplant program and specifically in the analysis of biopsy materials. Florida Hospital’s pathology department works closely with the kidney and liver transplant programs and according to Adventist, will not require any additional resources to meet the pathology requirements of the program. The laboratory is headed by Deborah Thoni, MD. There is also a letter of support (Attachment S - Laboratory, Pathology Tissue-Typing and Blood Bank Certifications) from Dr. Thoni, Chairperson, Department of Pathology with Central Florida Pathology Associates.

**Orlando Regional Healthcare System, Inc. (CON #10027)** states ORMC’s clinical laboratory currently performs nearly two million tests annually. The laboratory is headed by Cynthia Kuehn. The applicant states that two ORHS pathologists – Gary Pearl, MD, PhD and Ray Franklin, MD, PhD. have experience related to heart transplantation. A complete scope of service description is provided (Tab 8 – Service Agreement [ORMC Laboratory Transfusion Service]).

10. **Blood banking facilities.**

**Adventist Health System/Sunbelt Inc. d/b/a Florida Hospital (CON #10026)** provides a letter of support (CON #10026, Attachment S – Laboratory, Pathology Tissue-Typing and Blood Bank Certifications) from the Florida’s Blood Centers. The letter states a long-standing relationship with Florida Hospital and supports the applicant’s efforts to secure a CON for heart transplantation.
Orlando Regional Healthcare System, Inc. (CON #10027) provides a letter of commitment (Tab 8 – Service Agreement [Florida’s Blood Centers]) to address blood and blood component supply associated with this project. The applicant also provides a scope of service description (Tab 8 – Service Agreement [ORMC Laboratory Transfusion Service]) as it relates to blood and blood component supply. Ray Franklin, MD, PhD’s blood bank experience as a board certified pathologist since 1985 and director of the pathology department since 1997 is highlighted. The applicant reports transfusion service licensure through the Agency, as well as accreditation by the Clinical Laboratory Improvement Act and the American Association of Blood Banks.

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

Adventist Health System/Sunbelt Inc. d/b/a Florida Hospital (CON #10026) states that Florida Hospital’s TransLife offers extensive ongoing continuing education training for both new staff and existing staff working in all phases of the transplant program. In the heart transplant program, the clinical transplant coordinators will be responsible for providing continuing education to the nurses on the transplant unit. All of the transplant coordinators are certified clinical transplant coordinators (CCTCs). The applicant provides resumes of two of the transplant coordinators (Attachment H – Curricula Vitae and Resumes), these are Audrey Fearn-Troilo, RN and Anne Conforti, RN. Adventist also offers (Attachment T – Sample Educational Materials) an eight-week, 12-step written competency regimen that is applicable to its existing transplantation programs. The applicant states intentions of developing similar materials (if approved) for heart transplantation.

Orlando Regional Healthcare System, Inc. (CON #10027) provides an applicable staff training curriculum (Tab 9 – Staff Training). ORHS states the training curriculum was developed under the guidance of the program director, Dr. Javier Lafuente, and in accordance with the International Transplant Nurses Society. The applicant highlights Shelly Draves, RN, BSN as a Critical Care Education Coordinator, serving more than three years as an Organ Recovery Coordinator with TransLife. Training is designed with a multi-disciplinary approach.
12. **Education programs for patients, their families and the patient’s primary care physician regarding after-care for transplantation patients.**

**Adventist Health System/Sunbelt Inc. d/b/a Florida Hospital (CON #10026)** states all candidates for transplant and their families are provided written materials, on-site education, assigned to a clinical pre-transplant coordinator, and encouraged throughout the pre and post-transplant process to continue to learn and ask questions about transplant care. The patients’ education about “after-transplant care” begins at their first visit as a potential candidate for a heart transplant and continues for a lifetime. Adventist also offers (Attachment U – Patient Guide for Kidney Transplant and Liver Transplant Programs) as examples of related patient materials that will be developed for heart transplantation usage (if approved).

**Orlando Regional Healthcare System, Inc. (CON #10027)** plans to provide at the time of waiting list placement, a 41-page education program for patients and families (Tab 2 – ORHS Transplant Materials [Heart Transplantation 101/Patient and Family Education Guide]). The applicant also states a commitment to maintain close ties with applicable primary care and referring physicians. ORHS provides a draft copy of a 26-page booklet for community physicians (Tab 10 – Community Physician Education [Your Patient Following Heart Transplantation]). Upon commencement of full-time practice at ORMC, the applicant plans for its lead physician in this program, Dr. Javier Lafuente, to introduce himself and the planned program to area physicians, particularly cardiologists, cardiothoracic surgeons, and primary care physicians. The applicant indicates Dr. Lafuente will adapt materials he currently uses in Houston for this purpose. Dr. Lafuente will also participate in Community Grand Rounds – a program of quarterly presentations by nationally and internationally recognized physicians on the ORHS staff at both ORMC and community locations on their topics of expertise. There are also plans for web seminars and personal meetings to improve community physician awareness.
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.

Adventist Health System/Sunbelt Inc. d/b/a Florida Hospital (CON #10026), if approved, intends to acquire a UNOS current heart transplant surgeon and cardiologist. The applicant does not anticipate difficulty in this effort for two particular reasons. One is through having Dr. Robert Metzger (reportedly the only transplant physician in Florida that has been president of UNOS). The other is a letter of support from Dr. David Vegas, Director, Cardiac Transplant Program of Emory Healthcare (in Atlanta, Georgia) and current chair of the Thoracic Organ Transplantation Program at UNOS. Dr. Mark Milunski and Dr. Craig Barnett have also shown interest in becoming UNOS current. The applicant anticipates that this support will result in productive recruitment efforts to attain applicable UNOS current practitioners. The applicant further states that both heart and lung transplantation approval would lead to additional synergies, since heart and lung transplant surgeons are cross-trained and can perform either surgery. The applicant believes this would reduce potential burn-out of one-surgeon programs. Adventist does not discuss a physician with infectious disease as being a part of the transplant team; however, as Florida Hospital has existing transplant programs this should not be an issue.

Orlando Regional Healthcare System, Inc. (CON #10027) reports approximately 100 board-certified cardiologists with active medical staff privileges at ORHS affiliate hospitals.
The applicant references in its materials (Tab 3 – Curriculum Vitae) 18 cardiologists with interest and experience in the heart transplantation program. ORHS further states that it, along with Dr. Javier Lafuente, has identified and made contacts with candidates for the position of transplant physician. Two interested physicians that practice at ORMC are David Bello, MD and Paul Sanders, MD. Another interested physician is David Nykanen, MD, Director, Pediatric Cardiology and Cardiac Catheterization Laboratory, Arnold Palmer Hospital for Children. This supports the transition of pediatric heart patients as they age and potentially become candidates for adult heart transplantation. Two other physicians are also stated to be interested but not named. Dr. Lafuente is to serve as the program director and as the ORMC Heart Transplant Program designated transplant surgeon. This physician is experienced in not only hundreds of heart transplantations but also other related procedures, such a ventricular assist device (VAD) implantation surgery, ventricular remodeling and other advanced stage heart failure. Mark Wallace, MD, is reported to have over 20 years of practice in infectious disease, the past two years being at ORMC. Dr. Wallace also is stated to have held academic posts in medicine. In addition, ORHS reports it has engaged Kauser Akhter, MD, a board-certified infectious disease physician, to join ORMC in September 2008.

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.**

Adventist Health System/Sunbelt Inc. d/b/a Florida Hospital (CON #10026) states Florida Hospital will recruit a program director upon award of a CON for a lung transplant program, not a heart transplant program. As previously stated in this report, during this same batching cycle, the applicant is seeking approval of a lung transplantation program (CON #10028). However, in this section, Adventist does not state it will seek a qualified program director for its planned heart transplantation program. The applicant does not expect recruitment to be difficult in light of having support through Dr. Robert Metzger.
**Orlando Regional Healthcare System, Inc. (CON #10027)** states that Dr. Javier Lafuente is to serve as both the ORMC Heart Transplant Program Director and as the designated transplant surgeon. This physician is to join the ORMC medical education faculty as the Academic Chairman of Cardiothoracic Surgery. He recently served as Medical Director, Life Gift OPO in Houston, Texas, has practiced at The Methodist Hospital in Houston, Texas since 1985 and was involved in the implantation of the first Micromed-DeBakey heart pump in the United States.

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

**Adventist Health System/Sunbelt Inc. d/b/a Florida Hospital (CON #10026)** states that the transplantation program will have access to nurses and nurse practitioners with experience in the care of chronically ill patients and the support of their families.

**Orlando Regional Healthcare System, Inc. (CON #10027)** states it currently employs nearly 2,000 registered nurses (RNs), more than 75 clinical nurse practitioners (CNPs) and advanced registered nurse practitioners (ARNPs). Though ORHS concedes it does not seek to be an all-encompassing transplantation institute, it believes it is well positioned and mandated to offer heart transplantation as a part of its Comprehensive Heart Failure Program at ORMC.

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

**Adventist Health System/Sunbelt Inc. d/b/a Florida Hospital (CON #10026)** states that Florida’s Blood Centers currently has an ongoing relationship with Florida Hospital. Florida Hospital’s TransLife is stated to have an excellent working relationship with Florida’s Blood Centers, including working together to determine blood need for Adventist’s other transplant programs. Florida Hospital states it has the ability to meet the need for blood products by the proposed program.
Orlando Regional Healthcare System, Inc. (CON #10027) provides a letter of commitment (Tab 8 – Service Agreement [Florida’s Blood Centers]) to address blood and blood component supply associated with this project. ORHS also identifies Ms. Mildred Chen-Quee, on-site Director of Transfusion Services of Florida’s Blood Centers (within the ORHS core laboratory) as well positioned to meet blood banking needs. Central Florida Blood Bank, Inc.’s Medical Director, Richard Gammon, MD is on call and available to provide applicable guidance and expertise in this area.

The applicant reports two ORHS pathologists – Gary Pearl, MD, PhD and Ray Franklin, MD, PhD as also both having blood banking expertise.

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

Adventist Health System/Sunbelt Inc. d/b/a Florida Hospital (CON #10026) states that as an integral transplant team Florida Hospital will not need to expand its nutrition department in order to provide for this program.

Orlando Regional Healthcare System, Inc. (CON #10027) states that it has a wide variety of clinical dieticians and specialists with expertise in the nutritional needs of transplant patients. One such staff is clinical dietician Angela Alia at ORMC. Ms. Alia brings specific expertise in caring for transplant patients from her previous work at Johns Hopkins Hospital. A review of the curriculum vitae of Ms. Alia (CON #10027, Tab 3) indicates Ms. Alia was employed as a clinical dietician at Johns Hopkins Hospital, Baltimore, MD from May 2005 to November 2006. However, the resume is not specific about expertise with transplantation patients. ORHS also highlights Lenore Hodges, PhD, clinical dietician. Dr. Hodges is identified in the curriculum vitae (CON #10027, Tab 3) as employed from June 2005 to present as Counseling Dietician, M.D. Anderson Cancer Center – Orlando. However, the resume is not specific about expertise with transplantation patients.
6. **Respiratory therapists with expertise in the needs of transplant patients.**

**Adventist Health System/Sunbelt Inc. d/b/a Florida Hospital (CON #10026)** states that respiratory therapists at Florida Hospital have experience in the current transplant programs. The respiratory therapists are primarily involved with the needs of transplant patients during their inpatient stay and presently provide care to immunosuppressed transplanted patients. Florida Hospital will not need to expand its respiratory therapy department in order to provide for this program. Unlike co-batched applicant ORHS, Florida Hospital does not specify the number of respiratory therapists on staff.

**Orlando Regional Healthcare System, Inc. (CON #10027)** states six respiratory therapists with experience and training in caring for transplant patients. A review of the curriculum vitae (CON #10027, Tab 3) for each of the six staff identified in the application indicates that all six have experience with pre-post heart and/or lung transplant patients as described by the applicant.

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

**Adventist Health System/Sunbelt Inc. d/b/a Florida Hospital (CON #10026)** states that social workers, psychologists, and psychiatrists are available to provide support and assessments to patients and their families who are seeking transplantation. All potential transplantation patients are assessed by social workers. Services of psychologists, psychiatrists, and others such as addiction specialists are available as deemed appropriate by the patient, their family, or the transplant team. Financial evaluation will be completed as part of the pre-assessment process for heart transplant patients, social workers and financial counselors will work closely with the patient and their family prior to transplantation, during their inpatient stay, and also during the post-transplant follow-up care.
Adventist states this program calls for life-long support and will require extensive (and expensive) medications. Adventist provides a discussion of its Patient Assistance Fund, administered by the Florida Hospital Foundation (CON #10026, page 62), which covers living expenses such as rent, utility bills and insurance costs. The applicant indicates that since 1998, this fund has provided over $350,000 to patients for drug costs.

**Orlando Regional Healthcare System, Inc. (CON #10027)** reports a number of patient services, including the following: social workers; case managers (especially for continuity of care from inpatient to outpatient services and telemonitoring); discharge planners; patient/family counselors (licensed clinical psychosocial counselors); neurophysiologists and spiritual counselors (chaplains). Unlike co-batched applicant Adventist, ORHS provides a drug assistance program for patients who meet certain income eligibility requirements (Tab 6 – Pharmacy Assistance [Generic Equivalence Listing and Pharmacy Patient Assistance Programs]. ORHS highlights the 17 bedroom “Hubbard House” (CON #10027, page #87) as a possible housing option, with referral dependent upon factors that relate to severity of patient condition and traveling distance of family members. The applicant proposes to condition that it will assist heart transplant candidates who reside outside of Orange, Osceola, Seminole and Lake Counties in obtaining low cost temporary housing for themselves and their families while awaiting surgery and during the intensive post-transplant follow-up period.

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.

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
Adventist Health System/Sunbelt Inc. d/b/a Florida Hospital (CON #10026) states that as an existing transplant provider Florida Hospital currently complies with the organ transplant data reporting requirements and will continue to do so for “both the existing transplant programs” (CON #10027, page #54) and the proposed adult heart transplant program. It is noted that Adventist is currently approved for and must report data for bone marrow, kidney, liver and pancreas transplantations. Therefore, it is not clear which programs the applicant references when it states “both the existing transplant programs” since it currently has more than two.

Orlando Regional Healthcare System, Inc. (CON #10027) states that as an existing provider of hospital services, ORHS will incorporate applicable data reporting into existing data management and reporting capabilities without difficulty. The applicant indicates that one mechanism to achieve this end is purchase and installation of a suite of software applications dedicated to heart transplantation information management. ORHS identifies staff responsible for this function to be the chief information services applications officer.

3. Statutory Review Criteria

a. Is need for the project evidenced by the availability, quality of care, accessibility and extent of utilization of existing health care facilities and health services in the applicant's service area? ss. 408.035(1), (2) and (5), Florida Statutes.

Access

There is currently no adult heart transplant service provider in Organ Transplant Service Area (OTSA) 3 which is comprised of the following 10 counties: Volusia, Lake, Seminole, Orange, Osceola, Brevard, Indian River, Okeechobee, St. Lucie, and Martin. The four existing Florida heart transplant providers are located in OTSA 1 (Mayo Clinic and Shands at UF), OTSA 2 (Tampa General), and OTSA 4 (Jackson Memorial Hospital).
According to the data reported to the Agency (calendar year 2007), 176 of 185 (or 95.14 percent) of the patients receiving heart transplants performed in Florida were Florida residents. OTSA 3 residents accounted for 41 of the 185 procedures, representing 22.16 percent of all DRG 103s (heart transplant or implant of heart assist system) for the first three quarters of 2007 and for DRG 001s and 002s (heart transplant or implant of heart assist system) for the fourth quarter of 2007 procedures performed in Florida. With no current heart transplant provider located in OTSA 3, all heart transplants in 2007 for OTSA 3 residents were performed as follows: Shands in OTSA 1 (21 patients or 51.22 percent of OTSA 3 applicable patients); Tampa General Hospital in OTSA 2 (13 patients or 31.71 percent of OTSA 3 applicable patients);

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11 DRG 103 (in the first three quarters of 2007) and DRGs 001 and 002 (in the fourth quarter of 2007) includes heart assist device and many of these patients had stays of less than 40.6 days, the average length of stay for these DRGs. Patients with stays of less than 10 days totaled 15 patients or 8.12 percent. Eliminating these patients results in 170 patients remaining, while there were 127 heart transplant procedures reported to the local health councils for CY 2007. OPTN data reveals 129 adult heart transplants in Florida (subtracting the 26 procedures reported as pediatric transplants) by Florida facilities to the LHC. Regardless, some variation in the patient data is to be expected.

12 Of these 41 patients, only one had a stay of less than 10 days (this one stay was reported as a nine-day stay). Twenty-one of these 41 patients were treated at Shands UF which supports the ORMC application and commits to provide tissue typing services to ORMC. Shands provided more OTSA 3 resident heart transplantations than the three remaining heart transplantation providers combined.
Mayo Clinic in OTSA 1 (four patients or 9.76 percent of applicable OTSA 3 patients) and Jackson Memorial Hospital in OTSA 4 (three patients or 7.32 percent of applicable OTSA 3 patients).

### Adult Heart Transplants by Patient Residence
**Year Ended December 31, 2007**

<table>
<thead>
<tr>
<th>Service Area</th>
<th>Transplants Performed</th>
<th>Percent of Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>40</td>
<td>21.62%</td>
</tr>
<tr>
<td>2</td>
<td>54</td>
<td>29.19%</td>
</tr>
<tr>
<td>3</td>
<td>41</td>
<td>22.16%</td>
</tr>
<tr>
<td>4</td>
<td>41</td>
<td>22.16%</td>
</tr>
<tr>
<td>Out-of-State</td>
<td>9</td>
<td>4.86%</td>
</tr>
<tr>
<td>Total</td>
<td>185</td>
<td>100.00%</td>
</tr>
</tbody>
</table>

Source: Florida Center for Health Information and Policy Analysis database, DRG 103 (Heart Transplant or Implant of Heart Assist System) and DRGs 001 Heart Transplant or Implant of Heart Assist System with MCC (major complications or co-morbidities) and 002 (same diagnosis without MCC) for applicable quarters of 2007.

Florida Hospital is projecting 18 heart transplantation procedures in year two and co-batched applicant Orlando Regional (ORHS) is projecting 12 heart transplantation procedures by year two (with four ventricular assist device [VAD] procedures by the same time to total 16 heart procedures). ORHS’s estimates are only slightly more conservative than those of Florida Hospital. Neither applicant’s estimates match the number of heart transplantsations performed in CY 2007 for OTSA 3 residents. Provided both applications were approved and provided both applicants meet their estimates in the second year of operation, 34 heart transplantation procedures (four of the 34 being VAD procedures) would be below the 41 heart transplantations reported for OTSA 3 residents in CY 2007. The transplant centers presently serving SA 3 residents should not fall below the CMS minimum annual volume requirement of 10 procedures even with approval of both projects.

Although neither applicant demonstrates that patients needing this service were unable to obtain it, the establishment of an adult heart transplant program in OTSA 3 would improve access to these services, especially geographic access. As previously referenced, more than eight in 10 heart transplant recipients from OTSA 3 in 2007, traveled, one-way, an estimated 83 to 113 miles for the service (provided they reside in the vicinity of either applicant. Access to care is projected to be slightly enhanced more by the **Adventist (CON #10026)** application, in that 18 (as opposed to 16) patients are to be served by year two. However, care to Medicaid or charity care patients is projected to be enhanced more by the **ORHS (CON #10027)** application, in that ORHS’s Medicaid and charity care commitment is greater than co-batch applicant **Adventist (CON #10026)**. While **Adventist (CON #10026)** commits to a minimum of 10 percent of heart transplant cases to Medicaid and charity cases on a combined basis, **ORHS (CON #10027)** commits to 11 conditions,
among these a combined 12 percent heart transplant program discharges to Medicaid and charity patients in each of years one and two of operation and 19 percent in year three and thereafter.

Adventist Health System/Sunbelt Inc. d/b/a Florida Hospital (CON #10026) attests to need based on a lack of heart transplant availability, quality of care, efficiency, accessibility and extent of utilization of existing health care facilities and health services in the applicant’s service area by documenting no heart transplantations performed at any OTSA 3 facility for OTSA 3 residents. This is much like co-batched applicant ORHS (CON #10027). The applicant offers some quality of care characteristics such as existing transplantation services (Attachment E – 2007 Florida Hospital Transplant Center Reports) and quality improvement procedures (Attachment V – Florida Hospital Improvement Plan). These attachments attest to the applicant’s existing commitment to the quality, effectiveness and efficiency in its current multiple transplantation (as well as non-transplantation) hospital operations. By virtue of its existing multiple transplantation programs, the applicant gives rise to certain efficiencies and cost-effectiveness: shared space; shared ICU and transplant units; shared experienced staff; shared equipment; shared laboratory and shared data collection and transplant electronic medical records system.

Orlando Regional Healthcare System, Inc. (CON #10027) attests to need based on a lack of heart transplant availability, quality of care, efficiency, accessibility and extent of utilization of existing health care facilities and health services in the applicant’s service area by documenting no heart transplantations performed at any OTSA 3 facility for OTSA 3 residents. This is much like co-batch applicant Adventist (CON #10026). The applicant states a travel time study (by Tipton Associates Incorporated [TAI]) and provides point-to-point time study results from six cities to ORMC (page #84, Table 18 – Average Drive Time Comparison). Unlike co-batched applicant Adventist (CON #10026), this applicant states the proposed care team would work closely with transplant patients and their families to help arrange for temporary housing when needed (based on Federal Poverty Level income criteria). The applicant highlights the 17 bedroom “Hubbard House” (CON #10027, page #87) as a possible housing option, with referral dependent upon factors that relate to severity of patient condition and traveling distance of family members. Affordable housing options would further contribute to greater access, particularly for the anticipated and more vulnerable patients who meet Medicaid and charity case requirements. The applicant proposes to condition that it will assist heart transplant candidates who reside outside of Orange, Osceola, Seminole and Lake
Counties in obtaining low cost temporary housing for themselves and their families while awaiting surgery and during the intensive post-transplant follow-up period.

**Quality of Care**

**Adventist Health System/Sunbelt, Inc. (CON #10026)** is already a provider of the following adult transplantation programs: bone marrow; kidney; liver and pancreas. In addition, the applicant is also authorized to operate pediatric bone marrow and pediatric kidney programs. Adventist is the sole applicant, in the current batching cycle, to seek approval to perform lung transplantation (CON #10028). Approval to serve as a heart transplantation provider would further enhance Florida Hospital’s range of transplantation services and according to the applicant would increase efficiencies.

**Orlando Regional Healthcare System, Inc. (CON #10027)** provides no transplantation service, neither adult nor pediatric and is seeking approval for a first-time transplantation service - heart transplantation. Though ORHS concedes it does not seek to be an all-encompassing transplantation institute, it believes it is well positioned and mandated to offer heart transplantation as a part of its Comprehensive Heart Failure Program at ORMC. Approval of the project would be an enhancement to ORMC’s existing heart failure program.

Need for the projects 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(3), Florida Statutes.**

**Adventist Health System/Sunbelt Inc. d/b/a Florida Hospital (CON #10026):** Agency complaint data indicates that Florida Hospital-Orlando had 17 confirmed complaints and five confirmed complaints without deficiency for the three-year period ending June 11, 2008. The applicant’s complaint history is itemized below.
Adventist and Adventist states that Florida Hospital has received numerous accreditations, including from the Joint Commission on Accreditation of Healthcare Organization (JCAHO) and the College of American Pathology Accreditation. The applicant includes the latter (Attachment S – Laboratory, Pathology, Tissue-Typing and Blood Bank Certifications) to attest to its pathology laboratory certification; however, Adventist does not include the JCAHO certification.

Adventist Health System/Sunbelt, Inc. states it has received numerous awards recognizing its high quality of care. These awards or recognitions trace from the present back to 1996. Some examples are as follows (CON #10026, pages #58-60):

- HealthGrades Award for Clinical Excellence: Florida Hospital receives the Distinguished Hospital Awards for Clinical Excellence and for Patient Safety (2008) [Attachment K].

- One of America’s Best Hospitals. Florida Hospital has been recognized eight years in a row (1999-2007) by U.S. News and World Report as “One of America’s Best Hospitals” for clinical specialties.

- Medicare Leader: Florida Hospital is the largest provider of Medicare services in the nation (2004).

• Hospital of the 21st Century: Florida Hospital Celebration Health received the Premier Patient Services Innovator Award as “The Model for Healthcare Delivery in the 21st Century.

• America’s Heart Hospital: *MSNBC* named Florida Hospital “America’s Heart Hospital”. Florida Hospital performs nearly 15,000 complex cardiac procedures each year, the most in the nation, and was the first hospital in the state to be recognized as an Accredited Chest Pain Center by The Society of Chest Pain Centers and Providers (2003).

• Top Cardiac Center: *Modern Healthcare* named Florida Hospital one of the “Top 100 Hospitals for Cardiac Care” (2002).

• Leader in Cardiac Research: Florida Hospital is one of the top hospitals in the nation for patient enrollment in cardiac research studies.

• Teaching Hospital Designation: The Administrative Board of the Council of Teaching Hospitals and Health Systems (COTH) unanimously endorsed Florida Hospital for full COTH membership, distinguishing it as one of the nation’s teaching hospitals (2006).

• Leading Family Practice Residency Program: Florida Hospital has the largest family practice residency program in Florida and one of the largest in the nation.

**Orlando Regional Healthcare System, Inc. (CON #10027):** Agency complaint data indicates that ORMC experienced 10 confirmed complaints for the three-year period ending June 11, 2008 and zero confirmed complaints without deficiency. The applicant’s complaint history is itemized below.
Hospital Confirmed Compliant Totals
Orlando Regional Healthcare System (Orlando Regional Medical Center)
June 11, 2005 through June 11, 2008

<table>
<thead>
<tr>
<th>Complaint Category</th>
<th>Confirmed Total = 10</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chapter 394 - Baker Act</td>
<td>1</td>
</tr>
<tr>
<td>Discharge Planning</td>
<td>2</td>
</tr>
<tr>
<td>Falls/Injury</td>
<td>1</td>
</tr>
<tr>
<td>Inappropriate Discharge</td>
<td>1</td>
</tr>
<tr>
<td>Lack of Assessment</td>
<td>1</td>
</tr>
<tr>
<td>Lack of Supervision</td>
<td>1</td>
</tr>
<tr>
<td>Nursing Service</td>
<td>2</td>
</tr>
<tr>
<td>Patient Rights</td>
<td>1</td>
</tr>
</tbody>
</table>

Source: AHCA Complaint Review Records

ORHS provides (Tab 11 – Quality Materials) its 2005-2008 Joint Commission of Accreditation of Healthcare Organizations (JCAHO) certification. It further states its mission, vision and values. ORHS also identifies what it calls “Milestones” (CON #10027, pages #90-95). These awards, recognitions or major events in ORMC and sister facility histories trace from 2007 back to 1918. Some of the more prominent milestones over approximately the last eight are as follows:

- M.D. Anderson Cancer Center Orlando receives accreditation from the Accreditation Council of Graduate Medical Education, making it Central Florida’s first Hematology/Oncology fellowship program (2007).

- ORMC’s AirCare Team adds a second helicopter based at South Lake Hospital and celebrates the safe transport of its 21,000th patient (2007).

- M.D. Anderson Cancer Center Orlando receives its first ever peer-review grant from the Florida Department of Health to intensify its radiation therapy research focusing on lung, prostate, breast and spinal tumors (2007).

- Winnie Palmer Hospital celebrates its first anniversary and the birth of more than 14,000 babies, making the hospital’s Labor and Delivery Unit the busiest in Florida and one of the busiest in the nation (2007).

- M.D. Anderson Cancer Center Orlando performs the first thoracic surgery in Central Florida using the da Vinci Surgical System. The robotic system is used for gynecologic and prostate surgeries (2007).
• ORMC is one of only three facilities in the country to participate in a clinical study to determine the effectiveness of using a 64-slice Coronary Computer Tomography Angiography in the Emergency Department as a non-invasive method for quickly diagnosing coronary artery disease (2007).

• Orlando Regional Stroke Center at ORMC is designated a primary stroke center by the Agency (2006).

• The Thoracic Care Center opens at M.D. Anderson Cancer Center Orlando (2006).

• The Congenital Heart Institute (CHI) at Arnold Palmer Hospital became the only implant center in Florida for a national migraine study. As a participant in the study, CHI implanted the first device to close a tiny hole in the heart believed to be a cause of migraines (2006).

• Orlando Regional Lucerne Hospital successfully integrates the Brain Injury Rehabilitation Center with its rehabilitation program at the Orlando Regional Rehabilitation Institute, the only facility of its kind in Central Florida to offer inpatient brain and spinal cord injury care (2005).

• M.D. Anderson Cancer Center Orlando receives the “Best Hospital-Based Outpatient Services” designation by Florida Medical Business (2001).

ORHS also references quality measures in its application (Tab 11 – Quality Materials/Performance Improvement Plan and Utilization Measurement Plan).

ORHS further states it engages in numerous innovations not only in cancer research through M.D. Anderson Cancer Center Orlando but also in cardiac medicine. Jointly with ORMC and Arnold Palmer Hospital, ORHS states some 203 institutional review board approved and funded studies, 17 cardiac-specific studies and seven national clinical studies related to cardiovascular services. ORHS also plans to participate as a clinical site for the National Heart, Lung and Blood Institute of the National Institutes of Health VIRGO (Variation in Recovery: Role of Gender on Outcomes in Young AIM Patients). The principal researcher, Harlan Krumholtz, MD, is identified by ORHS as an internationally renowned cardiovascular treatment researcher who is studying improved health care outcomes for young female heart attack patients. Per the applicant, young female heart attack patients have poorer health
outcomes than their male counterparts and the study is designed to address this health disparity. ORHS also highlights its participation in graduate medical education (Tab 13 – Medical Education/ Graduate Medical Education Annual Report 2007). In addition, ORHS shares a list of schools with corresponding primarily clinical (but also some non-clinical) programs with whom ORHS has affiliation agreements (Tab 13 – Medical Education/Current Affiliation Agreements, Allied Health Personnel). As one of seven statutory teaching hospitals in the state, ORMC emphasizes its commitment and long-standing association with continuing medical education, training and cutting-edge efforts to address health disparities in a wide range of health fields.

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(4) Florida Statutes

Adventist Health System/Sunbelt, Inc. (CON #10026): The financial impact of the project will include the project cost of $532,725 and year two incremental operating costs of $4,413,136.

The audited financial statements of the applicant, for the periods ending December 31, 2006 and 2007 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 3.4 is well above average and indicates current assets are over three times current liabilities, a strong position. The ratio of cash flows to current liabilities of 0.6 is slightly above average, an adequate position. The working capital (current assets less current liabilities) of $1.7 billion 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 1.1 indicates long-term debt is greater than equity. Although the teaching hospital group is highly leveraged, this is well above average and a weak position. The ratio of cash flow to assets of 8.4 percent is slightly below average and an adequate position. The most recent year had revenue in excess of expenses of $281.8 million, which resulted in an operating margin of 7.3 percent. Overall, the applicant has a slightly weak but adequate long-term position. (See Table below).
**Capital Requirements:**
Schedule 2 indicates the applicant has $1 billion in capital projects, including a proposed adult lung transplant program (CON #10028) in the current batching cycle.

**Available Capital:**
The applicant indicates that funding for this project and the entire capital budget will come from a combination of cash reserves, cash from operations, proceeds from prior bond issues, and other financing methods such as tax-exempt bond issues. Operating cash flows for the most recent year was $434.2 million. As discussed above working capital is $1.7 billion. In addition, of the $147.2 million of assets limited as to use (see Table below) $135.1 million is designated as construction and capital replacement funds (these funds are not directly associated with the applicant’s heart transplantation proposal). The applicant also has access to a $1.9 billion revolving note which is available for general corporate needs including working capital, capital expenditures, and acquisitions.

**Staffing:**
As an existing provider of multiple transplant services, the applicant believes that most of the technical and clinical expertise along with supporting infrastructure is already in place at Florida Hospital. According to Schedule 6A, the applicant predicts 31.4 incremental FTEs for this project by June 30, 2013.

**Conclusion:**
The applicant appears to have the financial resources necessary to fund this project and all capital projects.
**ORLANDO REGIONAL HEALTHCARE SYSTEM, INC. (CON #10027):** The financial impact of the project will include the project cost of $1,781,632 and year two incremental operating costs of $3,615,786.

The audited financial statements of the applicant, for the periods ending September 30, 2006 and 2007 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:**
For the period ending September 30, 2007, the applicant’s current ratio of 2.9 is well above average and indicates current assets are nearly three times current liabilities, a strong position. The ratio of cash flows to current liabilities of 0.9 is above average, a good position. The working
capital (current assets less current liabilities) of $344 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 1.1 indicates long-term debt is greater than equity. Although the teaching hospital group is highly leveraged, this is well above average and a weak position. The ratio of cash flow to assets of 9.3 percent is above average and a good position. 2007 had revenue in excess of expenses of $38.5 million, which resulted in an operating margin of 2.7 percent. Overall, the applicant has a good long-term position. (See Table below).

**Capital Requirements:**
Schedule 2 indicates the applicant currently has $227.3 million in total capital projects, including costs associated with this project, which are approved, underway, or are planned for development.

**Available Capital:**
The applicant indicates that it intends to fund this project from cash. Operating cash flows for the most recent year was $170.1 million. As discussed above, working capital is $344 million. In addition, the applicant lists assets limited as to use totaling $462 million which are primarily composed of assets held by trustees under bond indenture agreements, and designated assets set aside by the Corporation’s Board of Directors for future capital investments and malpractice claims. Of these restricted assets, the Board of Directors retains control of, and may use designated assets for, other purposes. The applicant also has $10 million available under a line of credit with a local bank, which as of the balance sheet date had not been drawn upon.

**Staffing:**
Currently, the applicant does not provide any transplant services. However, ORHS facilities have staff on-hand with expertise and experience regarding heart transplantation and related cardiovascular skill and know-how. According to Schedule 6A, the applicant predicts 16.0 incremental FTEs for this project by March 31, 2012.
CON Action Number: 10026 & 10027

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Current Assets</td>
<td>$524,341,000</td>
<td>$470,290,000</td>
</tr>
<tr>
<td>Cash and Current Investment</td>
<td>$230,072,000</td>
<td>$200,151,000</td>
</tr>
<tr>
<td>Assets Limited as to Use</td>
<td>$461,960,000</td>
<td>$316,680,000</td>
</tr>
<tr>
<td>Total Assets</td>
<td>$1,833,103,000</td>
<td>$1,561,184,000</td>
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<tr>
<td>Current Liabilities</td>
<td>$180,341,000</td>
<td>$163,208,000</td>
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<tr>
<td>Total Liabilities</td>
<td>$1,035,700,000</td>
<td>$870,697,000</td>
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<tr>
<td>Net Assets</td>
<td>$797,403,000</td>
<td>$690,487,000</td>
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<tr>
<td>Total Revenues</td>
<td>$1,420,906,000</td>
<td>$1,266,522,000</td>
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<td>Interest Expense</td>
<td>$29,670,000</td>
<td>$28,864,000</td>
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<tr>
<td>Excess of Revenues Over Expenses</td>
<td>$38,538,000</td>
<td>$30,370,000</td>
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<tr>
<td>Cash Flow from Operations</td>
<td>$170,119,000</td>
<td>$103,612,000</td>
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<tr>
<td>Working Capital</td>
<td>$344,000,000</td>
<td>$307,082,000</td>
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</table>

**FINANCIAL RATIOS**

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Current Ratio (CA/CL)</td>
<td>2.9</td>
<td>2.9</td>
</tr>
<tr>
<td>Cash Flow to Current Liabilities (CFO/CL)</td>
<td>0.9</td>
<td>0.6</td>
</tr>
<tr>
<td>Long-Term Debt to Net Assets (TL-CL/NA)</td>
<td>1.1</td>
<td>1.0</td>
</tr>
<tr>
<td>Times Interest Earned (NPO+Int/Int)</td>
<td>2.3</td>
<td>2.1</td>
</tr>
<tr>
<td>Net Assets to Total Assets (TE/TA)</td>
<td>43.5%</td>
<td>44.2%</td>
</tr>
<tr>
<td>Operating Margin (ER/TR)</td>
<td>2.7%</td>
<td>2.4%</td>
</tr>
<tr>
<td>Return on Assets (ER/TA)</td>
<td>2.1%</td>
<td>1.9%</td>
</tr>
<tr>
<td>Operating Cash Flow to Assets (CFO/TA)</td>
<td>9.3%</td>
<td>6.6%</td>
</tr>
</tbody>
</table>

**Conclusion:**
The applicant appears to have the financial resources necessary to fund this project and all capital projects.

d. **What is the immediate and long-term financial feasibility of the proposal? ss. 408.035(6), Florida Statutes.**

A comparison of the applicants’ 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
CON Action Number: 10026 & 10027

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, 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 2006; the applicant will be compared to the hospitals in peer group 9 (Family Practice Teaching Hospital Group). The Agency also evaluated the projected cost of the 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 2006. Peer Group 9 has a total of five facilities including the applicant. Per diem rates are projected to increase by an average of 3.4 percent per year. Inflation adjustments were based on the new CMS Market Basket, 1st 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.

**Adventist Health System/Sunbelt, Inc. (CON# 10026):** Projected net revenue per adjusted patient day (NRAPD) of $2,242 in year one is between the control group median and highest values of $1,977 and $2,249 in year one. 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. The NRAPD of $2,311 in year two is slightly above the highest value in the peer group of $2,310. (See Table below). The applicant’s NRAPD in fiscal year two006 was reported as $2,032, which was the highest in the control group. The difference in the NRAPD reported in 2006 and the year two projected NRAPD of $2,311 results in an average compound annual increase of approximately 3.3 percent. This level of increase is consistent with the inflation percentage outlined in the CMS Market Basket, 1st Quarter, 2008, index. Net revenues appear to be reasonable.

Projected cost per adjusted patient day of $2,138 in year one and $2,198 in year two are above the control group highest values of $2,128 in year one and $2,185 in year two. The highest level is generally viewed as the
practical upper limit on efficiency. It should be noted that the applicant had the highest cost in the peer group. (See Table below). The applicant’s CAPD in calendar year two006 was reported as $1,922. The difference in the CAPD reported in 2006 and the year two projected CAPD of $2,198 results in an average compound annual increase of approximately 3.4 percent. This level of increase is consistent with the inflation percentage outlined in the CMS Market Basket, 1st Quarter, 2008, index. CAPD appear to be reasonable.

The projections for the transplant program include only the incremental cost of the program. The year two projected incremental cost per patient day (CPD) for the heart transplant patients is $9,081. The incremental CPD falls above the control group highest value of $6,095. The projected cost appears to be overstated when compared to the group. Overstating costs in a financial projection is considered a conservative assumption and is therefore reasonable.

The year two operating profit for the hospital of $84.1 million computes to an operating margin per adjusted patient day of $113 which is consistent with the applicant’s 2006 operating margin. (Florida Hospital had the largest operating margin in the peer group). 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 and is not likely to have a material impact on the existing operations of the applicant.
### ADVENTIST HEALTH SYSTEM/ SUNBELT, INC.

#### CON #10026

**2006 DATA Peer Group 9**

<table>
<thead>
<tr>
<th>Activity</th>
<th>Year Two Activity</th>
<th>Year Two Values Adjusted for Inflation</th>
<th>Highest</th>
<th>Median</th>
<th>Lowest</th>
</tr>
</thead>
<tbody>
<tr>
<td>Routine Services</td>
<td>4,315,043,276</td>
<td>5,790</td>
<td>1,339</td>
<td>948</td>
<td>399</td>
</tr>
<tr>
<td>Inpatient Ambulatory</td>
<td>0</td>
<td>0</td>
<td>264</td>
<td>202</td>
<td>70</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</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Outpatient Services</td>
<td>1,746,466,128</td>
<td>2,343</td>
<td>2,347</td>
<td>1,750</td>
<td>1,692</td>
</tr>
<tr>
<td>Total Patient Services Rev.</td>
<td>6,061,509,404</td>
<td>8,133</td>
<td>7,421</td>
<td>6,089</td>
<td>5,543</td>
</tr>
<tr>
<td>Other Operating Revenue</td>
<td>6,064,386</td>
<td>8</td>
<td>81</td>
<td>24</td>
<td>18</td>
</tr>
<tr>
<td><strong>Total Revenue</strong></td>
<td>6,067,573,790</td>
<td>8,141</td>
<td>7,449</td>
<td>6,170</td>
<td>5,562</td>
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<tr>
<td>Deductions from Revenue</td>
<td>4,345,417,384</td>
<td>5,831</td>
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<tr>
<td><strong>Net Revenues</strong></td>
<td>1,722,156,406</td>
<td>2,311</td>
<td>2,310</td>
<td>2,030</td>
<td>1,710</td>
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</table>

#### Expenses

<table>
<thead>
<tr>
<th>Activity</th>
<th>Year</th>
<th>Highest</th>
<th>Median</th>
<th>Lowest</th>
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</thead>
<tbody>
<tr>
<td>Routine</td>
<td>309,828,097</td>
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<td>408</td>
<td>293</td>
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<tr>
<td>Ancillary</td>
<td>514,663,726</td>
<td>691</td>
<td>802</td>
<td>663</td>
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<tr>
<td>Ambulatory</td>
<td>85,876,765</td>
<td>115</td>
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<tr>
<td>Total Patient Care Cost</td>
<td>910,368,588</td>
<td>1,222</td>
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<tr>
<td>Admin. and Overhead</td>
<td>566,867,518</td>
<td>761</td>
<td>0</td>
<td>0</td>
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<tr>
<td>Property</td>
<td>160,801,006</td>
<td>216</td>
<td>0</td>
<td>0</td>
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<tr>
<td>Total Overhead Expense</td>
<td>727,668,524</td>
<td>976</td>
<td>955</td>
<td>855</td>
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<tr>
<td>Other Operating Expense</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td><strong>Total Expenses</strong></td>
<td>1,638,037,112</td>
<td>2,198</td>
<td>2,185</td>
<td>1,965</td>
</tr>
</tbody>
</table>

#### Patient Days

- Total Patient Days: 530,008
- Adjusted Patient Days: 745,268
- Total Bed Days Available: 667,220
- Percent Occupancy: 79.44%

#### Payer Type

<table>
<thead>
<tr>
<th>Payer Type</th>
<th>Patient Days</th>
<th>% Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Self Pay</td>
<td>32,901</td>
<td>6.2%</td>
</tr>
<tr>
<td>Medicaid</td>
<td>71,725</td>
<td>13.5%</td>
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<tr>
<td>Medicare HMO</td>
<td>18,880</td>
<td>3.6%</td>
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<tr>
<td>Medicare HMO</td>
<td>211,537</td>
<td>39.9%</td>
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<td>Insurance</td>
<td>18,112</td>
<td>3.4%</td>
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<tr>
<td>HMO/PPO</td>
<td>135,003</td>
<td>25.5%</td>
</tr>
<tr>
<td>Other</td>
<td>15,245</td>
<td>2.9%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>530,008</td>
<td>100%</td>
</tr>
</tbody>
</table>
Orlando Regional Healthcare System, Inc. (CON #10027): Projected net revenue per adjusted patient day (NRAPD) of $2,226 in year one and $2,302 in year two is between the control group median and highest values of $1,825 and $2,410 in year one and $1,874 and $2,475 in year two. With net revenues per adjusted patient day falling between the median and highest values, the facility is expected to consume healthcare resources in proportion to the services provided. (See Table below).

The applicant’s NRAPD in fiscal year 2006 was reported as $1,927, which equaled the control group median. The difference in the NRAPD reported in 2006 and the year two projected NRAPD of $2,302 results in an average compound annual increase of approximately 4.03 percent. This level of increase is well above both the three percent rate indicated in the notes to the projections and the inflation percentage outlined in the CMS Market Basket, First Quarter 2008, index. Had the applicant used the rate indicated in the notes of three percent then the applicant would have fallen closer to the median level in the peer group. Net revenues appear to be slightly overstated, but reasonable.

Projected cost per adjusted patient day of $2,159 in year one and $2,226 in year two falls between the control group median and highest values of $1,814 and $2,554 in year one and $1,863 and $2,623 in year two. The highest level is generally viewed as the practical upper limit on efficiency. With anticipated cost between the median and highest value in the control group, the year two cost appear feasible. (See Table below).

The applicant’s CAPD in calendar year 2006 was reported as $1,892. The difference in the CAPD reported in 2006 and the year two projected CAPD of $2,226 results in an average compound annual increase of approximately 3.69 percent. This level of increase is well above both the three percent rate indicated in the notes to the projections and the inflation percentage outlined in the CMS Market Basket, First Quarter, 2008 index. While CAPD appears to be overstated, over stating costs in a financial projection is considered a conservative approach and is therefore reasonable.
CON Action Number:  10026 & 10027

The projections for the transplant program include only the incremental cost of the program. The year two projected incremental cost per patient day (CPD) for the heart transplant patients is $5,107. The incremental costs do not include shared fixed cost like overhead and property.

Therefore, the Agency added $612 per patient day (from Schedule 8) for overhead and property cost to estimate the fully allocated CPD of approximately $5,719 in year two for the transplant program. The estimated fully allocated CPD fall between the control group median and highest values of $6,259 and $5,403. The cost appears reasonable when compared to the control group.

The projected year two operating profit for the hospital of $44.8 million computes to an operating margin per adjusted patient day of $76 that falls between the peer group median and highest values of $12 and $128. The profit may be slightly overstated since revenue is projected to increase at a faster rate than expense; however, the overall profitability appears reasonable. This project is immaterial to the overall operations to 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 and is not likely to have a material impact on the existing operations of the applicant.
## ORLANDO REGIONAL HEALTHCARE SYSTEM, INC.

### CON #10027

**2006 DATA Peer Group 8**

<table>
<thead>
<tr>
<th></th>
<th>Mar-11</th>
<th>YEAR TWO ACTIVITY</th>
<th>YEAR TWO PER DAY</th>
<th>VALUES ADJUSTED FOR INFLATION</th>
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<tr>
<td></td>
<td></td>
<td></td>
<td>Highest</td>
<td>Median</td>
</tr>
<tr>
<td>ROUTINE SERVICES</td>
<td>635,222,113</td>
<td>1,072</td>
<td>1,172</td>
<td>697</td>
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<tr>
<td>INPATIENT AMBULATORY</td>
<td>0</td>
<td>0</td>
<td>187</td>
<td>103</td>
</tr>
<tr>
<td>INPATIENT SURGERY</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>INPATIENT ANCILLARY SERVICES</td>
<td>2,545,111,451</td>
<td>4,296</td>
<td>5,118</td>
<td>3,365</td>
</tr>
<tr>
<td>OUTPATIENT SERVICES</td>
<td>1,554,555,223</td>
<td>2,624</td>
<td>2,451</td>
<td>1,533</td>
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<tr>
<td>TOTAL PATIENT SERVICES REV.</td>
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<td>7,993</td>
<td>7,701</td>
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<td>OTHER OPERATING REVENUE</td>
<td>31,232,069</td>
<td>53</td>
<td>624</td>
<td>58</td>
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<td><strong>TOTAL REVENUE</strong></td>
<td>4,766,120,856</td>
<td>8,045</td>
<td>7,738</td>
<td>6,083</td>
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<td>DEDUCTIONS FROM REVENUE</td>
<td>3,402,381,562</td>
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<td><strong>NET REVENUES</strong></td>
<td>1,363,739,294</td>
<td>2,302</td>
<td>2,475</td>
<td>1,874</td>
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### EXPENSES

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<tr>
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<th>Routine</th>
<th>Ancillary</th>
<th>Ambulatory</th>
<th>TOTAL PATIENT CARE COST</th>
<th>Admin. and Overhead</th>
<th>Property</th>
<th>TOTAL OVERHEAD EXPENSE</th>
<th>OTHER OPERATING EXPENSE</th>
<th>TOTAL EXPENSES</th>
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<tr>
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<td>281,899,942</td>
<td>476</td>
<td>0</td>
<td>752,560,183</td>
<td>386,793,003</td>
<td>179,607,297</td>
<td>566,400,300</td>
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<td>1,318,960,483</td>
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<td>470,660,241</td>
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<td>1,433</td>
<td>653</td>
<td>303</td>
<td>1,039</td>
<td>0</td>
<td>2,226</td>
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<tr>
<td>TOTAL PATIENT CARE COST</td>
<td></td>
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<td></td>
<td></td>
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<td>ADMIN. AND OVERHEAD</td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TOTAL OVERHEAD EXPENSE</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>OTHER OPERATING EXPENSE</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TOTAL EXPENSES</td>
<td>1,318,960,483</td>
<td>2,226</td>
<td></td>
<td>2,623</td>
<td>1,863</td>
<td>1,657</td>
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### OPERATING INCOME

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<tr>
<th></th>
<th>44,778,811</th>
<th>76</th>
<th>128</th>
<th>12</th>
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<tr>
<td>PATIENT DAYS</td>
<td>395,304</td>
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<tr>
<td>ADJUSTED PATIENT DAYS</td>
<td>592,412</td>
<td></td>
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<tr>
<td>TOTAL BED DAYS AVAILABLE</td>
<td>584,000</td>
<td></td>
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<tr>
<td>ADJ. FACTOR</td>
<td>0.6673</td>
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<tr>
<td>TOTAL NUMBER OF BEDS</td>
<td>1,600</td>
<td></td>
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<tr>
<td>PERCENT OCCUPANCY</td>
<td>67.69%</td>
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### PAYER TYPE

<table>
<thead>
<tr>
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<th>% TOTAL</th>
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<tbody>
<tr>
<td>PATIENT DAYS</td>
<td></td>
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<tr>
<td>SELF PAY</td>
<td>6.3%</td>
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<tr>
<td>MEDICAID</td>
<td>18.4%</td>
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<td>MEDICAID HMO</td>
<td>4.0%</td>
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<tr>
<td>MEDICARE</td>
<td>24.4%</td>
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<tr>
<td>MEDICARE HMO</td>
<td>6.4%</td>
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<tr>
<td>INSURANCE</td>
<td>5.3%</td>
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<tr>
<td>HMO/PPO</td>
<td>31.8%</td>
</tr>
<tr>
<td>OTHER</td>
<td>3.4%</td>
</tr>
<tr>
<td>TOTAL</td>
<td>100%</td>
</tr>
</tbody>
</table>
e. Will the proposed project foster competition to promote quality and cost-effectiveness? ss. 408.035(7), Florida Statutes.

Adventist Health System/Sunbelt, Inc. (CON #10026) and Orlando Regional Healthcare System, Inc. (CON #10027): 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 2006, 46.9 percent of the 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.
CON Action Number: 10026 & 10027

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(8), Florida Statutes.

Adventist Health System/Sunbelt, Inc. (CON# 10026) proposes no construction or renovation for the project.

Orlando Regional Healthcare System, Inc. (CON #10027): The facility would use three existing operating rooms which are currently used for open heart surgeries. All spaces required for patients, staff and support services are existing and appear to be adequate.

The only construction related activities involved in the project would be to verify that the existing HVAC system provides the air flow and air changes required by code. Following the attempt to verify compliance of the HVAC system some minor corrective modifications may be required. The construction cost data and schedule prepared by the facility are reasonable.

The architectural review of the application shall not be construed as an in-depth effort to determine complete compliance with all applicable codes and standards. The final responsibility for facility compliance ultimately rests with the owner.

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(9), Florida Statutes.

The following table provides an indication of the applicant’s commitment to charity and Medicaid, with comparison to the district, based on Fiscal Year (FY) 2006 Actual Data prepared by AHCA:

<table>
<thead>
<tr>
<th>Applicant</th>
<th>Medicaid &amp; Medicaid HMO Days</th>
<th>Gross Charity Percentage of Charges</th>
<th>Combined Medicaid &amp; Charity Care</th>
</tr>
</thead>
<tbody>
<tr>
<td>Florida Hospital</td>
<td>16.8%</td>
<td>6.2%</td>
<td>23.0%</td>
</tr>
<tr>
<td>Orlando Regional Healthcare System, Inc.</td>
<td>23.0%</td>
<td>4.5%</td>
<td>27.5%</td>
</tr>
<tr>
<td>District 7 Average</td>
<td>16.4%</td>
<td>4.5%</td>
<td>20.8%</td>
</tr>
</tbody>
</table>

Source: Fiscal Year 2006 AHCA Actual Hospital Budget Data.
Both providers have a history of providing care to Medicaid and charity care patients with both facilities exceeding the combined Medicaid and charity care district average.

**Adventist Health System/Sunbelt, Inc. (CON #10026)** indicates that it has a consistent history of serving the needs of the Medicaid population and the medically indigent. However, unlike co-batch applicant ORHS (CON #10026), Adventist does not claim it will provide care to patients regardless of ability to pay. In its application (CON #10026, page #62), Adventist states the following for 2007, among its seven Florida Hospital campuses:

- Provision of more than 17,000 admissions to Medicaid inpatients.

- Inpatient and outpatient gross revenues to Medicaid patients of approximately $647,684,000.

- Provision of more than $379,438,000 in charity care or 7.4 of total gross revenue to patients who were medically indigent.

Projected revenues on the applicant’s Schedule 7A indicate that operating year one would provide a payer mix of six percent self-pay and 18 percent combined Medicaid and Medicaid HMO. Three percent is “other payers”. A total of 24 percent is reached when self-pay, Medicaid and Medicaid HMO are combined. These percentages are not indicated to change for years two or three of operations. Year one indicates a charity care deduction from revenue of $376,784,953 increasing to $395,774,915 for year two and $415,721,971 for year three. In comparison to co-batched applicant ORHS, Adventist proposes to realize higher charity deductions from revenue for each of the three years referenced in Schedule 7A (through December 31, 2011).

As previously stated, this applicant proposes to condition approval to a minimum of 10 percent of heart transplant cases being provided to Medicaid and charity cases on a combined basis.

**Orlando Regional Healthcare System, Inc. (CON #10027)** declares it will continue to extend services to all patients in need of care regardless of ability to pay. Co-batch applicant Adventist (CON #10026) does not make this claim. ORHS also states that Medicaid-sponsored Children’s Medical Services (CMS), self-pay and indigent patients are currently served in larger proportions by ORHS.
Projected revenues on the applicant’s Schedule 7A indicate that operating year one would provide a payer mix of six percent self-pay and 22 percent combined Medicaid and Medicaid HMO. Three percent is “other payers”. A total of 28 percent is reached when self-pay, Medicaid and Medicaid HMO are combined. These percentages are not indicated to change for years two or three of operations. Year one indicates a charity care deduction from revenue of $223,691,601 increasing to $232,328,449 for year two and $238,014,613 for year three. In comparison to co-batched applicant Adventist, ORHS proposes to realize lower charity deductions from revenue for each of the three years referenced in Schedule 7A (through March 31, 2012).

As previously stated, this applicant proposes to condition approval to a combined 12 percent of its heart transplant program discharges to Medicaid and charity patients in years one and two of operation and 19 percent in year three and thereafter.

F. SUMMARY

**Adventist Health System/Sunbelt, Inc. (CON #10026)** proposes the establishment of an adult heart transplant program in Organ Transplant Service Area (OTSA) 3 and is projected to have total project costs of $532,725. There are no construction or renovation costs. The applicant also seeks to establish an adult lung transplant program (CON #10028). Adventist presently has six (four adult and two children’s) organ transplantation programs.

**Orlando Regional Healthcare System, Inc. (CON #10027)** proposes the establishment of an adult heart transplant program in Organ Transplant Service Area (OTSA) 3 and is projected to have total project costs of $1,781,632, with 12,600 gross square feet (GSF) of renovated space. Though ORHS concedes it does not seek to be an all-encompassing transplantation institute, it believes it is well positioned and mandated to offer heart transplantation as a part of its comprehensive heart failure program at ORMC.

_in weighing and balancing the review criteria, the following relevant factors are noted:_
Fixed Need Pool

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

There are presently no adult heart transplant programs in OTSA 3. 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. TransLife, the organ procurement organization (OPO) that serves OTSA 3, supports both projects.

**Adventist Health System/Sunbelt, Inc. (CON #10026)** estimates that by the second year of operation the program will complete 18 heart transplants. In year one, the applicant estimates 12 of the procedures. Florida Hospital performs other transplantation procedures and provides evidence that patients in need of heart transplantation could be better served by a heart transplantation program local to OTSA 3 at Florida Hospital, as compared to the current situation which is 100 percent out migration to other heart transplant facilities in other OTSAs in the state.

**Orlando Regional Healthcare System, Inc. (CON #10027)** estimates that by the second year of operation the program will complete 12 heart transplants (and an additional four ventricular assist device [VAD] procedures, totaling 16 procedures in all). In year one, the applicant estimates six of the procedures (and an additional two VAD procedures, totaling eight procedures in all). ORHS facilities currently provide no transplant services and considers the proposal to be an enhancement of its Comprehensive Heart Failure Program. ORHS provides evidence that patients in need of heart transplantation could be better served by a heart transplantation program local to OTSA 3 at ORMC, as compared to the current situation which is 100 percent out migration to other heart transplant facilities in other OTSAs in the state. ORMC is a statutory teaching hospital and a Level 1 trauma center. ORHS claims it will serve all those who present for care regardless of ability to pay.

Need, as documented by 100 percent out migration, 41 heart transplantations for OTSA 3 residents in 2007 and a second year total heart transplantation estimate of 30 (18 for Florida Hospital and 12 planned procedures (with four additional VADs to total 16 procedures at Orlando Regional)), suggests both CON #10026 and CON #10027 can be supported.
The applicants (CONs #10026 and CON #10027) combined projected volume (18 and 12 respectively) for year two does not exceed the 41 residents of SA 3 who received heart transplants in other Florida transplant facilities during CY 2007. The transplant centers presently serving SA 3 residents should not fall below the CMS minimum annual volume requirement of 10 procedures even with approval of both projects.

**Quality of Care**

Both applicants have reasonably demonstrated that they meet the rule requirements per Chapter 59C-1.044, Florida Administrative Code, with regard to the provision of quality of care for transplant programs. Both applicants demonstrated that quality of care measures and appropriate policies and protocols are in place to accommodate the proposed projects. Both applicants’ projections meet the CMS minimum annual volume requirement for 10 procedures.

**Adventist Health System/Sunbelt, Inc. (CON #10026)** experienced 17 confirmed complaints and five complaints without deficiency, totaling 22 complaints in all, for the three-year period ending June 11, 2008. Aventist’s program will be part of its multi-organ transplantation center.

**Orlando Regional Healthcare System, Inc. (CON #10027)** experienced 10 confirmed complaints and had none categorized as confirmed without deficiency, for the three-year period ending June 11, 2008. ORHS intends to offer heart transplantation as a part of its comprehensive heart failure program.

**Cost/Financial Analysis**

**Adventist Health System/Sunbelt, Inc. (CON #10026):** The applicant has a good short-term position, a weak but adequate long-term position and overall appears to have the financial resources necessary to fund this project and all capital projects.

**Orlando Regional Healthcare System, Inc. (CON #10027):** The applicant has a good short-term and a good long-term position and overall appears to have the financial resources necessary to fund this project and all capital projects.

**Both** projects appear to be financially feasible and are not likely to have a material impact on the existing operations of the applicants.
Medicaid/Charity Care Commitment

Both applicants have a history of providing care to Medicaid and charity care patients. Both have agreed to condition award of the CON upon providing a given percentage to the medically indigent (Medicaid and charity cases).

Adventist Health System/Sunbelt, Inc. (CON #10026) proposes a minimum combined 10 percent Medicaid and charity care condition.

Orlando Regional Healthcare System, Inc. (CON #10027) proposes a combined 12 percent of its heart transplant program discharges to Medicaid and charity care patients in each of years one and two of operation and 19 percent in year three and thereafter.

Architectural Analysis

Adventist Health System/Sunbelt, Inc. (CON #10026) proposes no construction or renovation associated with this project.

Orlando Regional Healthcare System, Inc. (CON #10027): Some minor corrective modifications may be required. The construction cost data and schedule prepared by the facility are reasonable.

G. RECOMMENDATION

Approve CON #10026 to establish an adult heart transplantation program in Organ Transplant Service Area 3, involving a project cost of $532,725. There is no construction or renovation associated with the project.

CONDITION: A minimum of 10 percent of heart transplant cases will be provided to Medicaid and charity care cases on a combined basis.
CON Action Number: 10026 & 10027

Approve CON #10027 to establish an adult heart transplantation program in Organ Transplant Service Area 3, involving a project cost of $1,781,632. The project involves 12,600 gross square feet of renovation.

CONDITIONS:

(1) The ORHS heart transplant program will be operational within six months of final CON award.

(2) The ORHS heart transplant program will pursue a Medicare participation agreement as soon as eligible. In conjunction with this effort, ORMC will provide 10 heart transplantation surgeries to Medicare enrollees without charge at an estimated ORHS expense associated with this charity care of $2,038,000.

(3) Once certified for Medicare participation, the ORHS heart transplant program will comply at all times with Medicare conditions of participation, including the requirement of providing a minimum average annual volume of 10 heart transplants per year and meeting Medicare specified transplant patient survival standards.

(4) ORHS will discontinue operation of the heart transplant program if Medicare certification should lapse. Heart transplant programs can continue to operate following the loss of Medicare certification and some do. ORHS would not.

(5) ORHS will provide a combined 12 percent of its heart transplant program discharges to Medicaid and charity patients in each of years one and two of operation and 19 percent in year three and thereafter.

(6) ORHS will enter into a written affiliation agreement with the University of Florida College of Medicine, establishing a cardio-thoracic surgery fellowship fully funded by ORHS beginning within 15 months after initiation of program operations.

(7) ORHS will expand its collaboration with the University of Central Florida in simulation research and training to include heart assist device implantation and heart transplantation surgery.

(8) ORHS will expand its current array of translational research programs to include clinical studies to enhance the design and use of implantable heart assist devices.
(9) ORHS will assist heart transplant candidates who reside outside of Orange, Osceola, Seminole and Lake Counties in obtaining low cost temporary housing for themselves and their families while awaiting surgery and during the intensive post-transplant follow-up period.

(10) ORHS will assure that all heart transplant patients, family caregivers and referring community physicians have timely access to the heart transplant care team via a full range of face-to-face interaction, direct telephone and electronic communication options throughout the course of care and transplant candidates without a personal computer will be provided one without charge and robust security measures will be in place to preserve patient confidentiality at all times in accordance with HIPPA requirements.

(11) ORHS will acquire, install and implement a dedicated suite of software applications dedicated to heart transplantation information management. This support system will be capable of meeting the program’s patient care, quality and outcome measurement, reporting and research requirements.
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: ______________________

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

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Jeffery N. Gregg
Chief, Bureau of Health Facility Regulation