

**STATE AGENCY ACTION REPORT**  
**ON APPLICATION FOR CERTIFICATE OF NEED**

**A. PROJECT IDENTIFICATION**

1. Applicant/CON Action Number

**Adventist Health System/Sunbelt, Inc.**  
**d/b/a Florida Hospital/CON #10488**  
900 Hope Way  
Altamonte Springs, Florida 32714

Authorized Representative: Diane Godfrey  
AHS/Florida Hospital-  
Regulatory Administration  
(407) 303-9808

2. Service District/Subdistrict

Organ Transplantation Service Area (OTSA) 3: District 7 (Brevard, Orange, Osceola and Seminole Counties), District 9 (Indian River, Martin, Okeechobee and St. Lucie Counties, excluding Palm Beach County), District 3 (Lake County only) and District 4 (Volusia County only)

**B. PUBLIC HEARING**

A public hearing was not held or requested regarding the proposed project.

**Letters of Support**

**Adventist Health System/Sunbelt, Inc. d/b/a Florida Hospital (CON application #10488)** includes 13 unduplicated letters of support in Exhibit O of the application. Nine letters of support were submitted by physicians with seven indicating a direct Adventist Health System/Sunbelt, Inc. d/b/a Florida Hospital affiliation. Three of the support letters are from parents of children previously in need of pediatric liver transplantation. One support letters is from Brian Adams, Chief Executive Officer of Florida Hospital Tampa (OTSA 2).

The 13 support letters are all individually composed. Some of these support letters have individual as well as periodic recurring themes, some of which include:

- Florida Hospital for Children<sup>1</sup> has one of the largest infrastructures of pediatric services and patients in the central Florida area, as well as existing long-standing transplantation programs for children and adolescents, making it the obvious choice for the addition of a pediatric liver transplantation program.
- All the infrastructure that will be needed to create a successful and high quality liver transplant program exists at Florida Hospital for Children.
- Florida Hospital for Children's existing transplant programs provide a solid foundation for the addition of pediatric liver transplantation services and given that Florida Hospital has well-established transplant programs for children, the addition of a pediatric liver transplant program would seem a naturally perfect fit.
- Florida Hospital has already proven itself to be a leader among the nation's children's hospitals, providing successful pediatric bone marrow and kidney transplants.
- The adult liver transplantation team at Florida Hospital performed nearly 70 liver transplants last year<sup>2</sup>, confirming existence of a robust infrastructure to support the proposed project including but not limited to critical care facilities and personnel, blood bank services, immune monitoring, anesthesia and surgical support.
- *US News & World Report* has named Florida Hospital the #1 hospital in the central Florida/Orlando area.
- The current requirement to travel outside the service area for pediatric liver transplantation (when necessitated) imposes a huge financial and psychosocial burden on patients and families due to distance and travel time to reach the nearest functional pediatric liver transplant program. This requires patients and families to relocate, separate their families and restart their medical care in an unfamiliar environment with unfamiliar health care providers. This also disrupts the continuity/familiarity of care provided by the primary care physicians of the children during liver disease management and progression through the transplant process.

<sup>1</sup> According to the website <https://www.floridahospital.com/children/transplantation>, The Florida Hospital for Children is, among other services, a provider of pediatric bone marrow and pediatric kidney transplantation on the campus of Florida Hospital, 601 E. Rollins St., Orlando, Florida 32803.

<sup>2</sup> The reviewer confirms that according to the Agency's Florida Need Projections for Pediatric Open Heart Surgery Programs and Pediatric Cardiac Catheterization Programs and Utilization Data for Adult and Pediatric Organ Transplantation Programs for January 1, 2016 through December 31, 2016 publication, issued March 31, 2017, Florida Hospital performed 67 adult liver transplantation procedures for the 12 months ending December 31, 2016.

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- Life-long follow-up often required for pediatric liver transplantation with a transplant center places a further lifetime burden on these patients and families.
- Over the past several years, Florida Hospital for Children and the Florida Hospital Medical Group have sent many children out of the area for transplant services.
- Having a local transplant center with high quality medical doctors to perform surgeries and available as needs arise would be ideal.
- There needs to be a more central program available.
- Florida Hospital for Children operates a Pediatric Intensive Care Unit (PICU) and participates in the Virtual Pediatric Intensive Care Unit Systems (VPS). The mortality rate at Florida Hospital for Children is lower than the national average in the VPS database and further, the mortality rate in the PICU when corrected for severity of illness is lower than predicted by the VPS database.
- The Children's Hospital of Pittsburgh (CHP) of the University of Pittsburgh Medical Center (UPMC) Hillman Center for Pediatric Transplantation was recently noted to have the highest patient and graft survival in the country in Scientific Registry of Transplant Recipients (SRTR) and by directly extending CHP practice patterns, outcomes and experience to the program at Florida Hospital for Children, a new paradigm for quality and improvement in pediatric liver transplantation care will be established.
- Partnership with the Florida Hospital adult transplant team and the University of Pittsburgh assures that the quality, experience and oversight will be unmatched.
- Florida Hospital for Children has demonstrated a successful track record in partnering with other institutions in other fields, most notably in collaboration with Johns Hopkins in their pediatric heart surgery program and their bone marrow transplant efforts partnering with Duke Health.

**Adventist Health System/Sunbelt, Inc. d/b/a Florida Hospital (CON application #10488)** highlights the support letters from physicians and by parents of former/on-going pediatric liver transplantation patients. The reviewer confirms that these highlights account for excerpts of all nine of the physician support letters and the three parental support letters of former/on-going pediatric liver transplantation patients.

The reviewer notes that none of the physician support letters indicate a likely number of prior pediatric liver transplantation candidates within OTSA 3 who have been referred outside of OTSA 3 for liver transplantation evaluation in the past or a likely number that are expected to be so referred in the future.

**C. PROJECT SUMMARY**

**Adventist Health System/Sunbelt, Inc. d/b/a Florida Hospital (CON application #10488)**, a non-profit hospital system, also referenced as FH, or the applicant, is a Class 1 hospital which proposes to establish a new pediatric liver transplantation program at 601 E. Rollins St., Orlando, Florida 32803, Orange County, OTSA 3. The parent, Adventist Health System/Sunbelt, Inc. (or AHS/S), operates 45 hospitals that span nine states: Colorado, Florida, Georgia, Illinois, Kansas, Kentucky, North Carolina, Texas and Wisconsin. Of the parent's 45 hospitals, 22 are licensed in Florida. If approved, the proposed project will be part of the Florida Hospital Transplant Institute (FHTI) and will operate within Florida Hospital for Children (FHFC), a 202-bed pediatric pavilion licensed as part of FH.

FH (a statutory teaching hospital) is a 1,414-bed general hospital, licensed for 1,243 acute care beds, 28 Level II neonatal intensive care unit (NICU) bed, 74 Level III NICU beds, 59 adult psychiatric beds and 10 comprehensive medical rehabilitation (CMR) beds. FH is a pediatric cardiac catheterization and a pediatric open heart surgery provider and additionally performs the following inpatient transplantation services:

- Pediatric
  - Kidney
  - Bone marrow
- Adult
  - Kidney
  - Heart
  - Liver
  - Bone marrow
  - Lung
  - Pancreas

Non-CON regulated services that FH provides include Level II adult cardiovascular services and designation as a comprehensive stroke center.

Pursuant to Section 408.036(5)(c), Florida Statutes, FH provided the Agency with notification of intent to delicense 13 acute care beds (N160038), another 13 acute care beds (N160039) and an additional two acute care beds (N160040) – combined these notifications would result in the delicensure of 28 acute care beds.

The total project cost is \$492,125, and involves no reported gross square feet (GSF) of renovation and no new construction. Total project costs include equipment, project development and start-up costs.

The proposed pediatric liver transplantation program, if approved, is expected to have an initiation of service on January 1, 2018.

Schedule C of the application includes the following condition(s):

Florida Hospital Transplant Institute is an active member of the local and regional community. Our teams regularly engage with patients, caregivers and physician partners to enhance our relationship and ensure a continuum of care.

- In the first two years of operation of the pediatric liver transplant program (2018 and 2019), Florida Hospital Transplant Institute will plan four unique community outreach events to raise awareness of the program, grow community support and increase our referral base. These unique events will include physician, nursing and patient education in the form of organized educational events, local conferences, support groups and/or industry events. When appropriate, Florida Hospital Transplant Institute will ensure continuing education credit is provided.

NOTE: Should the project be approved, the applicant's condition would be reported in the annual condition compliance report as required by Rule 59C-1.013 (3) Florida Administrative Code.

#### **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 analyst Derron Hillman of the Bureau of Central Services, who evaluated the financial data. There is no reported construction or renovation associated with the proposed project.

**E. CONFORMITY OF PROJECT WITH REVIEW CRITERIA**

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

**1. Fixed Need Pool**

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

There is no fixed need pool publication for pediatric liver transplant programs. Therefore, it is the applicant's responsibility to demonstrate the need for the project, including a projection of the expected number of pediatric liver transplants that will be performed in the first years of operation. The reviewer notes that pursuant to 59C-1.008 (2) (e) 3.—the existence of unmet need will not be based solely on the absence of a health service, health care facility, or beds in the district, subdistrict, region or proposed service area.

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OTSA 3 has no CON approved or operational pediatric liver transplant program. OTSA 1 and OTSA 4 each have one pediatric liver transplantation program. Data reported to the Agency by the local health councils for the 12 months ending December 31, 2016 show the following pediatric liver transplant utilization, by facility, service area and district:

<b>Florida Pediatric Liver Transplantation Program Utilization</b>			
<b>January 2016 – December 2016</b>			
<b>Hospital</b>	<b>Service Area</b>	<b>District</b>	<b>Total Procedures</b>
UF Health Shands Hospital	1	3	0
Jackson Memorial Hospital	4	11	26
<b>TOTAL</b>			<b>26</b>

Source: Florida Pediatric Organ Transplantation Program Utilization data published March 31, 2017

As shown in the table above, for the 12 months ending December 31, 2016, Jackson Memorial Hospital (Miami-Dade County in OTSA 4) provided all the pediatric liver transplants in Florida (26 procedures). Below is a five-year chart to account for pediatric liver transplantation utilization, by service area, county and facility, for the five-year period ending December 31, 2016.

<b>Florida Pediatric Liver Transplantation Utilization</b>								
<b>12-Month Reporting Periods Ending December 31, 2012 to December 31, 2016</b>								
<b>Service Area</b>	<b>County</b>	<b>Facility</b>	<b>12-Month Reporting Periods JAN 1 to DEC 31</b>					<b>Total</b>
			<b>2012</b>	<b>2013</b>	<b>2014</b>	<b>2015</b>	<b>2016</b>	
1	Alachua	UF Health Shands Hospital	1	7	5	0	0	<b>13</b>
4	Miami-Dade	Jackson Memorial Hospital	27	16	20	25	26	<b>114</b>
		<b>Total</b>	<b>28</b>	<b>23</b>	<b>25</b>	<b>25</b>	<b>26</b>	<b>127</b>

Source: Florida Need Projections Utilization Data for Adult and Pediatric Transplant Programs issued March 2013 – March 2017

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. The reviewer notes that the Organ Procurement Transplantation Network (OPTN), the national database of patient waiting lists for organ transplantation in the United States, shows 15 pediatric patients in Florida currently registered on the liver transplantation waiting list<sup>3</sup>. See the organ waiting list timetable below.

<sup>3</sup> As of May 18, 2017 per the OPTN website @ <http://optn.transplant.hrsa.gov>. The age range for this database is 0-17 years.

**Organ Procurement and Transplantation Network (OPTN)  
Current Florida Wait List Registrants (Ages 0-17 Years)  
Based on OPTN Data as of May 18, 2017**

	<b>Liver</b>
Total	15
< 30 Days	1
30 to < 90 Days	2
90 Days to < 6 Months	5
6 Months to < 1 Year	4
1 Year to < 2 Years	3
2 Years to < 3 Years	0
3 Years to < 5 Years	0
5 or More Years	0

Source: <https://optn.transplant.hrsa.gov/data/view-data-reports/state-data/> on May 19, 2017

Donor/patient matches are also a factor in transplant services. The chart below contains the most recent five-year volume of liver donations by Florida residents. The all donor types total and the deceased donor total are ages 0 – 17.

**Florida Pediatric Liver Donors Recovered  
January 1, 2012-December 31, 2016  
Based on OPTN Data as of May 18, 2017**

<b>Pediatric</b>	<b>2017*</b>	<b>2016</b>	<b>2015</b>	<b>2014</b>	<b>2013</b>	<b>2012</b>
All Donor Types	11	47	36	49	57	56
Deceased Donor	11	47	36	49	57	56
Living Donor**	0	0	0	0	0	0

Source: <https://optn.transplant.hrsa.gov/data/view-data-reports/state-data/> on May 19, 2017

Note: \* For 2017, January 1 through April 30, 2017

\*\* Living donors are indicated as six to 10 years of age, with no data for living donor totals under age six or from ages 11 to 17

As shown above, there were 47 Florida pediatric liver donors in 2016. Florida Center for Health Information and Transparency data indicates there was a total of 25 pediatric liver transplant procedures performed at Florida hospitals for the 12 months ending December 31, 2016. The total procedures were noticeably fewer than the donor recovery total—a difference of 22 more donors than pediatric liver transplant procedures, for the 12 months ending December 31, 2016. In other words, in

CY 2016, there was a surplus of 22 liver donors that were not utilized in Florida, indicating a potential of 22 additional livers available for transplantation to transplant-appropriate candidates in Florida that were not transplanted in Florida.



Agency data indicates that 22 of 25 (or 88.00 percent) of the pediatric (under 15 years of age) liver patients receiving liver transplants performed in Florida in CY 2016 were Florida residents<sup>4</sup>. The remaining three pediatric patients had an unknown residence. Service Area 3 residents accounted for four of the 25 procedures, or 16.00 percent. Below is a chart to account for these totals.

**Pediatric Liver Transplants at Florida Hospitals  
by Patient Residence  
CY 2016**

<b>Service Area</b>	<b>Transplants Performed</b>	<b>Percent of Total</b>
1	5	20.00%
2	4	16.00%
3	4	16.00%
4	9	36.00%
Unknown	3	12.00%
<b>Total</b>	<b>25</b>	<b>100.00%</b>

Source: Florida Center for Health Information and Transparency CY 2016 database, MS-DRGs 005 and 006

Service Area 3 residents must migrate outside their home service area (their home OTSA) for pediatric liver transplantation, as there are currently no licensed pediatric liver transplantation providers in OTSA 3. Below is a chart to account for where OTSA 3 pediatric liver transplant patients received this procedure in CY 2016.

**Service Area 3 Resident Facility Selection  
Pediatric Liver Transplantation Procedures  
CY 2016**

<b>Facility/Organ Transplant Service Area</b>	<b>Patient Total</b>	<b>Patient Percent</b>
UF Health Shands Hospital (Service Area 1)	0	0.00%
Jackson Memorial Hospital (Service Area 4)	4	100.00%
<b>Service Area 3 Total</b>	<b>4</b>	<b>100.00%</b>

Source: Florida Center for Health Information and Transparency CY 2016 database, MS-DRGs 005 and 006

The Agency notes that OTSA 3 residents had the same number of pediatric liver transplant procedures as OTSA 2 residents and migrated at a rate of 100.0 percent beyond their home service area for the 12 months ending December 31, 2016, according to Agency discharge data. This out-migration would be due to the fact there is no pediatric liver transplantation provider in OTSA 3. In other words, for the 12 months ending December 31, 2016, OTSA 3 residents presented comparable demand for pediatric liver transplantation as OTSA 2 residents.

Local health council data for the five-year period ending December 31, 2016 indicates that procedures have generally been within a relatively narrow range, overall, statewide. The reviewer notes that for this same

<sup>4</sup> MS-DRGs 005 and 006 as reported in the Florida Center for Health Information and Transparency database for CY 2016. There were 26 total pediatric liver transplant procedures reported to the local health councils for CY 2016. Some variation in the patient data is to be expected.

five-year period, statewide, local health council data indicates that pediatric liver transplant procedures experienced a slight decline from 28 (12 months ending December 31, 2012) to 26 (12 months ending December 31, 2016). Again, due to no pediatric liver transplantation provider in OTSA 3, there is no OTSA 3 pediatric liver transplantation provider volume trending data to consider, as any residents would be required to out-migrate for pediatric liver transplantation and no residents would in-migrate to OTSA 3 for the same reason. The reviewer notes that considering there is no CON approved or authorized pediatric liver transplantation provider in OTSA 3 so no single OTSA 3 pediatric liver transplantation provider volume could be adversely impacted by approval of the proposed project. However, the reviewer also notes that approval of the proposed project would likely generate relatively light volume at the Florida Hospital location as proposed, due to:

- Relatively low and stable pediatric liver transplantation volume statewide for the five-year period ending December 31, 2016.
- No additional pediatric liver transplantation providers were CON approved or licensed anywhere statewide within the same five-year period.
- OTSAs that currently are CON-approved and licensed to provide pediatric liver transplantation services (OTSA 1 and OTSA 4) do so through a single provider in each of these two OTSAs.
- Section 408.032(17), Florida Statutes, defines a tertiary health service as, in part:  
*“...a health service which, due to its high level of intensity, complexity, specialized or limited applicability, and cost, should be limited to, and concentrated in, a limited number of hospitals to ensure the quality, availability, and cost-effectiveness of such service. Examples of such service include, but are not limited to, pediatric cardiac catheterization, pediatric open-heart surgery, organ transplantation, neonatal intensive care units, comprehensive rehabilitation...”*
- Per Rule 59C-1.002(41)(c), Florida Administrative Code, liver transplantation is a listed tertiary health service.

**Adventist Health System/Sunbelt, Inc. d/b/a Florida Hospital (CON application #10488)** presents the following five need justifications to warrant project approval:

- Lack of availability of pediatric liver transplant services in central and northern Florida.
- Burden of long travel times and distances to the only active provider in the state, which is located more than four hours away in Miami.
- Significant percentage of patients who leave Florida and/or OTSA 3 each year to obtain a pediatric liver transplant.

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- Logical extension of the numerous longstanding solid organ transplant programs offered by the FHTI, including adult liver and pediatric kidney transplant programs.
- Participating with UPMC’s Hillman Center for Pediatric Transplantation, one of the premier transplant centers in the nation, will bring world-class pediatric liver transplant practitioners and immediate expertise to the residents of central Florida. Through the partnership, FH and UPMC will further develop a pioneering pediatric transplant network that will be a national model for complex care and outcomes in pediatric liver transplantation.

FH discusses the total population and the age 0-14 years (pediatric) population for OTSA 3, and points out that OTSA 3 is currently home to nearly 4.2 million residents and is projected to increase to more than 4.5 million residents over the next five years by 2022. FH also points out the projected OTSA 3 total population growth (8.7 percent over five years) is expected to outpace statewide growth, which is expected to increase by 6.7 percent over the same five years. Additionally, FH indicates that the pediatric population in OTSA 3 is large and increasing and by 2022, growth in this age cohort is expected to significantly outpace statewide growth (7.0 percent compared to a statewide growth rate of 4.5 percent). The reviewer notes that FH selects July 1, 2017 and July 1, 2022 projections to reach the estimates offered. Below are two figures to account for the above population narratives, both for total population (all ages) and those for the pediatric population (ages 0 – 14 years).

**2017-2022 Total Population Growth  
OTSA 3 Compared to Florida**

County	Total Population		
	2017	2022	Change
Brevard	572,418	602,128	5.2%
Orange	1,313,793	456,218	10.8%
Osceola	330,898	383,227	15.8%
Seminole	451,277	475,796	5.4%
Indian River	149,454	160,568	7.4%
Martin	155,271	162,645	4.7%
Okeechobee	40,885	42,016	2.8%
St. Lucie	311,085	346,063	11.2%
Lake	334,715	372,541	11.3%
Volusia	517,053	538,926	4.2%
<b>OTSA 3 Total</b>	<b>4,176,849</b>	<b>4,540,128</b>	<b>8.7%</b>
<b>Florida Total</b>	<b>20,382,303</b>	<b>21,749,244</b>	<b>6.7%</b>

Source: CON application #10488, page 33, Figure 5

**2017-2022 Pediatric Population Growth, Ages 0-14  
OTSA 3 Compared to Florida**

County	0-14 Population		
	2017	2022	Change
Brevard	87,196	89,537	2.7%
Orange	256,821	282,713	10.1%
Osceola	66,907	75,175	12.4%
Seminole	80,177	84,061	4.8%
Indian River	21,454	22,236	3.6%
Martin	20,237	20,259	0.1%
Okeechobee	7,783	7,650	-1.7%
St. Lucie	55,477	60,151	8.4%
Lake	54,440	58,073	6.7%
Volusia	78,127	79,968	2.4%
<b>OTSA 3 Total</b>	<b>728,619</b>	<b>779,823</b>	<b>7.0%</b>
<b>Florida Total</b>	<b>3,474,148</b>	<b>3,629,495</b>	<b>4.5%</b>

Source: CON application #10488, page 33, Figure 6

The reviewer verifies that the applicant’s estimates shown above are consistent with the Florida Population Estimates and Projections by AHCA District 2010 to 2030 publication. The reviewer also verifies that the arithmetic total for OTSA 3 is correct, as well as the stated percentage changes, as shown in both of the applicant’s Figure 5 and Figure 6 (above). Using the same source, FH expects the pediatric population (ages 0-14 years) in OTSA 3 to experience the highest rate of growth of any OTSA in Florida, increasing by more than 50,000 residents (7.0 percent). See the table below.

**2017-2022 Pediatric Population Growth, Ages 0-14  
By OTSA**

OTSA	0-14 Population		
	2017	2022	Change
1 (Gainesville)	762,578	786,852	3.2%
2 (Tampa)	891,753	941,004	5.5%
3 (Orlando)	728,619	779,823	7.0%
4 (Miami)	1,091,198	1,121,816	2.8%
<b>Florida Total</b>	<b>3,474,148</b>	<b>3,629,495</b>	<b>4.5%</b>

Source: CON application #10488, page 34, Figure 7

In addition to its OTSA 3 facilities, the parent, AHS/S comments that it operates Florida Hospital Tampa in OTSA 2 and that like OTSA 3, OTSA 2 lacks a pediatric liver transplantation program. AHS/S also comments that FH’s extensive network of facilities and physicians with which Florida Hospital has affiliation or longstanding relationships will benefit pediatric patients who require assessment/evaluation for and ultimately receive a liver transplant.

FH notes that for the last full two calendar years, all Florida resident pediatric liver transplant patients have either gone to Jackson Memorial Hospital, left the state for the procedure or possibly not had a transplant due to limited accessibility of programs in Florida.

The applicant discusses that there are differences in pediatric liver transplantation procedures reported to the Agency’s inpatient hospital database and the UNOS (the United Network of Organ Sharing). FH maintains that given that UNOS is the ultimate clearinghouse for transplant data, the applicant will rely on UNOS data as much as possible. FH maintains that the relatively small universe of transplant patients’ results in variability in the volume of transplants on an annual basis and that growth rates are not a standalone statistic from which significant conclusions should be drawn. FH asserts that the need for the proposed project is based on the lack of geographically distributed providers in Florida, the large number of patients leaving Florida every year for the procedure and the expertise of FH in the provision of solid organ transplants. FH also asserts that the partnership with UPMC will add another layer of expertise and skill including clinical oversight and training of FH staff.

Using the UNOS Custom Reports, April 21, 2017, FH indicates that in 2014, one Florida resident received a pediatric liver transplant outside of Florida. Using the same source, FH indicates that in 2015 and in 2016, for each year, five Florida residents received a pediatric liver transplant outside of Florida (or 18.5 percent of total Florida residents that received a pediatric liver transplant procedure for each of those years). The applicant provides a figure to account for these totals. The reviewer collapses all non-Florida transplant center locations into a single category “Total Transplanted Out of Florida”. See the table below.

**Florida Resident Pediatric Liver Transplants, Ages 0-14  
Regardless of Transplant Center Location**

<b>Hospital</b>	<b>2014</b>	<b>2015</b>	<b>2016</b>
UF Health Shands Hospital	5	0	0
Jackson Memorial Hospital	19	22	22
Total Transplanted Out of Florida	1	5	5
<b>Total All Hospitals</b>	<b>25</b>	<b>27</b>	<b>27</b>
Total Transplanted In Florida	24	22	22
<b>Total Transplanted Out of State</b>	<b>1</b>	<b>5</b>	<b>5</b>
<b>Percent Transplanted Out of State</b>	<b>4.0%</b>	<b>18.5%</b>	<b>18.5%</b>

Source: CON application #10488, page 35, Figure 8

FH indicates that according to UNOS, UPMC (Florida Hospital’s clinical partner in the proposed program) as well as the closest program in neighboring Georgia (Children’s Healthcare of Atlanta) are two of the destinations for patients who choose to leave the state for a liver transplant. The reviewer notes that the applicant does not distinguish the OTSA patient origin of these stated patients.

Stating the use of the Agency’s inpatient hospital database for pediatric liver transplants, FH proceeds to define pediatric liver transplants as ICD-9 Code 50.59 and ICD-10 Code 0FY00Z0. FH then indicates the 2011-2015 pediatric liver transplants (ages 0-14 years) performed by Florida transplant centers, by OTSA. FH maintains that in CY 2015, OTSA 3’s pediatric population ages 0-14 generated more liver transplants (eight) than OTSA 4’s population (seven), which FH points out is the largest in the state. See the figure below.

**2011-2015 Pediatric Liver Transplants (0-14)  
Performed by Florida Transplant Centers**

<b>OTSA</b>	<b>2011</b>	<b>2012</b>	<b>2013</b>	<b>2014</b>	<b>2015</b>
1 (Gainesville)	3	5	2	2	2
2 (Tampa)	2	4	3	3	8
3 (Orlando)	4	2	4	3	8
4 (Miami)	7	11	4	8	7
<b>Total</b>	<b>16</b>	<b>22</b>	<b>13</b>	<b>16</b>	<b>25</b>

Source: CON application #10488, page 36, Figure 9

FH contends that full CY 2016 was not yet available in the Agency’s inpatient hospital database. The Agency notes that the full CY 2016 data referenced by the applicant was available at the Florida Center for Health Information and Transparency as early as June 8, 2017, the omissions deadline was June 28, 2017 and the applicant submitted its omissions response on June 23, 2017. Please see the table below for CY 2016 data.

**Pediatric Liver Transplants at Florida Hospitals  
by Patient Residence  
CY 2016**

<b>Service Area</b>	<b>Transplants Performed</b>	<b>Percent of Total</b>
1	5	20.00%
2	4	16.00%
3	4	16.00%
4	9	36.00%
Unknown	3	12.00%
<b>Total</b>	<b>25</b>	<b>100.00%</b>

Source: Florida Center for Health Information and Transparency CY 2016 database, MS-DRGs 005 and 006

FH presents 2010-2015 OTSA 3 resident pediatric liver transplants performed at Florida centers, for patients age 0-14 years, by patient county of residence. FH maintains that Orange County (the largest in the area) routinely generates two to three transplants annually. Further,

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the applicant points out that OTSA 3 pediatric liver transplant patients trended up significantly in 2015. Though not indicated by the applicant below, the Agency previously indicated that in CY 2016, a total of four OTSA 3 pediatric residents received a liver transplant at a CON approved liver transplant provider hospital in Florida. See the figure below.

**OTSA 3 Resident Pediatric Liver Transplants Performed at Florida Centers  
Ages 0-14 / Shown by Patient County of Residence**

<b>OTSA 3 Patient County</b>	<b>2010</b>	<b>2011</b>	<b>2012</b>	<b>2013</b>	<b>2014</b>	<b>2015</b>
Brevard						
Orange	2	1	2	3	2	3
Osceola		1			1	1
Seminole	1	2		1		1
Indian River						
Martin						
Okeechobee						1
St. Lucie						2
Lake						
Volusia						
<b>OTSA 3 Resident Liver Transplants Performed at Florida Centers Ages 0-14</b>	<b>3</b>	<b>4</b>	<b>2</b>	<b>4</b>	<b>3</b>	<b>8</b>

Source: CON application #10488, page 36, Figure 10

The Agency notes that the applicant previously indicated that Orange County has the greatest volume of pediatric residents (age 0-14 years) in OTSA 3, as of July 1, 2017 and is expected to have the greatest volume of this same age cohort of any single county in OTSA 3 at least to July 1, 2022. Therefore, the Agency concurs that it is reasonable that Orange County is likely to have the greatest volume of pediatric liver transplant patients of any county in OTSA 3 now and into the foreseeable future. FH indicates that since at least 2012, all OTSA 3 residents ages 0-14 who have received a liver transplant within Florida have traveled to Jackson Memorial Hospital in Miami-Dade (County) for the procedure. See the figure below.

**OTSA 3 Resident Pediatric Liver Transplants, Ages 0-14  
Performed at Florida Transplant Centers**

<b>Florida Transplant Center</b>	<b>2010</b>	<b>2011</b>	<b>2012</b>	<b>2013</b>	<b>2014</b>	<b>2015</b>
Jackson Memorial Hospital	2	3	2	4	3	8
UF Health Shands Hospital	1	1				
<b>OTSA 3 Total Transplanted In Florida</b>	<b>3</b>	<b>4</b>	<b>2</b>	<b>4</b>	<b>3</b>	<b>8</b>

Source: CON application #10488, page 37, Figure 11

FH discusses travel time from the Orlando metro area to Jackson Memorial Hospital. For a review of this travel distance, see item E.3.a of this report. FH indicates that Miami is more than four hours drive time from the Orlando metro area. The reviewer notes that according to Mapquest.com, as of June 27, 2017, the drive time from 601 E. Rollins St., Orlando, Florida 32803 (the physical address of FH) to 1161 NW 12<sup>th</sup> Ave., Miami, Florida 33136 (the physical address of Jackson Memorial Hospital) is three hours and 35 minutes.

Per FH, internal information from the four FHFC-affiliated gastroenterologists, one of whom is employed by Florida Hospital Medical Group, confirms that pediatric patients who require assessment for and receive liver transplant are primarily referred to Jackson Memorial Hospital. FH indicates that two physicians report that they send all referrals to Jackson Memorial Hospital or out of state. The reviewer notes that of the 13 support letters, two physicians indicate that they are pediatric gastroenterologists and that neither of these physicians in their support letters indicate that they have specifically referred any of their patients to any pediatric liver transplantation providers.

FH points out that its data to this point is for the age 0-14 years population only. The applicant contends that the 15-17 aged cohort is an important consideration in assessing the need for pediatric liver transplant services and the appropriate placement of such services in terms of the hospital in which the service is to be performed. FH states that it recognizes that the Agency considers pediatric to be a patient under the age of 15 years (pursuant to Rule 59C-1.044(2)(c), Florida Administrative Code). FH contends that adult programs are not always an appropriate venue for these teenage patients (those 15 to 17 years of age).



FH asserts that late teens tend to fall into a sort of “no man’s land” when it comes to organ transplant, as some patients can be effectively treated in ‘adult’ programs while some would be more appropriate for treatment in a ‘pediatric’ program. The applicant asserts that given FH currently offers a robust adult liver transplant program and proposes to offer a pediatric program, FH states that it is the best choice to serve a full range of patients from childhood through adulthood. If approved, FH notes that patients will have continuity of care within the same system of physicians, facilities and infrastructure as they transition from pediatric hepatology care to the need for adult hepatology specialists. The applicant maintains that approval of the proposed project will ensure a smooth transition as patients progress through disease and will increase access to liver transplant services for patients who fall outside the Agency’s definition of “pediatric” but are more appropriate for a pediatric program than an adult program.

Stating the use of the same course and the same ICD definition of pediatric liver transplant procedures as shown in the prior figure, FH indicates one to five liver transplants in patients age 15 to 17 from 2010 to 2015 in Florida but does not include patients in this age group that leave the state for this procedure. See the figure below.

**2010-2015 Liver Transplants (Age 15-17 Years)  
Performed by Florida Transplant Centers**

<b>OTSA</b>	<b>2010</b>	<b>2011</b>	<b>2012</b>	<b>2013</b>	<b>2014</b>	<b>2015</b>
1 (Gainesville)	1				1	
2 (Tampa)		2			1	
3 (Orlando)			1		1	
4 (Miami)	1	3		1		1
<b>Total</b>	<b>2</b>	<b>5</b>	<b>1</b>	<b>1</b>	<b>3</b>	<b>1</b>

Source: CON application #10488, page 38, Figure 12

FH states that the proposed project will ensure that patients age 15-17 do not “fall through the cracks” in the assessment and availability of transplant services. FH asserts that the ability to treat the entirety of the patient population experiencing end-stage liver disease who ultimately require transplantation is unique to Florida Hospital’s proposal.

The applicant indicates that according to the OPTN, as of May 15, 2017, a total of 18 Florida residents, ages 0-17, are waiting list candidates at Florida and out-of-state facilities (14 at Jackson Memorial Hospital, one at UF Health Shands Hospital and three out-of-state). See the figure below.

**Florida Resident Liver Transplant Waiting List Candidates  
Ages 0-17 Only**

	<b>Waiting List Candidates as of May 15, 2017</b>
Jackson Memorial Hospital	14
UF Health Shands Hospital	1
Out of State Facility	3
<b>Total Florida Resident Waiting List Candidates (Ages 0-17)</b>	<b>18</b>

Source: CON application #10488, page 38, Figure 13

FH indicates that based on wait times data from the OPTN, nearly half of Florida waiting list candidates who are listed at centers in Florida have been on the waiting list for more than six months.

**Florida Resident Liver Transplant Waiting List Candidates  
Time on Waiting List (Ages 0-17 Years)**

	<b>Waiting List Candidates as of May 15, 2017</b>
< 30 Days	1
30 to < 90 Days	2
90 Days to < 6 Months	5
6 Months to < 1 Year	4
1 Year to < 2 Years	3
2 Years to < 3 Years	0
3 Years to < 5 Years	0
5 or More Years	0
<b>Total Florida Resident Waiting List Candidates (Ages 0-17)</b>	<b>15</b>

Source: CON application #10488, page 39, Figure 14

The reviewer notes that the figure above is materially identical to the Agency's Florida resident liver transplant waiting list candidate table shown earlier in this section, item E.1.a of this report, from the same source, run on May 18, 2017. The applicant contends that pediatric livers are scarce. However, the Agency has previously indicated a surplus of donor livers statewide, 22 more donors than pediatric liver transplant procedures, for the 12 months ending December 31, 2016. AHS/S conditions that in the first two years of operation of the pediatric liver transplant program (2018 and 2019), FHTI will plan four unique community outreach events to raise awareness of the program, grow community support and increase the referral base. According to the applicant, its outreach efforts will provide transplant education and organ donation information/materials to educate the community on the importance of organ donation.

FH discusses split liver transplant or SLT (pages 39 and 40 of the application). According to FH, SLT is now a commonly accepted practice – particularly for the pediatric population. FH explains that in this procedure, one adult liver is split between two patients and the two segments of the organ can be split between an adult and a child or two children. The applicant indicates that due to size considerations, it is less common to split an organ between two adult patients. FH maintains that a large number of children undergoing liver transplantation are under the age of two years old and that these patients are historically difficult to transplant using a full liver, given the patient's small size. The applicant comments that for many of these patients SLT is viable and potentially allows two patients to be saved from life-threatening liver disease, thus increasing the number of available grafts for transplantation. The applicant also comments that overall outcomes using SLT are consistent with whole liver transplantation. FH asserts that liver transplant surgeons at FH have experience in performing SLT on both adults and pediatric patients. Based on this experience and history, according to the applicant, the proposed project will allow FH to more efficiently utilize available livers by performing SLT on a pediatric and adult patient or two pediatric patients, when clinically appropriate.

Stating the use of the Agency's inpatient hospital database for pediatric liver transplants, the Florida Population Estimates and Projections by AHCA District 2010 to 2030 publication, issued February 2015, for July 2010-2015, and the pediatric liver transplants as ICD-9 Code 50.59 and ICD-10 Code 0FY00Z0, FH generates a pediatric liver transplant use rate per 1,000,000 residents, by OTSA. According to this applicant-generated use rate, FH states a higher use rate than the statewide use rate for three of the six years shown below (2011, 2013 and 2015). Additionally, the applicant points out that for 2010 to 2015, use rate growth for OTSA 3 was the highest of any area in Florida. See the figure below.

**2010-2015 Pediatric Liver Transplants per 1,000,000 Population  
Florida Resident Transplants Performed at Florida Transplant Centers  
Patients Age 0-14**

0-14 Liver Transplants						
Patient OTSA	2010	2011	2012	2013	2014	2015
1	5	3	5	2	2	2
2	6	2	4	3	3	8
<b>3</b>	<b>3</b>	<b>4</b>	<b>2</b>	<b>4</b>	<b>3</b>	<b>8</b>
4	7	7	11	4	8	7
<b>Florida Resident Total, 0-14</b>	<b>21</b>	<b>16</b>	<b>22</b>	<b>13</b>	<b>16</b>	<b>26</b>
0-14 Population						
Patient OTSA	2010	2011	2012	2013	2014	2015
1	729,366	730,230	732,169	737,420	745,168	752,882
2	835,185	837,869	842,512	850,625	860,735	871,198
<b>3</b>	<b>673,339</b>	<b>676,219</b>	<b>680,604</b>	<b>689,005</b>	<b>698,920</b>	<b>709,047</b>
4	1,049,039	1,053,195	1,061,536	1,067,240	1,073,253	1,078,727
<b>Florida Resident Total, 0-14</b>	<b>3,286,929</b>	<b>3,297,513</b>	<b>3,316,821</b>	<b>3,344,290</b>	<b>3,378,076</b>	<b>3,411,854</b>
Use Rate per Million Pop						
Patient OTSA	2010	2011	2012	2013	2014	2015
1	6.9	4.1	6.8	2.7	2.7	2.7
2	7.2	2.4	4.7	3.5	3.5	9.2
<b>3</b>	<b>4.5</b>	<b>5.9</b>	<b>2.9</b>	<b>5.8</b>	<b>4.3</b>	<b>11.3</b>
4	6.7	6.6	10.4	3.7	7.5	6.5
<b>Florida Resident Total, 0-14</b>	<b>6.4</b>	<b>4.9</b>	<b>6.6</b>	<b>3.9</b>	<b>4.7</b>	<b>7.3</b>

Source: CON application #10488, page 40, Figure 15

Stating the use of the same courses and the same ICD definition of pediatric liver transplant procedures as shown in the prior figure, FH states that from 2010 to 2015, the use rate growth for OTSA 3 was the highest of any area in Florida. The applicant indicates an annual average growth rate of 30.6 percent for OTSA 3 compared to a statewide use rate of 2.9 percent for the age 0-14 year population from 2010 to 2015.

**2010-2015 Grow in Pediatric Liver Transplants per 1,000,000 Population  
Florida Resident Transplants Performed at Florida Transplant Centers  
Patients Ages 0-14**

Patient OTSA	Use Rate per 1,000,000 Pop						AAGR 2010-2015
	2010	2011	2012	2013	2014	2015	
1 (Gainesville)	6.9	4.1	6.8	2.7	2.7	2.7	-12.2%
2 (Tampa)	7.2	2.4	4.7	3.5	3.5	9.2	5.6%
<b>3 (Orlando)</b>	<b>4.5</b>	<b>5.9</b>	<b>2.9</b>	<b>5.8</b>	<b>4.3</b>	<b>11.3</b>	<b>30.6%</b>
4 (Miami)	6.7	6.6	10.4	3.7	7.5	6.5	-0.6%
<b>Florida Resident Total 0-14</b>	<b>6.4</b>	<b>4.9</b>	<b>6.6</b>	<b>3.9</b>	<b>4.7</b>	<b>7.3</b>	<b>2.9%</b>

Source: CON application #10488, page 41, Figure 16

FH asserts that given the variability of the use rates due to the relative low number of pediatric liver transplants, a blended use rate for 2010-2015 provides a more stable view of transplant utilization by patient OTSA. Again stating the use of the same courses and the same ICD definition of pediatric liver transplant procedures as shown in the prior figure, FH states that from 2010 to 2015, the OTSA 3 blended use rate for pediatric liver transplant services (5.8) is higher than the state use rate (5.6). According to FH, this supports the need for a transplant program more proximate to the service area population. See the figure below.

**2010-2015 Blended Pediatric Liver Transplant Use Rate by Patient OTSA of Residence, Ages 0-14**

Patient OTSA	Use Rate per 1,000,000 Pop						2010-2015 Blended Use Rate
	2010	2011	2012	2013	2014	2015	
1 (Gainesville)	6.9	4.1	6.8	2.7	2.7	2.7	4.3
2 (Tampa)	7.2	2.4	4.7	3.5	3.5	9.2	5.1
<b>3 (Orlando)</b>	<b>4.5</b>	<b>5.9</b>	<b>2.9</b>	<b>5.8</b>	<b>4.3</b>	<b>11.3</b>	<b>5.8</b>
4 (Miami)	6.7	6.6	10.4	3.7	7.5	6.5	6.9
<b>Florida Resident Total 0-14</b>	<b>6.4</b>	<b>4.9</b>	<b>6.6</b>	<b>3.9</b>	<b>4.7</b>	<b>7.3</b>	<b>5.6</b>

Source: CON application #10488, page 41, Figure 17

The applicant contends that in a conservative approach to the projection of pediatric liver transplant utilization at FH, it based the projection on the individual OTSAs' blended 2010-2015 pediatric liver transplant use rate and projected growth of the statewide average annual growth rate (2.9 percent for 2010-2015). Based on this, FH anticipates an OTSA 3 use rate of 6.3, 6.5 and 6.7 for 2018, 2019 and 2020, respectively. This is the expected use rate per 1,000,000 residents, ages 0-14. See the figure below.

**Projected 2018-2020 Pediatric Liver Transplant Use Rate per Million Population Ages 0-14 by Patient OTSA**

Patient OTSA	State AAGR	2010-2015 Use Rate	Use Rate		
			2018	2019	2020
1 (Gainesville)	2.9%	4.3	4.7	4.8	5.0
2 (Tampa)	2.9%	5.1	5.6	5.7	5.9
<b>3 (Orlando)</b>	<b>2.9%</b>	<b>5.8</b>	<b>6.3</b>	<b>6.5</b>	<b>6.7</b>
4 (Miami)	2.9%	6.9	7.5	7.7	8.0

Source: CON application #10488, page 42, Figure 18

Per FH, applying these projected use rates to each OTSAs' pediatric population yields a total number of pediatric liver transplants, ages 0-14, that the applicant indicates would reasonably be expected by the population of each area. Therefore, the applicant predicts a range of 24

to 25 pediatric residents statewide receiving the procedure from 2018-2020 and a range of five to six pediatric residents (in OTSA 3) receiving the procedure in the same three-year period. See the figure below.

**Projected 2018-2020 Pediatric Liver Transplants  
by Patient OTSA, Ages 0-14**

Patient OTSA	Projected 0-14 Liver Transplants		
	Year One 2018	Year Two 2019	Year Three 2020
1 (Gainesville)	4.0	4.0	4.0
2 (Tampa)	6.0	6.0	6.0
<b>3 (Orlando)</b>	<b>5.0</b>	<b>5.0</b>	<b>6.0</b>
4 (Miami)	9.0	9.0	9.0
<b>Florida Resident Total, 0-14</b>	<b>24.0</b>	<b>24.0</b>	<b>25.0</b>

Source: CON application #10488, page 42, Figure 19

FH states having made conservative market share assumptions by OTSA, as indicated below:

- No share of cases generated by OTSA 1 (Gainesville)
- 50 percent share of cases generated by OTSA 2 (Tampa), as it is proximate to FH’s location and does not have a pediatric liver transplant program
- 80 percent share of cases generated by OTSA 3 (Orlando), as it is FH’s home planning area
- No share of cases generated by OTSA 4 (Miami) as it is the home of Jackson Memorial Hospital

Based on its market share assumptions, if approved, the applicant expects (patients age 0-14 years) to perform a total of four to five pediatric liver transplant procedures from OTSA 3 residents and a sum total of seven to eight of these procedures (patients age 0-14 years) when OTSA 2 residents are taken into consideration, from 2018 to 2020. See the figure below.

**Florida Hospital Projected Pediatric Liver Transplants Ages 0-14  
Years One-Three of Operation (2018-2020)**

Patient OTSA	Projected 0-14 Liver Transplants			Florida Hospital Projected Transplants			
	Year One 2018	Year Two 2019	Year Three 2020	Market Share OTSA Resident Cases	2018	2019	2020
1(Gainesville)	4.0	4.0	4.0	0.0%	0	0	0
2 (Tampa)	6.0	6.0	6.0	50.0%	3	3	3
<b>3 (Orlando)</b>	<b>5.0</b>	<b>5.0</b>	<b>6.0</b>	<b>80.0%</b>	<b>4</b>	<b>4</b>	<b>5</b>
4 (Miami)	9.0	9.0	9.0	0.0%	0	0	0
<b>Florida Resident Total, 0-14</b>	<b>24</b>	<b>24</b>	<b>25</b>	<b>FH Total -14 Transplants</b>	<b>7</b>	<b>7</b>	<b>8</b>

Source: CON application #10488, page 43, Figure 20 and page 71, Figure 22

FH states that in addition to transplant for the 0-14 population indicated above, FH projects that it will do one additional case in its pediatric program annually in the 15-17 age cohort or resulting from in-migration from areas outside of OTSA 2 or 3. This results in a total range of eight to nine of these proposed procedures from 2018-2020. See the figure below.

**Florida Hospital Projected Total Pediatric Liver Transplants Ages 0-17  
Years One-Three of Operation (2018-2020)**

	<b>Year One 2018</b>	<b>Year Two 2019</b>	<b>Year Three 2020</b>
Ages 0-14	7	7	8
Ages 15-17 and/or in-migration	1	1	1
<b>FH/FHTI Total Pediatric Liver Transplants</b>	<b>8</b>	<b>8</b>	<b>9</b>

Source: CON application #10488, page 43, Figure 21 and page 72, Figure 23

FH again reiterates that because it currently offers an adult liver transplantation program, the proposed pediatric program (if approved) will allow FH to serve the needs of all liver transplantation patients regardless of age.

As further justification for the proposed project, FH points out having the most advanced medical, surgical and support services in its OTSA and is well equipped to care for the sickest children and the most complex cases. Also as additional justification, FH contends that the proposed project will not dilute volume at Jackson Memorial Hospital (OTSA 4). Further FH maintains that considering its existing transplantation and other highly complex product lines, the proposed project will build on Florida Hospital's expertise (particularly its adult liver and pediatric kidney programs).

- b. Applications for the establishment of new pediatric liver transplantation program shall not normally be approved in a service planning area unless the following additional criteria are met:**
- 1. The applicant must be a teaching hospital or research hospital with training programs relevant to liver transplantation. (Rule 59C-1.044(7)(a) Florida Administrative Code).**

**Adventist Health System/Sunbelt, Inc. d/b/a Florida Hospital (CON application #10488):** FH is a statutory teaching hospital, as defined by section 408.07(45) Florida Statutes. In addition to being a statutory teaching hospital, the applicant discusses its existing Graduate Medical Education programs and its Graduate Medical Education Department (pages 59 and 60 of the

application). In addition, the applicant lists nine titled current hepatology research initiatives (pages 61 through 64 of the application).

2. **Coordination of Services. The following services shall be available in the hospital, or through contractual arrangements. (Rule 59C-1.044(7)(b)).**
- (a) **A department of gastroenterology, including clinics, and adequately equipped procedure rooms.**
  - (b) **Radiology services to provide complex biliary procedures, including transhepatic cholangiography, portal venography and arteriography.**
  - (c) **A laboratory with the capability of performing and promptly reporting the results of liver function tests as well as required chemistry, hematology, and virology tests.**
  - (d) **A patient convalescent unit for further monitoring of patient progress for approximately one month post-hospital discharge following liver transplantation.**

**Adventist Health System/Sunbelt, Inc. d/b/a Florida Hospital (CON application #10488)** states having a department of gastroenterology and a pediatric gastroenterology team that can diagnose and treat gastroenterological problems in children and adolescents.

The reviewer notes that according to the FH website on gastrointestinal (GI) clinical services (<https://www.floridahospital.com/gastrointestinal>), FH is recognized by *US News & World Report* as one of America's best hospitals in gastroenterology.

FH indicates having an extensive Radiology Department including a comprehensive array of advanced interventional and non-invasive radiological procedures. The applicant points out that in support of FH's adult liver transplant program, radiologists at FH routinely perform complex biliary procedures, including transhepatic cholangiography, portal venography and arteriography. Per FH, there will be no need to add radiology or staff to accommodate the proposed project.

FH comments that it currently performs tissue-typing and other transplant lab services in-house.



FH states that pediatric patients who undergo a liver transplant at FH will be transferred to the PICU inside FH. The applicant indicates that when appropriate, patients will be transferred to a pediatric inpatient unit for continued care and monitoring. FH expects that average length of stay (ALOS) in the hospital for a pediatric patient who undergoes liver transplantation will be approximately 21 days. FH contends that after discharge from the hospital, outpatient follow-up clinic visits are typically one to two times per week and then less frequently as the patient improves.

- 3. Staffing Requirements. In addition to the general staffing requirements for all transplantation programs, program staff for liver transplantation programs shall be trained in the care of patients with hepatic diseases, and liver transplantation.**

**Adventist Health System/Sunbelt, Inc., d/b/a Florida Hospital (CON application #10488)** identifies the following practitioners and units as part of the FH Transplant Team:

- Regino P. Gonzalez-Peralta, MD, Medical Director-Pediatric Liver Transplantation (beginning mid-September 2017)
- L. Thomas Chin, MD, Surgical Director-Liver Transplantation
- Michael Angelis, MD, Surgical Director-Kidney Transplantation
- Linda Hernandez, MD, Pediatric Gastroenterology
- Nursing staff with expertise in caring for pediatric patients who have undergone a kidney transplant and are in the PICU
- Nursing staff with expertise in caring for pediatric patients with end-stage disease on FH's pediatric hepatology/nephrology/GI medical/surgical inpatient unit
- Respiratory therapists with extensive experience in caring for pediatric transplant patients
- Social workers, dieticians and psychosocial staff with experience in caring for pediatric transplant patients

**4. Need Determination.**

- (a) **The application includes documentation that a minimum of five liver transplants will be performed within two years of certificate of need approval. Such evidence shall include, at a minimum, the number of livers procured in the state during the most recent calendar year, and an estimate of the number of patients in the service delivery area who would meet commonly-accepted criteria identifying potential liver transplant recipients. The caseload estimate shall be based on the number of persons with end-stage hepatic diseases in the service planning area, for which death due to the disease is likely to occur within one year without the transplantation.**

**Adventist Health System/Sunbelt, Inc. d/b/a Florida Hospital (CON application #10488)** reiterates latter portions of its response to need in item E.1.a of this report. These reiterations are reproduced below, for convenience.

FH states having made conservative market share assumptions by OTSA, as indicated below:

- No share of cases generated by OTSA 1 (Gainesville), with the UF Health Shands Hospital program inactive
- 50 percent share of cases generated by OTSA 2 (Tampa), as it is proximate to FH's location and does not have a pediatric liver transplant program
- 80 percent share of cases generated by OTSA 3 (Orlando), as it is FH's home planning area
- No share of cases generated by OTSA 4 (Miami) as it is the home of Jackson Memorial Hospital, the only operational program in Florida

Based on its market share assumptions, if approved, the applicant expects (patients age 0-14 years) to perform a total of four to five pediatric liver transplant procedures from OTSA 3 residents and a sum total of seven to eight of these procedures (patients age 0-14 years) when OTSA 2 residents are taken into consideration, from 2018 to 2020. See the figure below.

**Florida Hospital Projected Pediatric Liver Transplants Ages 0-14  
Years One-Three of Operation (2018-2020)**

Patient OTSA	Projected 0-14 Liver Transplants			Florida Hospital Projected Transplants			
	Year One 2018	Year Two 2019	Year Three 2020	Market Share OTSA Resident Cases	2018	2019	2020
1(Gainesville)	4.0	4.0	4.0	0.0%	0	0	0
2 (Tampa)	6.0	6.0	6.0	50.0%	3	3	3
<b>3 (Orlando)</b>	<b>5.0</b>	<b>5.0</b>	<b>6.0</b>	<b>80.0%</b>	<b>4</b>	<b>4</b>	<b>5</b>
4 (Miami)	9.0	9.0	9.0	0.0%	0	0	0
<b>Florida Resident Total, 0-14</b>	<b>24</b>	<b>24</b>	<b>25</b>	<b>FH Total -14 Transplants</b>	<b>7</b>	<b>7</b>	<b>8</b>

Source: CON application #10488, page 43, Figure 20 and page 71, Figure 22

The applicant states that in addition to transplant for the 0-14 population indicated above, FH projects that it will do one additional case in its pediatric program annually in the 15-17 age cohort or resulting from in-migration from areas outside of OTSA 2 or 3. This results in a total range of eight to nine of these proposed procedures from 2018-2020. See the figure below.

**Florida Hospital Projected Total Pediatric Liver Transplants Ages 0-17  
Years One-Three of Operation (2018-2020)**

	Year One 2018	Year Two 2019	Year Three 2020
Ages 0-14	7	7	8
Ages 15-17 and/or in-migration	1	1	1
<b>FH/FHTI Total Pediatric Liver Transplants</b>	<b>8</b>	<b>8</b>	<b>9</b>

Source: CON application #10488, page 43, Figure 21 and page 72, Figure 23

FH indicates that for the year ending June 30, 2014, 154 OTSA 3 pediatric (ages 0-17 years) patients had an acute or chronic liver disease discharge regardless of hospital location and for the year ending June 30, 2015, this discharge total rose to 164 and for the year ending June 30, 2016, the discharge total rose to 231. See the figure below.

**Acute or Chronic Liver Disease Discharges and ALOS,  
OTSA 3 Residents, Ages 0-17**

Age Cohort	Year Ending June 30		
	2014	2015	2016
0-14	131	142	189
15-17	23	22	42
<b>Total OTSA 3 Resident Discharges, Regardless of Hospital Location</b>	<b>154</b>	<b>164</b>	<b>231</b>
<b>ALOS for These Patients</b>	<b>7.1</b>	<b>7.8</b>	<b>7.1</b>

Source: CON application #10488, page 72, Figure 24

FH contends that as the number of OTSA 3 pediatric residents with severe acute or chronic liver disease continues to expand, it is reasonable to assume that the demand for advanced hepatology services, including liver transplantation, will continue to increase. FH provides a list of liver disease/failure diagnosis codes that the applicant states were used to develop the dataset (Exhibit P of the application).

**(b) The application includes documentation that the new liver transplantation program improves patient access.**

The reviewer provides a chart with a brief narrative description (see item E.3.a of this report) to indicate the driving distances (in miles) to the two Florida pediatric liver transplant providers, from the proposed location for FH.

**Adventist Health System/Sunbelt, Inc. d/b/a Florida Hospital (CON application #10488)** contends that the existing (CON) approved program for pediatric liver transplantation is not geographically accessible to residents of central Florida. FH asserts that the proposed project will significantly improve patient access by eliminating the burden of travel and even relocation far away from home to receive transplant care, pre-, during and post-surgery.

**2. Agency Rule Criteria**

**Chapter 59C-1.044, Florida Administrative Code, contains criteria and standards the Agency uses 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 transplant 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 application #10488)** states having a significant number of staff and facilities capable of providing the resources necessary to care for the patient's chronic illness prior to transplantation, during transplantation and in the post-operative period. FH states that it has extensive clinical capabilities and a long history of the provision of transplant services to adults and pediatric patients at FHTI. FH indicates that it offers specialized emergency services and is a tertiary care center—providing a wide range of services on a 24-hour basis.

The applicant notes having infrastructure already in place for both adult and pediatric transplant programs, including comprehensive continuity of services to manage chronic illness. FH indicates that pre-transplant and post-transplant services will be provided through the FHTI. The applicant states that inpatient services for the proposed project will be provided at FH, with 24-hour availability of transplant nurses and physicians.

- (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 application #10488)** indicates that cadaveric transplantation will be part of the proposed project at FH. The applicant states that the Organ Procurement Organization (OPO) for FH's services is TransLife Organ and Tissue Donation Services (TransLife). According to the applicant, FH owns and operates TransLife.

FH states that Dr. Michael Angelis, who is one of FH's current abdominal transplant surgeons with experience in pediatric liver transplantation, is the Surgical Director of TransLife. The reviewer notes that this is confirmed in the curriculum vitae (CV) of Michale Angelis, MD, FACS (Exhibit J of the application). The physician's CV also indicates that among other distinctions/titles/affiliations, Dr. Angelis is

also Surgical Director of Kidney Transplantation (FHTI) and the Chief Surgical Director/Chairman of the Department of Transplantation at FH.

FH indicates having a long-standing agreement with TransLife in which the OPO provides a 24-hour call-line for the assessment, management and retrieval of all referred donors, cadaver donors or organs shared by other transplant programs or organ procurement agencies. According to FH, the OPO operates in conformance with the requirements of UNOS, OPTN and the US Department of Health and Human Services.

FH provides a copy of the agreement between FH and TransLife (Exhibit C of the application). The reviewer notes that this 11-page signed and dated agreement states on page one of the agreement that TransLife Organ and Tissue Donation Services is a division of Adventist Health System/Sunbelt, Inc. d/b/a Florida Hospital.

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

**Adventist Health System/Sunbelt, Inc. d/b/a Florida Hospital (CON application #10488)** indicates that pediatric patients who receive a liver transplant through FH will receive care in the ICU and inpatient units. The applicant also indicates that following transplantation, patients will be transferred to the pediatric ICU, which currently has the capability to offer prolonged reverse isolation, if needed.

**(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 application #10488)** maintains that consistent with FH's other solid organ transplant programs for pediatric and adult patients, the proposed pediatric liver transplantation program will include a thorough evaluation prior to acceptance into the program. The applicant states that it currently has detailed policies and procedures in place detailing the criteria by which patients are identified for evaluation for a potential solid-organ transplant. The

applicant briefly describes this process and itemizes the medical transplant practitioners and other transplant and transplant-related staff that compose the patient review committee (pages 46 and 47 of the application).

FH provides a copy of the six-page Transplant Multidisciplinary Team Policy, the three-page Liver Patient Review Policy, the three-page Liver Selection Criteria Policy and the two-page Liver Candidate Listing Policy for the adult liver transplant program at FH (Exhibit D of the application). The reviewer notes that all four of these established policies have a review date in either 2016 or 2017, indicating that these policies were reviewed recently by the provider.

- (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 application #10488)** states that given the long history of the provision of solid organ transplants at FH, the applicant has detailed policies and procedures in place for patient evaluation/selection, patient care and discharge management. The applicant also maintains that FH's existing infrastructure of transplant policies and procedures has been in place for many years and transplant team members are well-equipped in operating within facility-specific as well as regulatory guidelines for transplant services. FH maintains that this well-established transplant procedure framework will make the implementation of the proposed project seamless.

FH contends that through its partnership with UPMC, it will develop specific policies for a pediatric liver transplantation program. The applicant expects that policies and procedures for the proposed project will be consistent with its existing adult policies, to the extent they are appropriate, and will be supplemented/revised to reflect specific needs of the pediatric population as described in UPMC's policies.

The applicant provides a brief description of the UPMC's pediatric liver transplant policies and procedures (pages 46 through 48 of the application) and a brief description of FH's own adult liver transplant policies and procedures (pages 48 and 49 of the application).

FH also provides a copy of the following UPMC (pediatric liver transplant) and FH (adult liver transplant policies) in Exhibit E of the application:

- UPMC Pediatric Liver Policies
  - Pediatric Transplant Evaluation Protocol (two pages with an evaluation protocol checklist attachment and an evaluation safety checklist attachment)
  - Waitlist Management Policy (three pages)
  - Patient Management Policy (three pages)
  
- FH Adult Liver Policies
  - Liver Evaluation Policy (eight pages)
  - Abdominal Transplant Liver Post-Operative Management (one page)
  - Post-Operative Liver Management (two pages)
  - Increased Risk Transplant Follow-Up Testing (one page)
  - Abdominal Transplant Liver Post-Transplant Follow-Up (one page)
  - Liver Post-Transplant Follow-Up (two pages)

The reviewer notes that all nine of these established policies (both UPMC and FH combined) have a review date in either 2016 or 2017, indicating that these policies were reviewed recently by the provider. The reviewer also notes that the policies indicate reference to OPTN and/or UNOS notifications/policies or Centers for Medicare and Medicaid Services (CMS) regulations/conditions of participation.



- (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 application #10488)** maintains that given the long history of the provision of solid organ transplants at FH, the applicant has thorough clinical protocols and guidelines in place related to the acute and long-term management of liver transplant patients and potential complications. FH asserts that through the proposed partnership with UPMC, FH physicians and patients will have the capability to consult with UPMC physicians through the use of telemedicine.

FH comments that policies specific to the pediatric population will be consistent with these policies, to the extent they are applicable and will essentially be a hybrid of FH adult and UPMC pediatric liver transplant policies.

- (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 application #10488)** points out the CMS-certified OPO, TransLife, serves OTSA 3 in the provision of solid organ recovery services. The applicant indicates that TransLife provides necessary equipment and personnel to recover solid organs for transplantation, including but not limited to the surgical recovery, organ flushing/cooling, preservation and transportation of solid organs.

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

**Adventist Health System/Sunbelt, Inc. d/b/a Florida Hospital (CON application #10488)** states that FH currently performs tissue-typing and other transplant lab services in-house.

FH provides a copy of its American Society for Histocompatibility and Immunogenetics (ASHI) certificate (Exhibit F of the application). The reviewer notes that this ASHI certificate, issued to Florida Hospital Medical Center/Tissue Typing Laboratory (ASHI #10-3-FL-07-1 and CLIA #10D0663787) is effective from 9/1/2015 to 8/31/2017. The reviewer also notes that this certificate was issued to the facility under the direction of Deborah Thoni, MD. According to the Florida Department of Health (FDOH)/FLHealthSource.gov website at <https://appsmqa.doh.state.fl.us/MQASearchServices/HealthcareProviders/LicenseVerification?LicInd=45660&Procde=1501&org=%20>, on June 29, 2017, Deborah E. Thoni, MD, license ME54723, has specialty board certification with the American Board of Pathology. The same source also indicated that this physician has an address of record/primary practice address at 601 East Altamonte Avenue, Pathology Department, Altamonte Springs, Florida 32701 and also has staff privileges at FH. The reviewer notes that this address is a laboratory services location of Florida Hospital, per the website: <https://www.floridahospital.com/laboratory>.

FH provides a brief description of on-site tissue-typing laboratory services and protocols pursuant to the proposed project (page 50 of the application).

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

**Adventist Health System/Sunbelt, Inc. d/b/a Florida Hospital (CON application #10488)** indicates that after transplant surgery, patients must be monitored through routine bloodwork and testing, including liver tissue biopsies. According to the applicant, the biopsies are scheduled in advance and are not emergent in nature. FH states that the results of the biopsy give post-transplant hepatologists clear information related to patient and organ's response to the transplant. FH maintains that given the extensive nature of the existing transplant program, FH offers these services in-house and turn-around time is in 24 hours or less.

**(10) Blood banking facilities.**

**Adventist Health System/Sunbelt, Inc. d/b/a Florida Hospital (CON application #10488)** states that it meets the blood products requirements for solid organ transplantation procedures and maintains a contract with OneBlood, Inc. for blood banking services. FH contends that through the current agreement, OneBlood performs functions and services in the collection, preparation, processing, quality control and distribution of transfusable blood products for use by the applicant.

FH provides a copy of the 25-page agreement signed by senior executives of OneBlood, Inc. and ASH/S (Exhibit G of the application).

**(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 application #10488)** points out that through its numerous existing solid organ transplant programs for adult and pediatric patients, FH has existing staff who are well-trained in transplant patient management and will be able to draw on existing expertise as the basis for additional training for pediatric liver transplant.

The applicant briefly discusses registered nurse training protocols and timeframes that are specific to transplantation and particularly liver transplantation (page 51 of CON application #10488). The applicant provides 2017 transplant workshop materials, “Transplant Updates” (Exhibit H of the application). The applicant also briefly discusses that its existing transplant training materials along with those of the proposed partnership with UPMC will ensure the FH staff have a solid foundation in the most advanced techniques for medical and surgical management of young patients who require a liver transplant. UPMC pediatric liver transplantation materials are also provided (Exhibit H of the application).

**(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 application #10488)** discusses its existing education programs for patients, their families and the patient's primary care physician regarding the full array of transplantation services that are specific to each solid organ transplantation program at FH. The applicant also discusses the responsibilities of the provision of general education (both pre- and post-transplant). If a patient is deemed appropriate for transplantation, FH indicates that the patient/family are required to complete education classes focused on the overall transplant process and medication compliance after transplantation. FH maintains that patients receive a handbook/guide that is specific to their particular type of solid organ transplant. FH states that education material for pediatric transplant patients differs from education material for adult transplant patients but that FH currently has a pediatric kidney transplant handbook titled, "The Inside Story: A Kid's Guide to Kidney and Liver Transplants". The applicant provides a copy of this 49-page handbook (Exhibit I of the application).

Additionally, FH provides a copy of the 77-page "Pediatric Liver Transplant Handbook – A Guide for Health Care After Liver Transplantation", by UPMC. FH asserts that it will develop education materials through its existing handbooks/guides and will revise/supplement to that provided in UPMC's Pediatric Transplant Handbook.

**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 application #10488)** states that it already operates a robust adult liver transplantation program and has a number of physicians on its staff who have experience and expertise in caring for patients with end-stage liver disease and those who require transplant.

FH points out that Regino P. Gonzalez-Peralta, MD, was recently recruited to serve as the Medical Director of the Pediatric Transplant Program (as of 9/18/2017). FH states that this physician has extensive experience in caring for children and adolescents with liver disease. FH provides this physician's CV (Exhibit J of the application). According to Dr. Gonzalez-Peralta's CV, he was the Medical Director, Pediatric Liver Transplant Program at the University of Florida College of Medicine from 2000 to 2012. According to the FDOH/FLHealthSource.gov website at <https://apps.mqa.doh.state.fl.us/MQASearchServices/HealthcareProviders/Details?LicInd=47819&ProCde=1501>, on June 30, 2017, Regino P. Gonzalez-Peralta, MD, license ME56890, had specialty board certification with the American Board of Pediatrics, with specific certification in Pediatric Gastroenterology. According to the same source, this physician has an address of record/primary practice location at 1600 SW Archer Road, Gainesville, Florida 32610.

FH discusses the responsibilities of the applicant's Medical Director of the Pediatric Liver Transplant program (pages 53 and 54 of the application). FH comments that that Dr. Gonzalez-Peralta brings with him a large body of on-going research studies to FH, providing the opportunity for patients to access clinical trials, experimental procedures and research studies related to management of liver disease.

FH notes that two of Florida Hospital's four abdominal transplant physicians (Dr. Thomas Chin and Dr. Michael Angelis) currently on staff have experience in the provision of pediatric liver transplantation. Per FH, Dr. Chin will work side-by-side with UPMC's surgeons to provide the highest quality transplant surgery for children who require liver transplantation.

FH indicates four UPMC transplant surgeons (Drs. George Mazariegos, Gregory Bond, Rakesh Sindhi and Kyle Soltys)

who will provide clinical oversight and support for the applicant's existing surgeons in developing the pediatric liver transplant program. FH provides these physicians' CVs (Exhibit J of the application). The reviewer notes that according to each of these physicians' CVs, these four physicians have expertise in caring for patients with end-stage disease requiring transplantation and each of these CVs also indicate that each of these physicians have medical specialties or sub-specialties appropriate for the type of transplantation program that is being proposed.

FH indicates that in addition to the physicians named above, Linda Marie Hernandez Jaramillo, MD, with board certification in Pediatric Gastroenterology, will also be part of the proposed transplant team. According to this physician's CV (Exhibit J of the application), Dr. Hernandez Jaramillo has been a pediatric gastroenterologist with the Florida Hospital Medical Group since November 2014.

The reviewer notes that the applicant does not comment on a physician with one-year experience in the management of infectious diseases in the transplant patient as being a member of the proposed transplant team. However, the reviewer notes that according to the applicant's website at [https://www.floridahospital.com/find-a-doctor/infectious-disease-doctors?sort-by=name&speciality=infectious-disease-doctors&sub\\_specs=%7CInfectious%20Diseases](https://www.floridahospital.com/find-a-doctor/infectious-disease-doctors?sort-by=name&speciality=infectious-disease-doctors&sub_specs=%7CInfectious%20Diseases), FH lists 16 Orlando physicians and 104 physicians within the entire AHS/S with infectious disease specialty.

- (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 application #10488)** notes the expertise of Regino P. Gonzalez-Peralta, MD as well as Barry S. Friedman, Senior Administrative Director for FHTI and Jacquelyn Jean Parrish, Transplant Coordinator.

The applicant describes Dr. Friedman's responsibilities and role and discusses his expertise in administrative oversight of solid organ transplant, including liver programs, for adults and children (pages 55 and 56 of the application).

FH states that specific to the pediatric solid organ transplant program at FH, Ms. Parrish serves as the Kidney and Kidney/Pancreas Transplant Coordinator for pediatric and adult patients. The reviewer notes that FH is CON approved to provide pediatric and adult kidney transplantations and adult pancreas transplantation but not pediatric pancreas transplantation.

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

**Adventist Health System/Sunbelt, Inc. d/b/a Florida Hospital (CON application #10488)** reiterates currently providing pediatric kidney and pediatric inpatient bone marrow transplantation and already having a large network of physicians, nurses and other support staff with extensive experience in caring for the special needs of children. FH contends that through its partnership with UPMC, the applicant's pediatric nursing and support staff will be well-trained in the provision of care for pediatric patients before, during and after liver transplantation.

FH briefly discusses the responsibilities of its Pediatric RN Care Managers. The applicant provides the job description and specifications for these positions (Exhibit L of the application).

**(4) 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 application #10488)** states already having nurses and nurse practitioners with extensive experience in the care of chronically ill patients and the support of their families. FH maintains that the hospital currently has staffing in place, through both the FHTI and the FH, with particular note that the hospital already has nurses that provide care for children with end-stage renal disease and those who have undergone kidney transplants.

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

**Adventist Health System/Sunbelt, Inc. d/b/a Florida Hospital (CON application #10488)** points out currently meeting the blood products requirements for solid organ transplantation procedures. The applicant reiterates its contractual agreement with OneBlood, Inc.

- (6) **Nutritionists with expertise in the nutritional needs of transplant patients.**

**Adventist Health System/Sunbelt, Inc. d/b/a Florida Hospital (CON application #10488)** indicates that registered dieticians (RDs) assigned to the care of transplant patients are part of the FHTI Patient Review Committee. FH points out that the hospital's RDs currently perform nutritional assessments and other dietary counseling services for patients and their families.

FH states that duties of the transplant dieticians include:

- Informing potential transplant patients of potential diet and nutrition-related risks
- Providing education on optimizing nutritional status to prepare for surgery
- Provides inputs into interventions and care plans according to transplant center policies
- Participates in team Quality Assessment and Performance Improvement Programs
- Participates in Patient Review Committee
- Serves as a resource and nutrition educator to the multidisciplinary transplant team by remaining abreast of the current evidence-based practice guidelines and recommendation for transplant nutrition

FH indicates that Maria Sheila Opina, MS, RD, LDN is one of the current transplant dieticians at FH and will serve as the dietician for the proposed pediatric liver transplantation program, as she currently provides nutrition programming for FH's pediatric kidney transplant and adult liver transplant programs.



FH provides a copy of the job description for the Specialty Clinical Dietician, as well as the CV for Ms. Opina (Exhibit M of the application). The reviewer notes that the referenced job description was last reviewed 1/2/2010. The reviewer also notes according to Ms. Opina's CV, she has been a transplant dietician at FHTI since September 2015.

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

**Adventist Health System/Sunbelt, Inc. d/b/a Florida Hospital (CON application #10488)** states that its respiratory therapists (RTs) are primarily involved with the needs of transplant patients during the inpatient stay and that this is most typically provided in the ICU and/or in the step down unit. FH contends that its RTs presently provide care to immunosuppressed patients and pediatric patients who receive transplants in the existing programs offered by FH. The applicant asserts that there will be no need to expand its respiratory therapy department in order to provide services to the proposed pediatric liver transplant patients. FH comments that, if necessary, additional training for the care of pediatric liver transplant patients will be provided by the Transplant Team.

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

**Adventist Health System/Sunbelt, Inc. d/b/a Florida Hospital (CON application #10488)** states currently having experienced social workers and psychologists on staff to evaluate and counsel potential transplant candidates and their families, patients waiting for a transplant and those who have been transplanted. The applicant indicates that all potential transplantation patients are assessed by social workers and that services of psychologists, psychiatrists and others are available as deemed appropriate by the patient, their family or the Transplant Team.

FH states that Valorey Young is a licensed clinical social worker (LCSW) with a Master of Social Work (MSW),

currently employed as a full-time LCSW within FHTI. This practitioner is stated to be responsible for completing comprehensive psychosocial evaluations on adults and children who are potential transplant candidates.

FH states providing a copy of the job description of the FH Transplant Licensed Clinical Social Worker, as well as the Certified Clinical Transplant Social Worker, along with Ms. Young's CV (Exhibit N of the application). The reviewer notes that under the Certified Clinical Transplant Social Worker job description's licensure, certification or registration heading, a current Florida license as an LCSW is required as well as certification for a Clinical Transplant Social Worker through the Society of Transplant Social Workers. The reviewer further notes that a CV for Ms. Young is not included in the applicant's Exhibit N. However, according to the FDOH/FLHealthSource.gov website at <https://apps.mqa.doh.state.fl.us/MQASearchServices/HealthCareProviders/LicenseVerification?LicInd=10596&ProCde=5201&org=%20>, on June 30, 2017, Valorey B. Young, license SW8065, is licensed as an LCSW. The same source also indicated that this practitioner has an address of record at 2415 North Orange Avenue, Suite 700, Orlando, Florida 32804.

FH points out that financial evaluation is part of the pre-assessment process for all transplant patients.

FH asserts that there is no need to expand its social work and counseling departments in order to provide support to the proposed pediatric liver transplantation program.

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

**Adventist Health System/Sunbelt, Inc. d/b/a Florida Hospital (CON application #10488)** assures that it will comply with the organ transplant data reporting requirements of the Agency and agrees to provide data as required for the proposed project.

**3. Statutory Review Criteria**

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

The mileage chart below indicates the driving distance (in miles) to the two Florida pediatric liver transplant providers (UF Health Shands Hospital and Jackson Memorial Hospital), from the proposed location for CON application #10488.

<b>Driving Distance in Miles Adventist Health System/Sunbelt, Inc. d/b/a Florida Hospital (CON application #10488) and Florida Pediatric Liver Transplantation Providers</b>			
<b>Facility</b>	<b>Florida Hospital</b>	<b>UF Health Shands Hospital</b>	<b>Jackson Memorial Hospital</b>
Florida Hospital		113	236
UF Health Shands Hospital	113		334
Jackson Memorial Hospital	236	334	

Source: [www.Mapquest.com](http://www.Mapquest.com)

The chart above illustrates that from the proposed CON application #10488, the nearest pediatric liver transplant provider (UF Health Shands Hospital in OTSA 1) is 113 miles, with the second nearest (and last) provider (Jackson Memorial Hospital in OTSA 4) being 236 miles away. As previously indicated in item E.1.a of this report, for the five-year period ending December 31, 2016, Jackson Memorial Hospital has been the predominant provider of pediatric liver transplantation procedures statewide. Also as previously indicated, Jackson Memorial Hospital performed 89.76 percent of all pediatric liver transplants in the five-year period ending December 31, 2016 and 100 percent of all such transplants statewide in CY 2015 and in CY 2016. Again as previously stated, OTSA 3 has no operational or CON approved pediatric liver transplantation provider. The reviewer notes that pursuant to 59C-1.008 (2) (e) 3.—the existence of unmet need will not be based solely on the absence of a health service, health care facility, or bed in the district, subdistrict, region or proposed service area.

**Adventist Health System/Sunbelt, Inc. d/b/a Florida Hospital (CON application #10488)** restates that there is no pediatric liver transplantation program in OTSA 3 and only one active program in

Florida (at Jackson Memorial Hospital in OTSA 4 – the southernmost part of the state). FH maintains that this represents a geographic maldistribution of pediatric liver transplantation in the central and northern areas of Florida.

FH reiterates that the pediatric population (ages 0-14 years) in OTSA 3 is expected to realize the highest rate of growth of any OTSA in Florida, increasing by more than 50,000 residents by 2020 (a 7.0 percent increase from 2017 to 2022). The applicant notes the complex and high acuity service lines already provided in the area by the parent, AHS/S, including services at FH.

The applicant points out that for the 12 months ending June 30, 2016, FH discharged more than 10,000 patients ages 0-17, accounting for nearly 53,000 patient days, with FH having an average daily census (ADC) of 145 pediatric patients in the 0-17 age cohort resulting in approximately 65 percent occupancy on 244 beds.

FH contends and the Agency verifies that currently, FHTI offers pediatric kidney transplant and inpatient pediatric bone marrow transplant programs and that these two programs are the only operational pediatric transplant programs located within OTSA 3. However, the Agency notes that OTSA 3's Nemours Children's Hospital is CON approved to operate a pediatric lung transplantation program (CON #10473) and OTSA 3's Arnold Palmer Medical Center is CON approved to operate a pediatric inpatient bone marrow transplantation program (CON #10208).

FH comments that Florida Hospital Children's Network has a number of clinics and locations that are geographically distributed throughout central Florida. The applicant points out that the FHFC network has:

- Eight primary care offices
- Five specialty clinics
- Two pediatric urgent care locations (12,427 visits in 2016)
- Specialized pediatric emergency department units (100,241 visits in 2016)

The applicant maintains that the availability of specialized clinic services, including an extensive continuum of GI and Hepatobiliary Disease services through FH for Children's Network, coupled with its existing expertise in pediatric solid organ transplantation and its proposed partnership with world-class pediatric transplant provider UPMC, make FH the obvious choice for the addition of a pediatric liver transplant program.

**CON Action Number: 10488**

FH provides the figure below to account for a list of considerations that the applicant believes present favorable circumstances upon which to grant project approval. The reviewer deletes the column in the applicant's figure that referenced CON application #10489 (The Nemours Foundation d/b/a Nemours Children's Hospital) as that applicant did not submit an omissions response for this batching cycle.

**Florida Hospital**

	<b>Florida Hospital</b>
Number of Licensed Pediatric Beds	214
Number of Pediatric Discharges (Ages 0-17) for YE June 30, 2016	10,134
Number of Pediatric Patient Days (Ages 0-17 for YE June 30, 2016	52,933
Pediatric ADC (Ages 0-17 for YE June 30, 2016	145
Pediatric Occupancy for JE June 30,2016	67.80%
Statutory Teaching Hospital?	Yes
Part of a Larger Network of Facilities in OTSA 3?	Yes
Additional Pediatric ADC (Ages 0-17) at System Hospitals	69.3
Number of Operational Adult and Pediatric Solid Organ Transplant Programs	6
Total Number of Solid Organ Transplants (All Ages) Since Inception of FHTI	Nearly 5,000
Ability to Treat Liver Failure Patients of All Ages?	Yes
Adult Liver Transplant Program?	Yes
Number of Adult Liver Transplants for YE June 30, 2016	66
Transplant Infrastructure in Place to Seamlessly Add Pediatric Liver Program?	Yes

CON application #10488, page 79, Figure 28

FH states that according to 2016 data published by SRTR, FHTI has the lowest wait time in Florida for a liver transplant, with the median wait time being 2.3 months, while the national average is 15.7 months.

The applicant contends that the proposed clinical partnership with UPMC's Hillman Center for Pediatric Transplantation will ensure the highest quality pediatric liver transplant services are available to residents of Central Florida. FH further contends that UPMC has performed more than 1,200 pediatric liver transplants – more than any center in the country, according to UNOS. According to FH, the program is on the leading edge of expertise, innovation and patient/family centered care and is a transplant destination for patients from around the world. Also according to FH, the clinical, oversight and training that UPMC will offer FH's existing transplant staff expanded access to world-class services. The applicant indicates that UPMC's survival rates are among the best in the country.

FH again reiterates that with its existing wide array of highly complex product lines and its current high volume of adult liver transplants, the

proposed project (if approved) will ensure that all age cohorts can receive continuity of end-stage liver failure and transplant care in the appropriate setting (pediatric or adult) in the same health system/entity.

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

**Adventist Health System/Sunbelt, Inc. d/b/a Florida Hospital (CON application #10488)** submits Agency licensure (Exhibit R of the application) and Joint Commission accreditation (Exhibit Q of the application). AHS/S indicates that FH is comprised of the following seven hospital locations under one Medicare provider number:

- Florida Hospital Orlando
- Florida Hospital Altamonte
- Florida Hospital Apopka
- Florida Hospital Celebration Health
- Florida Hospital East Orlando
- Florida Hospital Kissimmee
- Winter Park Memorial Hospital

The applicant asserts that Florida Hospital provides a wide range of health services, including many nationally and internationally recognized programs in cardiology, cancer, women's medicine, neurosciences, diabetes, orthopedics, pediatrics, transplant and advanced surgical programs. As indicated previously, FH is a designated statutory teaching hospital.

Specific to transplantation services, the applicant maintains that FHTI has achieved several milestones in its existing solid organ transplant programs, including:

- 500<sup>th</sup> adult liver transplant performed (Dr. Thomas Chin, 2016).
- Awarded COIIN (Collaborative Innovation and Improvement Network) project participation which is a three-year pilot project funded by the US Health and Resources Services Administration (HRSA). The OPTIN/UNOS staff will be assessing effective practices for utilization of moderate to high "KDPI" kidneys while maintaining quality outcome measures (2017).
- #1 volume center in the southeast for heart transplant and #11 in the United States (2016).
- 32<sup>nd</sup> largest kidney program in the United States (2016).
- Translife OPO Recognized as fastest growth OPO in the United States (2016).

The applicant maintains that FH facilities have earned numerous awards, recognitions and certifications including:

- One of America's Best Hospitals - Florida Hospital was recognized 10 years in a row (1999-2008) by *US News & World Report* as "One of America's Best Hospitals" for clinical specialties (in 10 listed specialty areas)
- 2011 - Ranked as #1 in Orlando metro area, nationally ranked in gynecology (#30) and gastroenterology (45)
- 2012 - Ranked as #1 in Orlando metro area, #2 in region, #2 in the State of Florida, nationally ranked (in seven listed specialty areas, one of these seven being gastroenterology (#16))
- 2013 - Ranked as #1 in Orlando metro area, #1 in region, #1 in the State of Florida, nationally ranked (in eight listed specialty areas, one of these eight being gastroenterology and GI surgery (#47))
- 2014 - Ranked as #1 in Orlando metro area, #1 in region, #1 in the State of Florida, nationally ranked (in 10 listed specialty areas, one of these 10 being gastroenterology and GI surgery (#19))
- 2015 - Ranked as #1 in Orlando metro area, #1 in region, #1 in the State of Florida (in nine specialty areas, one of these nine being gastroenterology and GI surgery (#33))
- 2016 and 2017 - #1 hospital in the Orlando metro area by *US News & World Report*
- One of the Largest Hospitals in America - The American Hospital Association ranked Florida Hospital first in the country for number of inpatient admissions (more than 1,000,000 patient visits per year in 2009)
- Sterling Award - FH was the 1<sup>st</sup> Florida hospital to be the proud recipient of the Governor's Sterling Award (1994 and 2010)
- Largest Non-Catholic Religious Healthcare System - *Modern Healthcare* named Adventist Health System the largest non-Catholic religious healthcare system in the nation (2009)
- One of Central Florida's Largest Hospitals - FH is consistently recognized as one of Central Florida's largest hospitals (ranked by number of acute care beds by *The Orlando Business Journal*).

In addition to the above recognitions, the applicant highlights other awards and recognitions on pages 11 through 14 of the application. The reviewer notes that the applicant does not provide documentation to confirm any of the milestones, awards, recognitions and/or certifications listed above.

The applicant discusses the purpose and outlines (page 82 of the application) of the Florida Hospital Quality Assessment and Performance Improvement (QAPI) Policy for Transplant Services (Exhibit Q of the application). The reviewer notes that the five-page FH transplant policy (Policy #: 020.280) has an effective date of 10/26/2016 and last revised date of 3/27/2017. The reviewer also notes that the bulleted purpose and bulleted outlines of the policy (as indicated on page 82 of the application) are consistent with the policy. The reviewer further notes that the policy references CMS regulations.

FH contends that the hospital's transplant policy ensures that it continuously monitors all phases of the transplant process for all of its solid organ transplant programs and that the proposed project will continue the organization's quality focus by offering safe, effective, patient-centric care to residents of the OTSA.

The parent, AHS/S, had 24 substantiated complaints among a total of 5,407 licensed beds, spread among its 22 Florida facilities, for the 36-month period ending May 24, 2017. Florida Hospital had three substantiated complaints during the same 36-month period. A single complaint can encompass multiple complaint categories. The substantiated complaint categories, for the parent and for Florida Hospital, are listed below:

<b>AHS/S Substantiated Complaint Categories 36 Months Ending May 24, 2017</b>	
<b>Complaint Category</b>	<b>Number Substantiated</b>
Quality of Care/Treatment	8
Emergency Access	5
Admission/Transfer and Discharge	4
Infection Control	4
Nursing Services	4
EMTALA	3
Resident/Patient/Client Assessment	2
Life Safety Code	1
Pharmaceutical Services	1
Physician Services	1
Resident/Patient/Client Rights	1
Restraints/Seclusion General	1

Source: Florida Agency for Healthcare Administration Complaint Records

<b>Florida Hospital Substantiated Complaint Categories 36 Months Ending May 24, 2017</b>	
<b>Complaint Category</b>	<b>Number Substantiated</b>
Admission, Transfer and Discharge	1
Life Safety Code	1
Quality of Care/Treatment	1

Source: Florida Agency for Healthcare Administration Complaint Records

The applicant demonstrates it is a quality care provider.



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

**Adventist Health System/Sunbelt, Inc. d/b/a Florida Hospital (CON application #10488):**

**Analysis:**

The purpose of our analysis for this section is to determine if the applicant has access to the funds necessary to fund this and all capital projects. Our review includes an analysis of the short and long-term position of the applicant, parent, or other related parties who will fund the project. The analysis of the short and long-term position is intended to provide some level of objective assurance on the likelihood that funding will be available. The stronger the short-term position, the more likely cash on hand or cash flows could be used to fund the project. The stronger the long-term position, the more likely that debt financing could be achieved if necessary to fund the project. We also calculate working capital (current assets less current liabilities) a measure of excess liquidity that could be used to fund capital projects.

Historically we have compared all applicant financial ratios regardless of type to bench marks established from financial ratios collected from Florida acute care hospitals. While not always a perfect match to a particular CON project it is a reasonable proxy for health care related entities. The below is an analysis of the audited financial statements of Adventist Health System (applicant) where the short-term and long-term measures fall on the scale (highlighted in gray) for the most recent year.

<b>Adventist Health System</b>		
	<b>Dec-16</b>	<b>Dec-15</b>
Current Assets	\$7,413,654,000	\$6,611,806,000
Total Assets	\$14,245,138,000	\$12,991,166,000
Current Liabilities	\$2,407,451,000	\$2,131,875,000
Total Liabilities	\$5,843,977,000	\$5,396,815,000
Net Assets	\$8,401,161,000	\$7,594,351,000
Total Revenues	\$9,651,689,000	\$9,116,187,000
Excess of Revenues Over Expenses	\$666,160,000	\$710,879,000
Cash Flow from Operations	\$1,129,640,000	\$699,237,000
<b>Short-Term Analysis</b>		
Current Ratio (CA/CL)	3.1	3.1
Cash Flow to Current Liabilities (CFO/CL)	46.92%	32.80%
<b>Long-Term Analysis</b>		
Long-Term Debt to Net Assets (TL-CL/NA)	40.9%	43.0%
Total Margin (ER/TR)	6.90%	7.80%
<b>Measure of Available Funding</b>		
Working Capital	\$5,006,203,000	\$4,479,931,000

<b>Position</b>	<b>Strong</b>	<b>Good</b>	<b>Adequate</b>	<b>Moderately Weak</b>	<b>Weak</b>
Current Ratio	above 3	3 - 2.3	2.3 - 1.7	1.7 - 1.0	< 1.0
Cash Flow to Current Liabilities	>150%	150%-100%	100% - 50%	50% - 0%	< 0%
Debt to Equity	0% - 10%	10%-35%	35%-65%	65%-95%	> 95% or < 0%
Total Margin	> 12%	12% - 8.5%	8.5% - 5.5%	5.5% - 0%	< 0%

**Capital Requirements and Funding:**

The applicant indicates on Schedule 2 capital projects totaling \$2,054,013,980 which includes this CON, contingencies, maturities of long-term debt, and other projects. Funding for this project will be provided by cash on hand. The applicant provided a copy of its December 31, 2016 and 2015 audited financial statements. These statements were analyzed for the purpose of evaluating the applicant’s ability to provide the capital and operational funding necessary to implement the project. Based on our analysis above, the applicant has an adequate financial position.

**Staffing**

The Schedule 6A table below shows the FH’s projected incremental staffing for the proposed project in years one, two and three. The reviewer notes that Schedule 6A does not indicate an ending date for years one through three of the proposed project. However, Schedule 7A indicates that year one ends December 31, 2018, year two ends December 31, 2019 and year three ends December 31, 2020). The table below only accounts for FTEs to be added as a result of the proposed project, if approved. The reviewer notes that in year one and in year two, the total FTE count is 5.8 and in year three, 6.2. See the table below.

<b>Adventist Health System/Sunbelt, Inc. d/b/a Florida Hospital (CON application #10488) Pediatric Liver Transplantation Program Staffing Patterns</b>			
	<b>Year One Ending Date 12/31/2018</b>	<b>Year Two Ending Date 12/31/2019</b>	<b>Year Two Ending Date 12/31/2020</b>
<b>PHYSICIANS</b>			
Transplant team phys. (contract)	0.2	0.2	0.2
<b>NURSING</b>			
Transplant Care Coordinators	1.0	1.0	1.0
Care Coordinator	1.0	1.0	1.0
RNs	2.3	2.3	2.6
Other Ancillary	1.3	1.3	1.4
<b>TOTAL</b>	<b>5.8</b>	<b>5.8</b>	<b>6.2</b>

Source: CON application #10488, Schedule 6A

Notes to Schedule 6A indicate that as an existing provider of transplant services, much of the technical and clinical expertise is currently available and can serve both the existing transplant programs and the proposed pediatric liver transplant program efficiently and effectively.

**Conclusion:**

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

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

**Adventist Health System/Sunbelt, Inc. d/b/a Florida Hospital (CON application #10488):** Our comparison is of the applicant’s estimates to its latest FHURs report.

Because the proposed pediatric liver transplant program cannot operate without the support of the hospital, we have evaluated the reasonableness of the projections of the entire hospital including the project. The applicant will be compared to its latest AHCA filing which was December, 2016. Inflation adjustments were based on the new CMS Market Basket, 3rd Quarter, 2016.

	PROJECTIONS PER APPLICANT		Actual Data Inflated to
	Total	PPD	2019
Net Revenues	3,453,742,540	4,770	4,994
Total Expenses	3,068,588,850	4,238	4,387
Operating Income	385,153,690	532	618
Operating Margin	11.15%		
	Days	Percent	Percent
Occupancy	724,012	62.44%	72.58%
Medicaid/MDCD HMO	108,293	14.96%	14.06%
Medicare/MCARE HMO	369,812	51.08%	53.25%

NRPD, CPD, and profitability or operating margin that fall close to the actual data are considered reasonable projections.

The projections for NRPD (95.5 percent), CPD (96.6 percent), and operating income (86.1 percent) are all slightly under the inflated actual data but appear to be reasonable.

The pediatric liver transplant program represents .08 percent of the hospital's total revenue and .06 percent of the hospital's expenses. Projections indicate a \$260,877 profit margin at the end of year two. Because the transplant program is such a minor part of the hospital's overall operations, the hospital could easily support the pediatric liver transplant program even if extended losses were projected.

**Conclusion:**

This project appears to be financially feasible and the projected NRPD, CPD, and profitability appear to be attainable.

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

**Adventist Health System/Sunbelt, Inc. d/b/a Florida Hospital (CON application #10488):**

**Analysis:**

Strictly from a financial perspective, the type of competition that would result in increased efficiencies, service, and quality is limited in health care. Cost-effectiveness through competition is typically achieved via a combination of competitive pricing that forces more efficient cost to remain profitable and offering higher quality and additional services to attract patients from competitors. In addition, competitive forces truly do not begin to take shape until existing business' market share is threatened. The existing health care system's barrier to price-based competition via fixed price payers limits any significant gains in cost-effectiveness and quality that would be generated from competition.

**Conclusion:**

This project is not likely to have a material impact on competition to promote quality and cost-effectiveness.

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

**Adventist Health System/Sunbelt, Inc. d/b/a Florida Hospital (CON application #10488)** reports no construction and no renovation associated with the proposed project.

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

Below is a chart to account for the applicant's and District 7's Medicaid and charity care percentages for fiscal year (FY) 2015, as indicated by the Agency's Florida Hospital Uniform Reporting System (FHURS).

**Medicaid and Charity Care for  
Adventist Health System/Sunbelt, Inc. d/b/a Florida Hospital  
(CON application #10488)  
Compared to the District for FY 2015**

<b>Applicant*</b>	<b>Medicaid and Medicaid HMO Days</b>	<b>Charity Percentage Service</b>	<b>Combined Medicaid and Charity Care</b>
Florida Hospital	14.94%	4.53%	19.47%
<b>District 7 Average</b>	17.49%	3.86%	21.35%

Source: Fiscal Year 2015 Agency for Health Care Administration Actual Hospital Data  
Note: \*For this review, FH's FY end date was 12/31/2015.

As previously indicated in item C of this report, FH is licensed as a Class 1 hospital. The table below illustrates FH's (CON application #10488's) FY 2016-2017 low-income pool (LIP) and disproportionate share hospital (DSH) program participation, as of June 7, 2017.

<b>Adventist Health System/Sunbelt, Inc. d/b/a Florida Hospital (CON application #10488) LIP and DSH Program Participation FY 2016-2017</b>		
<b>Applicant/Program</b>	<b>Annual Total Allocation</b>	<b>Year-to-Date Total Allocation As of June 7, 2017</b>
Florida Hospital/LIP	\$24,804,758	\$0
Florida Hospital/DSH	\$5,513,911	\$5,513,911

Source: Agency Division of Medicaid, Office of Program Finance

The reviewer notes that, statewide, during the 12-month period ending December 31, 2016, there were 15 Medicaid/Medicaid Managed Care patients that received pediatric liver transplantation.<sup>5</sup>

**Adventist Health System/Sunbelt, Inc. d/b/a Florida Hospital (CON application #10488)** asserts being the most financially accessible hospital entity in the State of Florida, in terms of uncompensated care defined as bad debt and charity care. AHS/S asserts that FH provided \$948.7 million of bad debt and charity care in the 12 months ending December 31, 2015, which the applicant states was more than any other licensed hospital entity in Florida. Also, FH contends having provided more than two billion dollars in care to Medicaid patients in 2015. ASH/S indicates that for reporting purposes, FH includes the seven licensed hospitals listed in item E.3.b of this report. FH uses CY 2015 FHURS, to indicate FH bad debt, charity and bad debt and charity combined (in dollars) as well as the bad debt, charity and bad debt and charity combined (in percentages) for FH and for nine other licensed

<sup>5</sup> Based on the Agency's Florida Center for Health Information and Transparency hospital discharge data

hospitals in Florida. The reviewer collapses the bad debt column and the charity column into one bad debt and charity column and reproduces only the FH totals and not those of the remaining nine hospitals. See the figure below.

**Florida Hospital Bad Debit and Charity Care for FY 2015**

Facility System	FY 2015		FY 2015 Total Percent Revenue	
	Bad Debt and Charity	Medicaid	Bad Debt and Charity	Medicaid
Florida Hospital	\$948,661,131	\$2,155,713,754	7.0%	15.8%

Source: CON application #10488, page 86, Figure 29

ASH/S states the use of 2013-2015 FHURS data to discuss a three-year financial access summary of Florida Hospital. For this three-year period, ASH/S indicates a highest Medicaid and Medicaid HMO percentage total of 14.9 percent (2015) and a lowest Medicaid and Medicaid HMO percentage of 10.1 percent (2014). Using this same source for the same three years, ASH/S indicates a highest total bad debt and charity (in dollars) of \$1,051,899,186 (2014) and a lowest debt and charity (in dollars) of \$921,246,404.

In the proposed pediatric liver transplantation program, FH expects in both year one and year two, five cases (63 percent) to be a Medicaid/Medicaid HMO payer mix. In year three, FH expects five cases (56 percent) to be a Medicaid/Medicaid HMO payer mix. See the figure below.

**Florida Hospital Pediatric Liver Transplant Projected Payer Mix  
Year One to Year Three**

Payer Mix	Years One and Two		Year Three	
	Cases	Percent	Cases	Percent
Medicaid/Medicaid HMO	5	63%	5	56%
Managed Care	2	25%	2	22%
Global Payers	1	12%	2	22%
<b>Total</b>	<b>8</b>	<b>100%</b>	<b>9</b>	<b>100%</b>

Source: CON application #10488, page 86, Figure 29

The reviewer notes that the anticipated case totals for year one and for year two (eight) and for year three (nine), as shown above, are consistent with CON application #10488, page 43, Figure 21 and page 72, Figure 23.

The reviewer notes that the payer mix shown above is also consistent with Schedule 7A of the application, for year one and two (ending December 31, 2018 and December 31, 2019, respectively) and for year three (ending December 31, 2020).

FH offers no Medicaid/no charity care patient day conditions and no Medicaid/no charity care procedures conditions, regarding the proposed project.

**F. SUMMARY**

**Adventist Health System/Sunbelt, Inc. d/b/a Florida Hospital (CON application #10488)** proposes to establish a new pediatric liver transplantation program at FH, in Orlando, Orange County, OTSA 3. FH is Adventist Health System/Sunbelt, Inc.'s flagship hospital in Florida a Class 1 hospital with a statutory teaching hospital designation. The parent, AHS/S, operates 45 hospitals that span nine states. If approved, the proposed project will be part of the FHTI and will operate within FHFC, a 202-bed pediatric pavilion licensed as part of FH.

The total project cost is \$492,125, and involves no reported GSF of renovation and no new construction. Total project costs include equipment, project development and start-up costs.

Schedule C of the application includes one condition (see item C of this report).

**Need:**

Need is not published by the Agency for pediatric liver transplants. It is the applicant's responsibility to demonstrate need. The planning for organ transplantation programs in Florida is done on a regionalized basis covering four regions defined by rule. Pursuant to Rule 59C-1.008 (2)(e) 3, Florida Administrative Code—the existence of unmet need will not be based solely on the absence of a health service, health care facility, or beds in the district, subdistrict, region or proposed service area.

The Agency notes that the four OTSA 3 residents that received a pediatric liver transplant in the 12-month period ending December 31, 2016 out-migrated to another OTSA to receive this service (to OTSA 4 in 100 percent of cases). No OTSA 3 pediatric liver transplantation provider volume could be adversely impacted by approval of the proposed project, as there is currently no pediatric liver transplantation provider in the OTSA. However, the Agency notes that approval of the project would likely generate relatively light volume at the Florida Hospital location as proposed, due to:



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- Relatively low and stable pediatric liver transplantation volume statewide for the five-year period ending December 31, 2016.
- No additional pediatric liver transplantation providers were CON-approved or licensed anywhere statewide within the same five-year period.
- OTSAs that currently are CON-approved and licensed to provide pediatric liver transplantation services do so through a single provider.
- Section 408.032(17), Florida Statutes, defines a tertiary health service as, in part:  
*“...a health service which, due to its high level of intensity, complexity, specialized or limited applicability, and cost, should be limited to, and concentrated in, a limited number of hospitals to ensure the quality, availability, and cost-effectiveness of such service. Examples of such service include, but are not limited to, pediatric cardiac catheterization, pediatric open-heart surgery, organ transplantation, neonatal intensive care units, comprehensive rehabilitation...”*
- Per Rule 59C-1.002(41)(c), Florida Administrative Code, liver transplantation is a listed tertiary health service.

**Adventist Health System/Sunbelt, Inc. d/b/a Florida Hospital (CON application #10488)** presents the following five need justifications to warrant project approval:

- Lack of availability of pediatric liver transplant services in central and northern Florida.
- Burden of long travel times and distances.
- Significant percentage of patients who leave Florida and/or OTSA 3 each year to obtain a pediatric liver transplant.
- Logical extension of the of the numerous longstanding solid organ transplant programs offered by FH/FHTI, including adult liver and pediatric kidney transplant programs
- Participating with UPMC’s Hillman Center for Pediatric Transplantation, one of the premier transplant centers in the nation, will bring world-class pediatric liver transplant practitioners and immediate expertise to the residents of central Florida. Through the partnership, FH and UPMC will further develop a pioneering pediatric transplant network that will be a national model for complex care and outcomes in pediatric liver transplantation.

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In addition to these justifications, the applicant provides the following list of considerations that the applicant believes present favorable circumstances upon which to grant project approval.

**Florida Hospital**

	<b>Florida Hospital</b>
Number of Licensed Pediatric Beds	214
Number of Pediatric Discharges (Ages 0-17) for YE June 30, 2016	10,134
Number of Pediatric Patient Days (Ages 0-17 for YE June 30, 2016	52,933
Pediatric ADC (Ages 0-17 for YE June 30, 2016	145
Pediatric Occupancy for JE June 30,2016	67.80%
Statutory Teaching Hospital?	Yes
Part of a Larger Network of Facilities in OTSA 3?	Yes
Additional Pediatric ADC (Ages 0-17) at System Hospitals	69.3
Number of Operational Adult and Pediatric Solid Organ Transplant Programs	6
Total Number of Solid Organ Transplants (All Ages) Since Inception of FHTI	Nearly 5,000
Ability to Treat Liver Failure Patients of All Ages?	Yes
Adult Liver Transplant Program?	Yes
Number of Adult Liver Transplants for YE June 30, 2016	66
Transplant Infrastructure in Place to Seamlessly Add Pediatric Liver Program?	Yes

Additionally, FH maintains that with its existing wide array of highly complex product lines and its current high volume of adult liver transplants, the proposed project (if approved) will ensure that all age cohorts can receive continuity of end-stage liver failure and transplant care in the appropriate setting (pediatric or adult) in the same health system/entity. FH also maintains that this arrangement enhances continuity of care at its facility. FH further indicates being well equipped already to serve the sickest children and the most complex cases.

The applicant notes that the proposed service will be able to perform SLT where one adult liver is split between two patients and the two segments of the organ can be split between an adult and a child or two children. FH asserts that liver transplant surgeons at FH have experience in performing SLT on both adults and pediatric patients. Based on this experience and history, according to the applicant, the proposed project will allow FH to more efficiently utilize available livers by performing SLT on a pediatric and adult patient or two pediatric patients, when clinically appropriate.

If approved, FH expects to perform a total of eight pediatric liver transplants each in year one and year two (ending 12/31/2018 and 12/31/2019, respectively) and a total of nine in year three (ending 12/31/2020).

The Agency has determined that within the context of the criteria specified in Section 408.035, Florida Statutes, and 59C-1.044, Florida Administrative Code, that the applicant did demonstrate need for the proposed service and that the proposed service will enhance access to liver transplant services to all ages, especially the pediatric population, in the OTSA. The proposed program will allow for continuity of care for accessible and available services in Florida Hospital's identified service district for transplant services. The applicant has also demonstrated that it has the available resources for project accomplishment and operation.

**Quality of Care:**

**Adventist Health System/Sunbelt, Inc. d/b/a Florida Hospital (CON application #10488):** The applicant demonstrated plans to meet the rule requirements per Chapter 59C-1.044, Florida Administrative Code, with regard to the provision of quality of care for the proposed pediatric liver transplant program. Demonstrated quality of care measures through numerous awards and recognitions are indicated. Policies and protocols to accommodate the proposed project are in place or are in development and will be complete prior to initiation of service. The applicant is Agency licensed and is accredited by The Joint Commission.

Agency records, for the three-year period ending May 24, 2017, indicate that the parent, AHS/S, had 24 substantiated complaints, among its 5,407 licensed beds (spread among its 22 Florida facilities). From the same source for the same period, the applicant's Florida Hospital had three substantiated complaints.

The applicant is a quality care provider.

**Financial/Cost:**

**Adventist Health System/Sunbelt, Inc. d/b/a Florida Hospital (CON application #10488):**

- Funding for this project and the entire capital budget should be available as needed
- This project appears to be financially feasible and the projected NRPD, CPD, and profitability appear to be attainable
- This project is not likely to have a material impact on competition to promote quality and cost-effectiveness

**Medicaid/Indigent Care:**

Below is the ASH/S d/b/a FH participation in the LIP and DSH programs in FY 2016-2017, as of June 7, 2017.

<b>Adventist Health System/Sunbelt, Inc. d/b/a Florida Hospital (CON application #10488) LIP and DSH Program Participation FY 2016-2017</b>		
<b>Applicant/Program</b>	<b>Annual Total Allocation</b>	<b>Year-to-Date Total Allocation As of June 7, 2017</b>
Florida Hospital/LIP	\$24,804,758	\$0
Florida Hospital/DSH	\$5,513,911	\$5,513,911

Source: Agency Division of Medicaid, Office of Program Finance

**Adventist Health System/Sunbelt, Inc. d/b/a Florida Hospital (CON application #10488):** According to the Agency’s 2015 FHURS Data Report, FH (a Class 1 hospital) provided 14.94 percent of its total annual patient days to Medicaid/Medicaid HMO patients and 4.53 percent to charity care patients in FY 2015.

Below is the applicant’s estimated Medicaid/Medicaid HMO payer mix cases and percentages for the proposed project.

**Florida Hospital Pediatric Liver Transplant Projected Payer Mix  
Year One to Year Three**

<b>Payer Mix</b>	<b>Years One and Two</b>		<b>Year Three</b>	
	<b>Cases</b>	<b>Percent</b>	<b>Cases</b>	<b>Percent</b>
Medicaid/Medicaid HMO	5	63%	5	56%
Managed Care	2	25%	2	22%
Global Payers	1	12%	2	22%
<b>Total</b>	<b>8</b>	<b>100%</b>	<b>9</b>	<b>100%</b>

Source: CON application #10488, page 86, Figure 29

The reviewer notes that the payer mix shown above is also consistent with Schedule 7A of the application, for year one and two (ending December 31, 2018 and December 31, 2019, respectively) and for year three (ending December 31, 2020).

FH offers no Medicaid/no charity care patient day condition(s) and no Medicaid/no charity care procedures condition(s), regarding the proposed project.

**G. RECOMMENDATION**

Approve CON #10488 to establish a new pediatric liver transplantation program at District 7, Organ Transplantation Service Area 3, Orange County. The total project cost is \$492,125, and involves no reported GSF of renovation and no new construction.

**CONDITION:**

- In the first two years of operation of the pediatric liver transplant program (2018 and 2019), Florida Hospital Transplant Institute will plan four unique community outreach events to raise awareness of the program, grow community support and increase our referral base. These unique events will include physician, nursing and patient education in the form of organized educational events, local conferences, support groups and/or industry events. When appropriate, Florida Hospital Transplant Institute will ensure continuing education credit is provided.

**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: \_\_\_\_\_

\_\_\_\_\_  
Marisol Fitch  
**Health Administration Services Manager**  
**Certificate of Need**