

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

A. PROJECT IDENTIFICATION

1. Applicant/CON Action Number

**Variety Children's Hospital
d/b/a Nicklaus Children's Hospital/CON #10421**
3100 SW 62nd Avenue
Miami, Florida 33155

Authorized Representative: April Andrews-Singh
General Counsel
(786) 624-2233

2. Service District/Subdistrict

Organ Transplantation Service Area (OTSA) 4: District 10 (Broward County), District 11 (Miami-Dade and Monroe Counties), District 8 (Collier County only), and District 9 (Palm Beach County only)

B. PUBLIC HEARING

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

Letters of Support

Variety Children's Hospital d/b/a Nicklaus Children's Hospital (CON application #10421) submitted 17 signed letters of support. All but one of these letters of support was of TSA 4 origin. The applicant states and the reviewer confirms that many of these support letters favor the proposed project, as well as pediatric kidney and pediatric liver transplantation programs at Nicklaus Children's Hospital (NCH). However, the applicant states that NCH (NCH) elected to submit the pediatric heart transplantation proposal because the applicant is at the most advanced stage for initiation, given the wide range of cardiac physicians, its cardiology volume and lack of volume at the purported existing providers". All the support letters are individually composed but some have recurring themes. Of these letters, four of the total of six physician letters of support indicate being on the staff of NCH, with three

of these four physicians stating being board-certified in pediatric cardiology and one stating being board-certified in pediatric anesthesiology. The general themes of these letters include:

- NCH is a renowned integral provider of pediatric specialty care in South Florida
- NCH has the most complex pediatric cardiac patients in the State of Florida
- NCH must transfer out its most complex cardiac patients in need of transplantation which interrupts the patient's continuum of care
- NCH should be approved because of its patient population, capabilities, reputation and wherewithal to implement a highly successful program
- NCH has the necessary support of the local OPO and for collaboration on organ procurement, blood banking, pathology services, tissue typing and any other histocompatibility needs
- A pediatric heart transplant program at NCH will provide an additional teaching opportunities for the many medical students, nursing students and others who rotate at NCH

Some support letters are noted from the following:

- Manny Diaz Jr. (District 103) and Erik Fresen (District 114), State Representatives, The Florida House of Representatives
- Board of County Commissioners/Miami-Dade County Commission
 - District 11 Commissioner
- President/CEO
 - Lee Memorial Health System
 - Jupiter Medical Center
 - OneBlood, Inc.
- Chief Medical Officer and Interim Executive Director
 - Life Alliance Organ Recovery Agency (LAORA)/University of Miami-Miller School of Medicine
- Senior Vice President for Health Affairs and Dean
 - Florida International University (FIU), Herbert Wertheim College of Medicine
- Dean, College/School of Nursing and Health Studies/Sciences
 - University of Miami
 - Nova Southeastern University
 - Barry University
 - West Coast University

One support letter is from a mother who states that her son has been a patient at NCH for 25 years, who has benefited immeasurably over the ensuring years from the expert, dedicated, compassionate care of the

Cardiac Team there and that her son now needs a heart transplant. The mother indicates that if NCH had a pediatric heart transplant program in place now, “we would without equivocation” list him for transplant there. The reviewer notes that an approved pediatric heart transplant program would only serve pediatric patients (under the age of 15 years old).

Letter of Opposition

The Agency received one letter of opposition to the proposed project, this being from Carlos A. Migoya, President & Chief Executive Officer, Jackson Health System (JHS). The letter of opposition is 13 pages, with eight tables and one map detailing the locations of the two existing OTSA 4 pediatric heart transplantation providers (Jackson Memorial Hospital and Memorial Regional Hospital) in relation to NCH. JHS’s letter of opposition also includes:

- Excerpt from Nicklaus’ Opposition Statement to Jackson Hospital West (CON application #10395)
- Physician letter (from two physicians), Miami Transplant Institute, JHS and UHealth – University of Miami Health System
- Research/journal articles on:
 - Institutional volume and the effect of recipient risk on short-term mortality after orthotopic heart transplant (The Journal of Thoracic and Cardiovascular Surgery, Vol. 143, Number 1)
 - Post-Heart Transplant Survival Is Inferior at Low-Volume Centers Across All Risk Strata Journal of the American Heart Association, issued September 14, 2010

In his cover letter, Mr. Migoya states that for a small number of services expansion of service represents a clear danger to patients and the broader system of health delivery and that this is the case with the proposed pediatric heart transplantation programs. Mr. Migoya also states opposition to the proposed project in the strongest possible terms and states his opposition demonstrates compelling evidence that children have better success and survival rates when treated by physicians and facilities that have sufficient volumes to maintain and improve their expertise. In addition, Mr. Migoya indicates that the existing programs in South Florida have more than sufficient capacity to successfully manage the community’s needs and that any further dilution of pediatric heart transplant in Florida would be a disservice to sick children and their desperate families.

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JHS points out and the Agency confirms that Jackson Memorial Hospital (JMH) is CON approved to perform every CON-regulated solid organ pediatric transplantation program in Florida - liver, lung, heart, intestines, pancreas and kidney. According to the opposition, there is no need for the proposed project in OTSA 4, based on a variety of factors, including:

- Nicklaus' proposal does not comply with the need standards set forth in Rule 59C-1.044(6)(b).
- Pediatric heart transplants are very low volume, highly technical procedures with flat volumes in both Florida and in OTSA 4.
- The number of pediatric candidates currently on the waiting list for heart transplants in OTSA 4 and Florida is insufficient to support an additional pediatric heart transplant program.
- There is limited demand for pediatric heart transplant services in OTSA 4 and patients currently have access to heart transplant services in the OTSA. Approval of the proposed project would not improve access to or foster competition for pediatric heart transplant programs.
- The most recent approval of a second pediatric heart transplant provider in OTSA 4 in 2008 resulted in a loss of volume at Jackson Memorial Hospital, as the total volume of pediatric heart transplants was then split between two providers – a scenario that would repeat itself if the proposed project was approved.
- No special circumstances exist that justify approval of a third pediatric heart transplant program in OTSA 4.

JHS indicates that through the seven years ending calendar year (CY) 2014 and for the nine months ending September 30, 2015, JHM has realized a decline in pediatric heart transplant volume since the Agency approved CON application #10044 (Memorial Regional Hospital) to establish a pediatric heart transplant program in OTSA 4. The Agency notes that CON application #10044 was approved on April 29, 2009 and Memorial Regional Hospital was licensed to provide pediatric heart transplants effective December 15, 2010. JHS states and the Agency agrees that existing providers are well below the minimum volume requirement of 59C-1.044 (6)(b)1., Florida Administrative Code. JHS expects that NCH will state it will meet the minimum requirement of 12 procedures by year two of operation through an overstated projected methodology but is unlikely that NCH will be able to meet that volume. JHS states that the number of pediatric heart transplants in Florida and OTSA 4 has been low and stable for many years.

According to JHS, in the past several years, there have been many advancements in the treatment and medical management of children with heart failure and that many of these therapies serve to delay or avoid heart transplantation. The opposition maintains that its pediatric cardiologists have been able to delay or even avoid heart transplantation in a growing number of children referred for transplant evaluation. JHS states having the only university-based pediatric heart transplant program in south Florida and the only provider in the area to offer mechanical circulatory support to children as a bridge to heart transplantation when necessary. JHS comments offering the option of temporary or permanent mechanical support, using extracorporeal membrane oxygen (ECMO) and an increasing variety of devices such as Heart Mate and Abiomed systems. JHS contends that as technologies and advanced therapies continue to evolve, it is reasonable to assume that transplant volumes will continue to remain stable or decline.

JHS asserts that the pediatric population (ages 0-14) statewide and in OTSA 4 is declining and has declined nearly three times faster than Florida's pediatric population between 2008 and 2014 (see the figure below).

2008 and 2014 Pediatric Population (Ages 0-14)

	2008	2014	Change
OTSA 4	1,134,745	1,073,891	-5.4%
Florida	3,442,376	3,382,656	-1.7%

Source: JHS Letter of Opposition, page 6. Figure 4

Given the rates of decline in pediatric population shown above and a flat trend in pediatric heart transplant volume over the same period, JHS contends it is unlikely that the utilization trend will increase in the future.

JHS asserts that there are not enough Organ Procurement and Transplantation Network (OPTN) waiting list candidates statewide to drive each of the four exiting providers (in Florida) above the 24 heart transplant threshold discussed by rule. JHS indicates that as of December 4, 2015, OPTN data indicates 35 candidates on the OPTN pediatric heart transplant waiting list at Florida pediatric heart transplant providers. The Agency notes that according to the figure below, UF Health Shands Hospital would meet the minimum of 24 procedures, referenced by rule. See JHS's figure below.

Pediatric Heart Transplant Waiting List Candidates

Candidates as of December 4, 2015	
UF Health Shands Hospital	28
All Children's Hospital	1
Jackson Memorial Hospital	2
Memorial Regional	4
Florida Total	35

Source: JHS Letter of Opposition, page 7, Figure 5

JHS asserts that project approval would result in an unnecessary duplication of services and would adversely impact existing providers, including JHM.

Using the Agency's inpatient hospital database, JHS states that in 2014, all four OTSA 4 pediatric residents who received a pediatric heart transplant, received the procedure at Memorial Regional Hospital and that from 2010 to 2014, no more than two OTSA 4 pediatric residents outmigrated. See the figures below.

**2014 Pediatric Heart Transplants Generated by OTSA 4 Population
Transplanted at an Existing Florida Provider**

Hospital/Patient County	2014
All Children's Hospital	0
Jackson Health System	0
Memorial Regional Hospital	4
Broward County, FL	1
Collier County, FL	1
Miami-Dade County, FL	1
Palm Beach County, FL	1
UF Health Shands Hospital	0
Statewide Total	4

Source: JHS Letter of Opposition, page 8, Figure 6

**2010-2014 Pediatric Heart Transplants Generated by OTSA 4
Transplants by Place of Service**

Hospital/Patient County	2010	2011	2012	2013	2014
All Children's Hospital					
Collier County, FL	0	1	0	0	0
Jackson Health System					
Miami-Dade County, FL	0	0	2	0	0
Memorial Regional Hospital					
Broward County, FL	0	1	1	4	1
Collier County, FL	0	1	0	0	1
Miami-Dade County, FL	0	1	1	1	1
Palm Beach County, FL	0	0	1	0	1
UF Health Shands Hospital					
Broward County, FL	0	1	0	0	0
Miami-Dade County, FL	1	0	0	0	0
Palm Beach County, FL	1	0	0	0	0
Total OTSA 4 Patients	2	5	5	5	4
Transplanted in OTSA 4 Hospitals	0	3	5	5	4
Outmigration to Other Areas	2	2	0	0	0

Source: JHS Letter of Opposition, page 9, Figure 7

JHS maintains that the data clearly illustrates accessibility for pediatric heart transplant services and that there is no lack of access to quality heart transplant care.

JHS provides a map demonstrating that the proposed project is approximately a nine-mile drive from JMH and “just over” a 20-mile drive from Memorial Regional Hospital. The reviewer notes that according to the Agency’s floridahealthfinder.gov website at <http://www.floridahealthfinder.gov/facilitylocator/ListProximityFacilities.aspx>, the driving distance from the proposed project to JMH is 6.14 miles and the driving distance from the proposed project to Memorial Regional Hospital is 20.27 miles. Per JHS, the addition of a third pediatric heart transplant program within a 10-mile radius of two existing providers would do nothing to increase access to services. The Agency notes that the proposed project is within an approximate 20-mile radius of the two existing pediatric heart transplant providers, not within a 10-mile radius as indicated by JHS.

JHS maintains that the pediatric heart transplants are rare and even a large population base does not produce a significant number of pediatric heart transplants. Using OPTN data 2008-2014, JHS contends that there is a direct inverse relationship between JMH’s volume and Memorial Regional Hospital’s volume, while the overall OTSA 4 volume remained essentially the same in 2008 and 2014. See the figure below.

**Historical Pediatric Heart Transplant Volume
New Program Actual Effect on JMH**

	2008	2009	2010	2011	2012	2013	2014	Change in Percent
Jackson Memorial Hospital	6	5	0	0	2	1	2	-66.7%
Memorial Regional Hospital	0	0	1	3	4	4	5	66.7%
Total OTSA 4	6	5	1	3	6	5	7	

Source: JHS Letter of Opposition, page 11, Figure 9

JHS briefly discusses the NCH’s opposition to CON application #10395 and references NCH’s comments that low volume pediatric programs do not achieve the same levels of quality as high volume pediatric programs and that research, studies and journals in this field support the nexus between volume and quality, particularly with respect to complex care. JHS references its Letter of Opposition-Attachment A.

JHS asserts that if barriers to pediatric heart transplant did in fact exist in the area, then Memorial Regional Hospital’s services would have had an effect on the total number of pediatric heart transplants performed and Memorial Regional Hospital would have achieved its projected volume. JHS contends that there are no data points or market conditions that justify the need for the proposed project and therefore concludes that the Agency should deny the proposed project.

C. PROJECT SUMMARY

Variety Children’s Hospital d/b/a Nicklaus Children’s Hospital (CON application #10421) also referenced as NCH or the applicant, a not-for-profit Class 2 hospital, affiliated with Miami Children’s Health System (MCHS), proposes to establish a new pediatric heart transplantation program at NCH, in Miami, Miami-Dade County, OTSA 4. NCH is the sole hospital operated by MCHS.

Nicklaus Children’s Hospital is a 289-bed specialty hospital, licensed for 218 acute care beds, 21 Level II neonatal intensive care unit (NICU) beds, 30 Level III NICU beds, 20 child/adolescent psychiatric beds, is a pediatric cardiac catheterization provider and is a pediatric open heart surgery provider. NCH is a designated Pediatric Trauma Center¹. The applicant is currently a provider of inpatient pediatric bone marrow transplantation services. NCH does not have statutory teaching hospital designation.

¹ http://www.floridahealth.gov/licensing-and-regulation/trauma-system/_documents/traumacenterlisting20151.pdf . According to the Florida Department of Health (DOH), NCH is the only pediatric trauma center in OTSA 4, as of May 2015.

NCH maintains that its existing Heart Program is a world leader in pediatric cardiology, with many first-in-the-world procedures that were pioneered by the program's own internationally renowned cardiologists and cardiovascular surgeons. NCH states that pediatric heart transplant is the only gap Heart Program does not provide. NCH contends that it performs more complex pediatric cardiac surgeries and has the most clinically complex cardiac patients than any other hospital in Florida.

Project costs total \$1,893,034. These costs include equipment, project development and start-up costs. There is no reported construction or renovation associated with the project.

The proposed pediatric heart transplantation program, if approved, is expected to be licensed in June 2017, with initiation of service in July 2017.

Schedule C of the application has conditioned approval on the provision of the following:

- Location: The NCH heart transplant program will be located on Nicklaus Children's Hospital's campus at 3100 SW 62nd Ave., Miami, Florida 33155
- Certified Transplant Coordinators and Transplant Nurses: 100 percent of NCH's transplant coordinators and transplant nursing staff will become certified according to their area of specialty within the first two years of serving in that capacity. This will be measured by submitting copies of applicable certifications to AHCA.
- Nurse Orientation: All (not just transplant) new nurses at NCH, as part of their orientation, will have an orientation to transplant. Topics to be covered will include but are not limited to organ donation, overall transplant evaluation and eligibility and organ specific education. All existing nurses at NCH will be provided and orientation to transplantation and the transplant program within 12 months of initiating the transplant programs at the Hospital. These will be measured by submitting an annual report by the Hospital to AHCA certifying that these orientations have taken place.
- Pediatric Surgery Residents: All pediatric surgery residents at NCH will rotate through the transplant service as part of the pediatric surgery residency curriculum. This will be measured by submission of an annual report by the Hospital to AHCA certifying this rotation is in place.

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

D. REVIEW PROCEDURE

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

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

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

As part of the fact-finding, the consultant Steve Love, analyzed the application in its entirety with consultation from the financial analyst Everett (Butch) Broussard 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 heart transplant programs. Therefore, it is the applicant's responsibility to demonstrate the need for the project, including a projection of the expected number of pediatric heart transplants that will be performed in the first years of operation.

OTSA 4 includes Districts 10 and 11, Collier County in District 8 and Palm Beach County in District 9 and has two operational pediatric heart transplant programs—Memorial Regional Hospital (District 10-Broward County) and Jackson Memorial Hospital (District 11/Miami-Dade County). OTSA 1 and OTSA 2 each have one pediatric heart transplantation program and OTSA 3 has no pediatric heart transplantation program. Data reported to the Agency by the local health councils for the 12 months ending June 30, 2015 show the following pediatric heart transplant utilization, by facility, service area and district:

Florida Pediatric Heart Transplantation Program Utilization			
July 2014 – June 2015			
Hospital	Service Area	District	Total Procedures
UF Health Shands Hospital	1	3	17
All Children’s Hospital	2	5	10
Memorial Regional Hospital	4	10	4
Jackson Memorial Hospital	4	11	1
TOTAL			32

Source: Florida Pediatric Organ Transplantation Program Utilization data published October 2015

As shown in the table above, for the 12 months ending June 30, 2015, UF Health Shands Hospital (Alachua County) provided 17 procedures and was the single largest volume provider of this procedure for the period. Below is a five-year chart to account for pediatric heart

transplantation utilization, by service area, county and facility, for the five-year period ending June 30, 2015.

Florida Pediatric Heart Transplantation Utilization								
12-Month Reporting Periods Ending June 30, 2011 to June 30, 2015								
Service Area	County	Facility	12-Month Reporting Periods July 1 to June 30					Total
			2011	2012	2013	2014	2015	
1	Alachua	UF Health Shands Hospital	6	7	13	4	17	47
2	Pinellas	All Children's Hospital	5	4	6	13	10	38
4	Broward	Memorial Regional Hospital	2	2	5	3	4	16
4	Miami-Dade	Jackson Memorial Hospital	0	3	1	2	1	7
Total			13	16	25	22	32	108

Source: Florida Need Projections Utilization Data for Adult and Pediatric Transplant Programs issued October 2011 - October 2015

During for the five-year period, OTSA 4 providers had the lowest volume of pediatric heart transplants by volume (21.30 percent), of the three operational service areas.

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 35 pediatric patients in Florida currently registered on the heart transplantation waiting list². See the organ by waiting time table below.

**Organ Procurement and Transplantation Network (OPTN)
Current Florida Wait List Registrants
Based on OPTN Data as of December 10, 2015**

	Heart
Total	35
< 30 Days	1
30 to < 90 Days	5
90 Days to < 6 Months	5
6 Months to < 1 Year	5
1 Year to < 2 Years	7
2 Years to < 3 Years	3
3 Years to < 5 Years	3
5 or More Years	6

Source: <http://optn.transplant.hrsa.gov/latestData/rptData.asp>, as of December 4, 2015

Donor/patient matches are also a factor in transplant services. The chart below contains the most recent five-year volume of heart donations by Florida residents.

² As of December 4, 2015 per the OPTN website @ <http://optn.transplant.hrsa.gov>. The age range for this data base is 0-17 years.

**Florida Pediatric Heart Donors Recovered
January 1, 2009-December 31, 2014
Based on OPTN Data as of December 4, 2015**

Pediatric	2015*	2014	2013	2012	2011	2010
All Donor Types	25	38	45	33	36	30
Deceased Donor	25	38	45	33	36	30
Living Donor	0	0	0	0	0	0

Source: <http://optn.transplant.hrsa.gov/latestData/rptData.asp>, as of May 15, 2015

Note: * For 2015, January 1 through September 30, 2015

As shown above, there were 38 Florida pediatric heart donors in 2014. Florida Center for Health Information and Policy Analysis data indicates there were a total of 33 pediatric heart transplants and 11 pediatric heart implant assist device procedures performed at Florida hospitals for the 12 months ending June 30, 2015. The total procedures were slightly fewer than the donor recovery total--a difference of three more donors than pediatric heart transplant procedures, for the 12 months ending June 30, 2015. The reviewer notes that this comparison contemplates two different timeframes, one being fiscal year (FY) and one being CY.

Agency data indicates that all 33 of 33 (or 100.0 percent) of the pediatric patients (under 15 years of age) receiving heart transplants performed in Florida in the 12 months ending June 30, 2015 were Florida residents³. OTSA 4 residents accounted for three of the 33 procedures, or 9.09 percent. Below is a chart to account for these totals.

**Pediatric Heart Transplants at Florida Hospitals
by Patient Residence
12 Months Ending June 30, 2015**

Service Area	Transplants Performed	Percent of Total
1	8	24.2%
2	13	39.4%
3	9	27.3%
4	3	9.1%
Unknown	0	0.0%
Total	33	100.0%

Source: Florida Center for Health Information and Policy Analysis database for 12 months ending June 30, 2015. MS-DRGs 001 and 002 (excluding heart implant assist devices). In this table, the Agency rounded to the nearest 1/10th of one percent to attain a 100.0 percent total

The Agency notes that OTSA 4 residents had the fewest pediatric heart transplant procedures of any area in Florida and migrated at a rate of 0.00 percent (no outmigration) beyond their home service area for the 12 months ending June 30, 2015. As indicated, all three OTSA 4 residents

³ There were 32 total pediatric heart transplant procedures reported to the local health councils for the 12 months ending June 30, 2015. Some variation in the patient data is to be expected.

who had a pediatric heart transplant remained within OSTA 4 for the procedure and the total pediatric heart transplant procedures were four in OTSA 4 due to in-migration.

The reviewer notes that for the 12 months ending June 30, 2015, OTSA 4 had the most operational pediatric heart transplant providers of any service area statewide and had the fewest pediatric heart transplants performed according to Agency inpatient discharge data. Local health council data for the four-year period ending June 30, 2015 indicates that procedures have remained relatively stable in the OTSA. The reviewer notes that for the five-year period ending June 30, 2015, statewide, local health council data indicates that pediatric heart transplant procedures have generally increased from a low of 13 (12 months ending June 30, 2011) to a high of 32 (12 months ending June 30, 2015). In the same five-year period, OTSA 4 experienced its fewest procedures (two) for the 12-month period ending June 30, 2011 and its most procedures (six) for the 12-month period ending June 30, 2013. The reviewer indicates that OTSA 4 has relatively low but stable pediatric heart transplant volume for the four-year period ending June 30, 2015 and no outmigration for the 12-month period ending June 30, 2015, therefore it is reasonable to conclude that a third provider in OTSA 4 would likely reduce already relatively low volumes at the existing pediatric heart transplantation provides in OTSA 4.

The Agency notes that for the 12 months ending June 30, 2015, there has been a proportionate rise in the implantation of pediatric heart assist devices. For the 12 months ending June 30, 2011, statewide, pediatric heart assist devices accounted for 25.0 percent of total pediatric heart transplant/assist discharges and for the 12 months ending June 30, 2015, statewide pediatric heart assist devices accounted for the same percent of total pediatric heart transplant/assist discharges. Therefore, for the five-year period ending June 30, 2015, it appears that the rise in pediatric heart assist devices has increased at the same percentage as the rise in pediatric heart transplantations--with these procedures paralleling each other, the data does not indicate a correlation that a rise in pediatric heart assist device procedures is reducing or lessening the rise in pediatric heart transplantations.

The chart below overall trends equally between rising pediatric heart assist procedures and rising pediatric heart transplant procedures, statewide, for the five-year period ending June 30, 2015. A Florida hospital is not required to have a pediatric heart transplantation

program in order to provide pediatric heart assist implants. The chart below shows the state's pediatric heart transplants and pediatric heart assist volume for the previous five years, ending June 30, 2015.

**Pediatric Heart Transplant and Pediatric Heart Assist Implant Discharges
All Florida Hospitals
Five Years Ending June 30, 2015**

<i>Year Ending June 30</i>	<i>Pediatric Heart Transplants</i>	<i>Pediatric Heart Assist</i>	<i>Total Pediatric Heart Transplant/ Assist Discharges</i>
<i>2011</i>	<i>12</i>	<i>4</i>	<i>16</i>
<i>2012</i>	<i>17</i>	<i>9</i>	<i>26</i>
<i>2013</i>	<i>25</i>	<i>7</i>	<i>32</i>
<i>2014</i>	<i>19</i>	<i>7</i>	<i>26</i>
<i>2015</i>	<i>33</i>	<i>11</i>	<i>44</i>

Source: Florida Center for Health Information and Policy Analysis Hospital Discharge data for the appropriate years

Note: Heart Assist ICD-9 Codes include 37.6, 37.60, 37.62, 37.65, 37.66 and 37.68

As shown above, pediatric heart assist implantation increased from four procedures for the 12 months ending June 30, 2011 to 11 in the 12 months ending June 30, 2015, or by 275.0 percent. According to local health council data, pediatric heart transplant volume increased statewide by approximately 246.15 percent over this same five-year period (from 13 procedures to 33 procedures). The same procedure over the same period increased for OTSA 4 by 250.0 percent (two procedures to five procedures, respectively). The Agency notes that while percentage increases are great, total procedures per year have been relatively modest. The highest year-over-year increase in the five-year period was 10 procedures (statewide) for the 12 months ending June 30, 2015 and the highest year-over-year increase in the same period was three procedures in OTSA 4.

The two OTSA 4 providers of pediatric heart transplantation (Memorial Regional Hospital and JMH) averaged 2.50 procedures each for the 12 months ending June 30, 2015.

The reviewer notes that NCH's overall need justification is based on pediatric patients as being age 0-17 years (including the two methodologies that follow later in this report). The Agency notes that Rule 59C-1.044(2)(c), Florida Administrative Code defines a pediatric transplantation patient as a patient under the age of 15 years. Using Agency Population Estimates, published February 2015 and NHA

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analysis, NCH offers current (2015) and forecasted (2018-2020) residents age 17 and under for OTSA 4. The reviewer collapses the county totals to display the totals of OTSA 4 in its entirety for the age 17 and under population (see below).

Service Area 4 Population by County Current and Forecasted Estimates, Age 17 and Under 2015 and 2018 Through 2020						
County	2015	2018 (Year One)	2019 (Year Two)	2020 (Year Three)	Net Change, 2015-2019	Percent Change 2015-2019
Total	1,304,437	1,321,720	1,329,249	1,337,161	32,724	2.5%

Source: CON application #10421, page 38

NCH discusses existing pediatric heart transplant programs in Florida over the five years ending December 31, 2014, the actual versus expected survival rates by program in 2014 (statewide) and OTSA 4 pediatric heart transplant candidates and recipients over the three years ending December 31, 2014. NCH uses UNOS and NHA analysis to indicate the pediatric heart candidates and transplant recipients among OTSA 4 pediatric residents in CY 2014. The applicant indicates that the percentage of candidates transplanted ranges from 100.0 percent to 20.0 percent, depending on the county of residence (see below).

Pediatric Heart Transplant Candidates and Transplant Recipients Service Area 4 Pediatric Residents CY 2014			
Resident County	Candidates	Transplants	Percent Candidates Transplanted
Broward	1	1	100.0%
Collier	1	1	100.0%
Miami-Dade	5	1	20.0%
Monroe	0	0	--
Palm Beach(1)	0	1	--
Total	7	4	57.1%
Restated without Palm Beach	7	3	42.9%

(1) The patient transplanted from Palm Beach County in 2014 was added to the waitlist prior to 2014, therefore the "restated without Palm Beach County" line item more accurately portrays the experience.
Source: CON application #10421, page 42

NCH contends that with only one in five candidates receiving a transplant in Miami-Dade County, it is apparent there is a gap in service. NCH further contends that JMH did not transplant any Miami-Dade County residents in the past three years and Memorial Regional Hospital only transplanted one patient from Miami-Dade County. NCH asserts that it is evident that neither of these programs are accessible nor available to Miami-Dade County residents. NCH additionally contends that between 2012 and 2014, one of the five Miami-Dade County resident

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pediatric heart transplants was performed in OTSA 4 (at Memorial Regional Hospital) and the remaining four procedures (80 percent) were performed outside of Florida. NCH asserts that only five transplants given the complex cardiac surgery and heart indicators for this County demonstrates a program availability issue. NCH maintains that 50 percent outmigration between 2012 and 2014 (with eight of 16 procedures being performed at Memorial Regional Hospital, and none performed at JMH and the remaining eight procedures being performed outside of Florida) indicates an access issue for the entire service area.

Using UNOS, Agency inpatient hospital database results and NHA analysis, NCH contends an 85.7 percent outmigration rate in CY 2012, a 20.0 percent outmigration rate in CY 2013 and a 25.0 percent outmigration rate in CY 2014 (see below).

Service Area 4 Resident Pediatric Heart Transplants Ages 0-17 CY 2012-2014			
Patient Origin	CY 2012	CY 2013	CY 2014
Jackson Memorial Hospital	0	0	0
Memorial Regional Hospital	1	4	3
Total Transplanted within Service Area 4	1	4	3
Transplanted Outside Service Area 4 Within Florida	0	0	0
Transplanted Outside Florida	6	1	1
Total Transplants	7	5	4
Percent Outmigration	85.7%	20.0%	25.0%

Source: CON application #10421, page 44

As shown earlier in this section of the report, according to the Florida Need Projections Utilization Data for Adult and Pediatric Transplant Programs issued October 2011 - October 2015, for the five-year period ending June 30, 2015, JMH performed seven procedures and Memorial Regional Hospital performed 16. From the same source, the Agency notes that for the past three-year period (ending June 30, 2015), JMH performed four of these procedures and Memorial Regional Hospital, 12. Therefore, the Agency notes that the most recent published data available, ending June 30, 2015, is indicating a higher volume of procedures within OTSA 4 than indicated by the applicant. The Agency notes that the most recent Florida Need Projections Utilization Data for Adult and Pediatric Transplant Programs was available to the applicant on October 2, 2015 for the 12 months ending June 30, 2015 but NCH elected to utilize less up-to-date data regarding pediatric heart transplant procedures in basing its need justification for CON application #10421.

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The applicant uses Claritas, Agency inpatient hospital database and NHA analysis to determine estimated NCH pediatric heart transplant totals (ages 0-17), the average length of stay (ALOS) and patient days related to performed transplants, for the three-year period ending June 30, 2020. See the summary below.

**Summary of Forecasted NCH Pediatric Heart Transplants
Ages 0-17**

12 Months Ending June 30, 2018 and June 30, 2019 and June 30, 2020

Forecasted Pediatric Heart Transplants	Year One Ending 6/30/18	Year Two Ending 6/30/19	Year Three Ending 6/30/20
Need Methodology #1	6	12	15
Need Methodology #2	6	11	13
Forecasted NCH Transplants	4	6	8
ALOS	126	115	110
Patient Days Related to Performed Transplants(1)	504	690	880

(1) Note patient days related to transplants performed in the forecast year. Patient transplants in the 4th quarter of each year will actually experience some of their patient days in the next fiscal year
Source: CON application #10421, page 33

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

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

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

NCH indicates that its Heart Program has 21 board-certified cardiologists with various sub-specializations with five being pediatric cardiologists. The applicant includes a curriculum vitae (CV) for four physicians indicated to be in NCH's Heart Program. The reviewer notes that none of these CVs in the referenced tab coincide with any of the pediatric cardiologists named in the applicant's narrative (CON application #10421, page 95). However, the reviewer notes that the Florida Department of Health (DOH) FLHealthSource.gov website at <https://appsmqa.doh.state.fl.us/MQASearchServices/HealthCareProviders/Details?LicInd=119446&ProCde=1501>, indicates that one of the five listed pediatric cardiologists

stated by the applicant, David Mark Drossner, is a Florida licensed medical doctor with specialty board certification in pediatric cardiology. This licensee's primary practice location is stated to be at the applicant's address.

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

The applicant contends that the cardiac anesthesiology team is well qualified and highly capable of handling pediatric cardiac transplant surgeries. NCH indicates having three cardiac anesthesiologists that are integral to the proposed program. Of these three named physicians, the applicant provides a narrative of each of their experience and the CV. A review of the applicant's narrative of each of these three physicians and a review of each of their CVs does not indicate experience in heart transplantation. However, the reviewer notes that the Florida Department of Health (DOH) FLHealthSource.gov website (Practitioner Profile) <https://appsmqa.doh.state.fl.us/MQASearchServices/HealthCareProviders>, indicates that the three stated physicians have specialty board certification with the American Board of Anesthesiology. The DOH Practice Profile also indicates that Christopher Francis Tirota, MD has specialty certification in pediatric anesthesiology. This licensee's primary practice location is stated to be at the applicant's address.

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

NCH assures having one isolation room being constructed within the cardiac intensive care unit dedicated to pediatrics. The applicant states that the proposed project will utilize existing facility space within the Advanced Pediatric Care Pavilion (APCP) on NCH's existing campus. NCH states that the APCP is already under construction and is expected to be completed in 2016. According to the applicant, the APCP will house the following services:

- Level 1: Public lobby and connection to Emergency Department, imaging and main corridor
- Level 2: Cardiac Intensive Care Unit and Heart Transplant with connection to existing surgery and PACU

- Level 3: Pediatric Intensive Care Unit with connection to existing patient floor
- Level 4: Neonatal Intensive Care Unit
- Level 5: Neurosciences
- Level 6: Oncology

The reviewer notes that from January 1, 2010 through January 15, 2016, the Agency has no record of NCH adding or delicensing beds, pursuant to ss. 408.036(5)(c), Florida Statutes, should the proposed project call for the addition or delicensing of beds.

(b) Need Determination: An application for a certificate of need to establish a new heart transplantation program shall not normally be approved in a service area unless: (Rule 59C-1.044(6)(b) Florida Administrative Code).

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

The Agency notes that the applicant states that this criterion is not applicable because the applicant is seeking to establish a pediatric heart transplant program.

The reviewer verifies that according to local health council data, neither of the existing pediatric heart transplantation providers in the applicable service area performed a minimum of 24 heart transplants in the most recent calendar year preceding the application deadline for new programs. The minimum volume criterion has not been met by any existing pediatric heart transplantation provider, statewide, at least for the five-year period ending June 30, 2015. As stated previously, for the 12-month ending June 30, 2015, the two existing OTSA 4 pediatric heart transplantation providers averaged 2.5 procedures.

NCH states having carried out two methodologies to determine need for the proposed project, that both methodologies arrive at the same conclusion and that both result in approximately the same forecasted procedures in the first few years of the planned project. Each of the applicant's methodology is briefly summarized below.

Need Methodology #1 – Ratio of Transplant to Cardiac Surgeries at Transplant Centers

The applicant states having the single largest pediatric cardiac surgery program of any hospital in Florida. NCH further states performing one-fourth of all surgeries performed throughout Florida and almost four times the volume that the next closest Miami-Dade County facility (Jackson Memorial Hospital) performs. Using Agency inpatient hospital database and NHA analysis, the applicant offers a table to account for these results (see below).

**Pediatric Cardiac Surgery Cases by Hospital
Ages 0-17
CY 2014**

Hospital	Cases	Percent of Total
Nicklaus Children's Hospital	209	25.0%
All Children's Hospital	146	17.5%
Baptist Medical Center Jacksonville	105	12.6%
UF Health Shands Hospital	84	10.0%
Arnold Palmer Children's Hospital	75	9.0%
Memorial Regional Hospital	61	7.3%
Florida Hospital Orlando	58	6.9%
Jackson Memorial Hospital	55	6.6%
St. Joseph's Hospital	24	2.9%
St. Mary's Medical Center	6	0.7%
All Others	13	1.6%
Total	836	100.0%

Note: St. Mary's pediatric cardiac program has since closed; this is discussed on page 54.
Source: CON application #10421, page 48 and 49

NCH indicates that on a comparative basis, patients and their families opt for NCH for pediatric cardiac surgery over JMH and Memorial Regional Hospital, stating that these two providers have low volume pediatric cardiac surgery programs.

NCH states that using Florida Need Projections, July 2017, July 2016 and July 2015 Planning Horizon results, there is a positive correlation between the volume of cardiac surgeries

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performed at a hospital to the number of transplants performed. The applicant indicates that transplants as a percent of cardiac surgery is 9.6 percent for All Children’s Hospital and is 9.5 percent for UF Health (see below).

**Pediatric Cardiac Surgery Cases by Hospital
Ages 0-17
CY 2014**

Hospital	Cardiac Surgeries	Transplants	Transplant as Percent of Cardiac Surgery
Nicklaus Children’s Hospital	209	--	--
All Children’s Hospital	146	14	9.6%
UF Health Shands Hospital	84	8	9.5%
Memorial Regional Hospital	61	5	6.0%
Jackson Memorial Hospital	55	2	3.6%

Source: CON application #10421, page 49

The reviewer confirms that transplant column results shown above is consistent with the Florida Pediatric Organ Transplantation Program Utilization data published April 3, 2015, for the July 2017 Planning Horizon. The reviewer notes that results for the July 2016 and July 2015 Planning Horizon are different than for the July 2017 Planning Horizon and do not correlate to the results shown in the applicant’s transplant column results shown in the table above.

Based on a 9.5 percent rate of transplant to cardiac surgery, as shown in the table above, NCH expects that in 2014, it would have had 20 transplants, 13 if the transplant rate had been 6.0 percent (in the case of Memorial Regional Hospital).

NCH maintains that because of its highly specialized services of pediatric care, NCH is a referral center from all over the country but first and foremost, children in the local communities. The applicant contends that in CY 2014, overall, 62.2 percent pediatric cardiac surgeries performed in OTSA 4 (patients ages 0-17) were performed at NCH. Further, the applicant contends that for each county in OTSA 4, the following procedures were performed at NCH: 49.3 percent of cases (Broward County) and 75.0 percent of cases (Monroe County). Using Agency inpatient hospital database results and NHA analysis, for CY 2014, NCH

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indicates total pediatric cardiac surgery cases and market share (by hospital) from residents within OTSA 4, as well as percentages (see below).

**Pediatric Cardiac Surgery Cases by Hospital and Resident Origin
Ages 0-17
CY 2014**

Hospital	Broward	Collier	Miami-Dade	Monroe	Palm Beach	Total	Percent of Total
Nicklaus Children's Hospital	35	8	80	3	32	158	62.2
Memorial Regional Hospital	32	0	8	0	9	49	19.3
Jackson Memorial Hospital	4	1	21	1	7	34	13.4
Broward Health Medical Center	0	0	1	0	5	6	2.4
St. Mary's Medical Center	0	0	0	0	1	1	0.4
Baptist Hospital of Miami	0	0	0	0	0	0	0.0
All Children's Hospital	0	6	0	0	0	6	2.4
Total	71	15	110	4	54	254	100.0
NCH Market Share by County	49.3%	53.3%	72.7%	75.0%	59.3%	62.2%	--

Source: CON application #10421, page 50

NCH contends that by applying 2014 discharge use rates computed from the above data to forecast pediatric population for each of the planning years to determine estimated NCH pediatric heart transplant totals (ages 0-17). The applicant estimates 259 pediatric cardiac surgeries in year one (12 months ending June 30, 2018), 260 of these surgeries for year two (12 months ending June 30, 2019) and 261 for year three (12 months ending June 30, 2020). In the same corresponding years one, two and three, NCH expects to capture 161, 162 and 163 pediatric heart surgeries, respectively, among OTSA 4 residents only (see below).

**Forecasted NCH Pediatric Cardiac Surgeries by Resident Origin
Ages 0-17
12 Months Ending June 30, 2018, June 30, 2019 and June 30, 2020**

	Broward	Collier	Miami-Dade	Monroe	Palm Beach	Total
2014 Population Ages 0-17	391,039	65,386	560,006	10,948	271,676	1,299,055
2014 Cardiac Surgery Discharge Use Rate per 1,000 Pop	0.18	0.23	0.20	0.37	0.20	0.20
Forecasted Population Age 0-17:						
Year 1 (12 Months Ending 6/30/2018)	391,540	68,641	570,125	10,679	280,735	1,321,720
Year 2 (12 Months Ending 6/30/2019)	392,085	69,575	573,398	10,625	283,568	1,329,249
Year 3 (12 Months Ending 6/30/2020)	392,678	70,534	576,933	10,578	286,438	1,337,161
Forecasted Pediatric Cardiac Surgeries:						
Year 1 (12 Months Ending 6/30/2018)	71	16	112	4	56	259
Year 2 (12 Months Ending 6/30/2019)	71	16	113	4	56	260
Year 3 (12 Months Ending 6/30/2020)	71	16	113	4	57	261
NCH 2014 Market Share	49.3%	53.3%	72.7%	75.0%	59.3%	62.2%
NCH Forecasted Pediatric Cardiac Surgeries – Service Area 4 Residents Only:						
Year 1 (12 Months Ending 6/30/2018)	35	8	81	3	33	161
Year 2 (12 Months Ending 6/30/2019)	35	9	82	3	33	162
Year 3 (12 Months Ending 6/30/2020)	35	9	82	3	34	163

Source: CON application #10421, page 51

The applicant contends that the application of a 2014 market share to forecasted market cases is extremely conservative, given that once the proposed project is approved, market share for all other heart programming will increase as the Heart Program at NCH will become even more renowned. NCH further contends that its 2014 in-migration of 25 percent will likewise increase due to further recognition. NCH asserts that the forecast volume, the average ratio of transplant to cardiac surgery is estimated at one-third of the rate at Florida’s two largest pediatric heart transplant programs in year one, two-thirds that rate in year two and less than three-fourths that rate in year three.

NCH estimates total pediatric heart transplants at its location of six, 12 and 15 for year one, year two and year three, respectively (see below).

**Forecasted NCH Pediatric Heart Transplants
Ages 0-17
12 Months Ending June 30, 2018, June 30, 2019 and June 30, 2020**

	Year One Ending 6/30/18	Year Two Ending 6/30/19	Year Three Ending 6/30/20
NCH Pediatric Cardiac Surgeries:			
From Service Area	161	162	163
In-Migration (25%)	53	53	54
Total	214	215	217
Avg. Ratio of Transplant to Cardiac Surgery(1)	3.0%	6.0%	7.0%
Forecasted NCH Pediatric Heart Transplants	6	12	15

Source: CON application #10421, page 52

Need Methodology #2 – Ratio of Transplant to ICD-9 Diagnosis Codes That Are Most Frequent Indicators for Transplant

NCH asserts that this need methodology evaluates the most common indications for pediatric heart transplant in terms of diagnoses codes, with 24 ICD-9 codes that almost all pediatric transplant patients have been diagnosed with, as a primary diagnosis. The applicant refers to this set of 24 ICD-9 codes as “Most Common Indicators” (heretofore referenced as MCI) for pediatric heart transplant and provides an alphabetical listing of each code. The applicant states that these 24 codes are various forms of myopathy and congenital defects including:

- Coronary Artery Disease
- Dilated Myopathy
- Ehlers-Danlos Syndrome
- Eisenmenger’s Syndrome
- HyperTrophic Cardiomyopathy
- Pulmonic Stenosis
- Restrictive Myopathy
- Valvular Heart Disease

Using Agency inpatient hospital database results and NHA analysis, for all hospitals statewide in 2014, patients age 0-17, NCH indicates that there were 499 such MCI cases, with 120 (24.2 percent) discharged from NCH. The Agency notes that the applicant states 120 cases in its narrative but indicates 121 cases in its table (see below).

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**Most Common Indicators for Heart Transplant by Hospital
Ages 0-17
CY 2014**

Hospital	Cases	Percent of Total
Nicklaus Children's Hospital	121	24.2%
All Children's Hospital	66	13.2%
UF Health Shands Hospital	59	11.8%
Baptist Medical Center Jacksonville	51	10.2%
Arnold Palmer Children's Hospital	45	9.0%
Memorial Regional Hospital	45	9.0%
Florida Hospital Orlando	31	6.2%
Jackson Memorial Hospital	21	4.2%
St. Mary's Medical Center	21	4.2%
St. Joseph's Hospital	17	3.4%
All Others	22	4.4%
Total	499	100.0%

Source: CON application #10421, page 53

NCH indicates that families opt for NCH to provide their children with pediatric cardiac care over JMH and Memorial Regional Hospital, stating that JMH has low volume and that Memorial Regional Hospital is a low volume transplant center. NCH indicates that of the 121 patients with one of the MCIs for transplant in CY 2014, 90 originated from OTSA 4--equating to a 25 percent in-migration factor. The applicant also discusses the numerical totals and ranges in its table (see below).

**Service Area Pediatric Resident Discharges
Most Common Indicators for Heart Transplant
Ages 0-17
CY 2012-2014**

Hospital	CY 2012	CY 2013	CY 2014	Three-Year Total
Nicklaus Children's Hospital	100	106	90	296
All Other Hospitals	73	75	88	236
Total	173	181	178	532
Percent From NCH	57.8%	58.6%	50.6%	55.6%

Source: CON application #10421, page 54

NCH states an expectation that the two transplant centers would have the largest portion of these types of cases that potentially lead to heart transplant in children but that NCH has the majority of the volume, with Memorial Regional Hospital having 125 such cases and JMH having 51, over the past three years. NCH indicates that it has absorbed many of these patients previously discharged by St. Mary's

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Medical Center. NCH offers a summary of OTSA 4 resident cases for MCIs, by hospital, for CY 2012, 2013 and 2014 (see below).

**Service Area Pediatric Resident Discharges
By Resident County and Hospital
Most Common Indicators for Heart Transplant
Ages 0-17
Three-Year Aggregate (CY 2012-2014)**

Hospital	Broward	Collier	Miami-Dade	Monroe	Palm Beach	Total
Nicklaus Children's Hospital	46	15	192	2	41	296
Memorial Regional Hospital	78	4	28	0	15	125
Jackson Health System	1	4	39	1	6	51
St. Mary's Medical Center	0	0	0	0	38	38
All Other	3	6	7	1	5	22
Total	128	29	266	4	105	532
Percent from NCH	35.9%	51.7%	72.2%	50.0%	39.0%	55.6%

Source: CON application #10421, page 55

NCH asserts that the data is evidence that the two existing pediatric heart transplant providers in OTSA 4 are generally not available or accessible to a majority of residents. NCH points out having between 36 percent and 72 percent of the market share for each county in OTSA 4.

NCH indicates that on average for the past three years, 11.2 percent of patients from the four Florida pediatric transplant centers with a primary diagnosis consisting of the ICD-9 data set were ultimately transplanted. NCH also indicates that in 2014, All Children's Hospital, the busiest program in Florida, had a rate of 21.5 percent and UF Health Shands Hospital had a rate of 13.6 percent. NCH maintains that with its robust Heart Program as its basis, NCH can reasonably achieve a ratio of transplants to MCIs of between 11 and 15 percent within five years of the proposed transplant program's inception. The Agency notes that NCH reaches this 11 to 15 percent estimate based on NCH's next table. NCH calculates a statewide ratio of transplants to MCIs of 7.9 percent (CY 2012), 10.6 percent (CY 2013) and 15.2 percent (CY 2014), see below.

**Hospital Discharges By Year
Most Common Indicators for Heart Transplant and Heart Transplants
Ages 0-17
CY 2012-2014**

Hospital	Most Common Indicators for Transplant		
	CY 2012	CY 2013	CY 2014
All Children's Hospital	62	64	66
UF Health Shands Hospital	50	56	59
Memorial Regional Hospital	59	43	45
Jackson Health System	31	26	21
Total	202	189	191
Hospital	Heart Transplants		
	CY 2012	CY 2013	CY 2014
All Children's Hospital	3	7	14
UF Health Shands Hospital	9	6	8
Memorial Regional Hospital	2	5	5
Jackson Health System	2	2	2
Total	16	20	29
Hospital	Ratio Transplants To Most Common Indicators		
	CY 2012	CY 2013	CY 2014
All Children's Hospital	4.8%	10.9%	21.2%
UF Health Shands Hospital	18.0%	10.7%	13.6%
Memorial Regional Hospital	3.4%	11.6%	11.1%
Jackson Health System	6.5%	7.7%	9.5%
Average	7.9%	10.6%	15.2%

Source: CON application #10421, page 56

NCH estimates that had it had a pediatric heart transplantation program in CY 2014 it could have expected 13 procedures (CY 2014), using the ratios of Memorial Regional Hospital for CY 2013 and CY 2014 or could have expected 18 procedures (CY 2014), using the average ratios of all existing pediatric transplant programs statewide (see below).

**Expected Pediatric Heart Transplants at NCH
Ages 0-17
CY 2014**

NCH Most Common Indicators for Transplant	121
Ratio at Memorial Regional Hospital in 2013 and 2014	11%
Expected Transplants	13
Average Ratio of Four Transplant Centers in 2014	15%
Expected Transplants	18

Source: CON application #10421, page 57

The applicant states that to forecast the number of cases qualifying as MCIs for heart transplant originating from OTSA 4, NCH applied 2014 MCI discharge use rates to the forecasted pediatric population for each of the planning years. The reviewer combines two the applicant’s tables to account for the applicant’s total estimated OTSA 4 cases and NCH’s estimated cases (see below).

**Forecasted Service Area Pediatric Most Common Indicators
for Heart Transplant
Ages 0-17**

12 Months Ending June 30, 2018, June 30, 2019 and June 30, 2020

	Broward	Collier	Miami-Dade	Monroe	Palm Beach	Total
2014 Population Ages 0-17	391,039	65,386	560,006	10,948	271,676	1,299,055
2014 Most Common Indicator Discharge Use Rate per 1,000 Pop	0.09	0.23	0.15	0.00	0.20	0.13
Forecasted Population Age 0-17:						
Year 1 (12 Months Ending 6/30/2018)	391,540	68,641	570,125	10,679	280,735	1,321,720
Year 2 (12 Months Ending 6/30/2019)	392,085	69,575	573,398	10,625	283,568	1,329,249
Year 3 (12 Months Ending 6/30/2020)	392,678	70,534	576,933	10,578	286,438	1,337,161
Forecasted Pediatric Most Common Indicators, Service Area 4 Cases						
Year 1 (12 Months Ending 6/30/2018)	37	16	86	0	38	177
Year 2 (12 Months Ending 6/30/2019)	37	16	86	0	39	178
Year 3 (12 Months Ending 6/30/2020)	37	16	87	0	39	179
NCH 3-Yr Combined Market Share	35.9%	51.7%	72.2%	50.0%	39.0%	55.6%
Forecasted Pediatric Most Common Indicators, NCH Cases						
Year 1 (12 Months Ending 6/30/2018)	13	8	62	0	15	98
Year 2 (12 Months Ending 6/30/2019)	13	8	62	0	15	98
Year 3 (12 Months Ending 6/30/2020)	13	8	63	0	15	99

Source: CON application #10421, page 57 and 58

NCH contends that the application of a 2014 market share to forecasted market cases is extremely conservative, given that once the proposed project is approved, market share for all other heart programming will increase as the Heart Program at NCH will gain further recognition. NCH further contends that in 2014, NCH had 25.6 percent in-migration of these types of cases to NCH. The applicant expects this rate of in-migration to also increase, if the proposed project is approved.

NCH estimates total pediatric heart transplants at its location of six, 11 and 13 for year one, year two and year three, respectively (see below).

**Forecasted NCH Pediatric Heart Transplants
Ages 0-17
12 Months Ending June 30, 2018, June 30, 2019 and June 30, 2020**

	Year One Ending 6/30/18	Year Two Ending 6/30/19	Year Three Ending 6/30/20
NCH Most Common Indicators for Heart Transplants Cases:			
From Service Area	98	98	99
In-Migration (25%)	32	33	33
Total	130	132	132
Average Ratio of Transplant to Most Common Indicator Cases:			
	5.0%	8.0%	10.0%
Forecasted NCH Pediatric Heart Transplants	6	11	13

Source: CON application #10421, page 59

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

The Agency notes that the applicant states that this criterion is not applicable because the applicant is seeking to establish a pediatric heart transplant program.

Based on the applicant’s methodology number one, by year two (ending June 30, 2019) NCH expects 12 procedures and based on the applicant’s methodology number two, by year two (ending June 30, 2019) NCH expects 11 procedures.

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

The applicant states that in CY 2014, NCH performed 207 open heart surgeries and 367 cardiac catheterizations. NCH provides a table to account for CY 2013, 2014 and 2015 interventional volume (see below).

NCH Heart Program Interventional Volume CY 2013, 2014 and YTD 2015			
	2013	2014	2015(*)
Catheterizations	289	362	193
Electrophysiology Cases	113	119	94
Open Heart Surgeries, Total	204	207	127
Neonates (0-30 Days)	42	53	21
Non-Neonates (31+ Days)	162	154	106

(*) YTD 2015 is through July 31, 2015
Source: CON application #10421, page 99

The reviewer notes that the applicant's narrative total of 367 cardiac catheterizations (CY 2014) is different from the table total of 362 catheterizations (CY 2014). However, both totals exceed the minimum cardiac catheterizations of 200 for the CY preceding the CON application deadline.

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

NCH states having the requisite staff and resources to care for the heart transplant patient's chronic illness pursuant to this rule. The applicant states that for those positions for which it does not currently have on staff, NCH has the expertise and wherewithal to effectively recruit the best

talent in the country. NCH asserts having a full range of services and facilities for inpatient and outpatient care available to the patient population on a 24-hour basis.

NCH states that it already has a program to educate its staff regarding transplant care and specific issues surrounding transplant care, as it relates to its existing inpatient pediatric bone marrow transplant program. NCH contends that care for the transplant patient will be provided by way of a multidisciplinary and highly coordinated approach. NCH also discusses its other pediatric programs (CON application #10421, pages 74 – 76).

- 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.**

NCH states that there is already a well-established relationship between the applicant and LAORA. The applicant provides a written organ and tissue procurement agreement between the applicant and LAORA (CON application #10421, Vol. II, Tab 14), along with an addendum to the agreement. The reviewer notes that the agreement and addendum both lack an effective date. However, NCH contends having been the donor hospital for 42 organ procurements from 12 patients between 2012 and 2014. NCH asserts that it will work with LAORA to acquire cadaveric organs from LAORA and that it will meet requirements, referenced by rule. NCH maintains that LAORA will provide the necessary equipment and personnel to recover solid organs for transplant according to policies and procedures as set forth by OPTN. Per NCH, this will include equipment for cooling, flushing, and transporting organs as well as equipment for organ preservation through mechanical perfusion, as necessary.

NCH states that a pediatric heart transplant surgeon will be recruited for the proposed project and that the surgical team and staff are well acquainted with applicable processes and procedures for organ recovery.

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

NCH states that it has three pediatric intensive care units (PICUs), with 108 total beds increasing to 127 total ICU beds, once the new tower opens in 2016. NCH discusses its pediatric cardiac intensive care unit (CICU) on page 78 of the application and maintains that pediatric heart transplant patients will be treated in the pediatric CICU. The reviewer notes that the applicant does not directly address the provision of prolonged reverse isolation, when required.

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

Per NCH, on the basis of their thorough evaluation, previous medical records and psychosocial information, a decision will be made by a Transplant Selection Committee (TSC) regarding the advisability of cardiac transplantation for patients with severe functionality impairment and with no medical or surgical options. According to NCH, these TSC meetings will be held as needed at the inception of the program, increasing to regularly held meetings once volume increases. NCH maintains that the TSC will include transplant surgeons, cardiologists, transplant coordinators, social workers, psychiatrists, bioethicists and anesthesiologists. A decision regarding candidacy is made by consensus, based on information provided to the TSC.

NCH points out that the TSC will make a decision to transplant or not transplant and that after institutional approval, patients must be listed with UNOS. NCH indicates that candidates are prioritized by the status they are listed with, either status 1A, 1B or 7, based on severity. NCH asserts that once patients are listed with UNOS, they will be notified by mail within 10 business days. NCH states that another outcome of the TSC other than to transplant could be to surgically implant mechanical circulatory support as a

bridge to transplant. According to NCH, most commonly this is a left ventricular assist device (LVAD). NCH states that whatever the outcome of the TSC, the patient and family will be notified by the transplant coordinator, prepared and educated.

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

The applicant maintains that NCH is in the process of developing written protocols for patient care for pediatric heart transplant and these written protocols will include patient selection criteria for patient management and evaluation during the pre-hospital, inpatient and immediate post discharge phases of the program. NCH indicates that protocols for long-term management of the patient are also under development.

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

The applicant maintains that NCH is in the process of developing written protocols for patient care for pediatric heart transplant including detailed therapeutic and evaluative procedures for the acute and long-term management and management of commonly encountered complications. NCH states that protocols for long-term management of the patient are also under development.

The applicant provides a brief narrative description of discharge planning and indicates that several weeks after transplant, the patient must have a cardiac catheterization and intravascular ultrasound and that these tests are then repeated annually. NCH maintains that it is required that the patient follow-up with a handful of other physicians aside from their cardiologist to detect any problems that may occur after transplant. The applicant stresses the importance of family involvement and understanding of the detailed therapeutic and evaluative procedures required for

the long-term management why long-term follow-up care is necessary. NCH indicates that it will make available many sources of help to provide support to patients and their families.

- 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.**

NCH asserts that it will obtain its own equipment for cooling, flushing and transporting organs. NCH indicates having already received an estimate from Ecolab for the ORS-1075HS Hush-Slush® Machine. The reviewer confirms that a cost of \$306,100 is included on line #24 “Major Technical Equipment” under Equipment Costs on Schedule 1. The reviewer notes that Schedule 1 notes indicate that equipment includes cooling/flushing equipment.

The reviewer notes that the applicant previously provided its written agreement with LAORA.

- 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.**

NCH asserts that it will contract with OneBlood, Inc., for its tissue typing needs. The applicant references excerpts of a letter of support from the president and CEO of OneBlood, Inc. NCH maintains having a contractual arrangement with OneBlood HLA laboratory within the State of Florida which meets the requirements of the American Society of Histocompatibility. NCH also maintains having a contractual arrangement with One Blood Reference Laboratory for antibody problems which cannot be identified in-house, or for consultation and assistance if needed. NCH states that One Blood is AABB and CAP accredited.

The reviewer notes that the applicant does not provide a shell or draft contractual agreement with OneBlood, Inc., or an executed contract with OneBlood and further notes that the applicant does not provide a copy of the stated existing contractual agreement with OneBlood HLA laboratory or a contractual agreement with One Blood Reference Laboratory.

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

The applicant indicates having a Department of Pathology and Laboratory Services at NCH, stating that it is a state-of-the-art comprehensive facility that serves as the leading provider of pathological and laboratory services for children in the region—and all pathologists are board-certified. NCH maintains that it will train at least one of its pathologists in surgical pathology as it relates to heart transplantation. NCH also maintains that if the pathology test is not performed in-house, it will be referred to Mayo Medical Laboratories and various pathology labs according to specialty and specific test required.

The reviewer notes that the NCH does not name any of its pathologists, does not offer a CV of any of its pathologists, does not offer a laboratory license from the Agency and does not include a draft or sample contract with Mayo Medical Laboratories or any other pathology labs.

10. Blood banking facilities.

NCH asserts that it contracts with OneBlood, Inc., for blood banking. NCH maintains having a contractual arrangement with OneBlood HLA laboratory within the State of Florida which meets the requirements of the American Society of Histocompatibility. NCH also maintains having a contractual arrangement with One Blood Reference Laboratory for antibody problems which cannot be identified in-house, or for consultation and assistance if needed.

The reviewer notes that the applicant does not provide a shell or draft contractual agreement with OneBlood, Inc., or an executed contract with OneBlood.

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

NCH asserts that it has developed a comprehensive education and training protocol for staff regarding the special care of pediatric heart transplantation patients. The applicant offers a three-page Staff Transplant Training Program/Plan in Tab 21 of CON application #10421. According to NCH, the program provides the necessary training to demonstrate established levels of competency for all necessary staff and will be required in addition to existing required hospital training and competency training. NCH assures that documentation of attendance and competency will be documented in the employee record and ongoing transplant-specific training will be provided as needed. According to NCH, upon completion of the training, the staff member will be able to carry out the following tasks:

- List organizational transplant resources and leaders
- Discuss the transplantation system and related health care policy in the United States
- Describe the transplant process and common complications that occur in all organ transplants
- Anticipate the expected organ specific care trajectory and identify patients that are not progressing
- Understand transplant immunology and the impact of medications commonly used to prevent rejection
- Identify common complications experienced by the transplant patient
- Provide comprehensive patient and family education extending through the transplant process
- Appraise the psychosocial impact of the transplant process on the patient and family

NCH states the education format offers classroom and online instruction in a tiered approach for a maximum of eight hours of training per employee. The applicant states “Tier 1” and “Tier 2” training with program components include:

- Level I: Basic transplant overview (maximum 1.5 hours)
- Level II: Clinical transplant fellowship (maximum 6.5 hours)
- Level III: ABTC transplant certification
- Level IV: Mentoring for professional development/career ladder opportunities

NCH points out that joining The International Transplant Nurses Society (and starting a local chapter) or “NATCO”, the organization for transplant professionals, can provide additional education and focus.

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

NCH states it created a Transplant Patient Education Plan for the proposed project in Tab 22 of CON application #10421. NCH maintains that transplant education should provide patients and families with the tools for making informed decisions, changing behaviors for a healthy lifestyle and placing emphasis on wellness. The applicant maintains that the Education Plan sets forth topics to be covered during each phase of the transplant process. The applicant includes the following Education Plan key objectives:

- During the initial contact/pre-evaluation stage
 - For the transplant coordinator to understand the patient/parent baseline understanding
 - For the patient/family to verbalize understanding of the transplant process
 - Transplant candidate evaluation requirements
 - Patient/family will be able to prepare for transplant evaluation
- During the evaluation stage of the process, the patient/family will understand
 - Transplant candidate evaluation requirements
 - Transplant related processes
 - Risks and benefits of transplantation
 - Alternative treatment options
 - Transplant team members’ roles and responsibilities
- During the transplant episode which begins at patient’s call through transplant hospitalization
 - Prepare the patient and family with the knowledge and skills to actively participate in the long-term health care management needed
 - Prepare for discharge and outpatient follow-up

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. 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.

NCH indicates initially having one primary cardiovascular surgeon on staff to perform heart transplants and will serve as both the heart transplant program director and surgical director. NCH asserts that upon CON approval, NCH will immediately begin recruitment for the OPTN certified pediatric heart transplant/heart failure cardiologist as the program's first recruitment. NCH also states that the program's second recruitment will be an OPTN certified pediatric heart transplant surgeon.

NCH states that its Heart Program has two cardiovascular surgeons, four pediatric cardiologists in two sets of specialties, four pediatric cardiac intensivists, two cardiologists with pediatric specializations, three specialists in pediatric imaging and five pediatric cardiologists. According to NCH, the following seven of its Heart Program cardiologists/cardiac surgeons made the 2015-2016 Best Doctors in America® list:

- Dr. Redmond Burke, Director, Cardiovascular Surgery
- Dr. Steven B. Fishberger, Cardiology
- Dr. Ronald J. Kanter, Cardiology
- Dr. Cecilio (Leo) Lopez, Cardiology
- Dr. Madeleen Margaret Mas, Cardiology
- Dr. Anthony Rossi, Cardiac Intensivist
- Dr. Elizabeth Welch, Cardiology

Per NCH, 61 of its physicians have made the Best Doctors in America® list for 2015-2016. The reviewer notes that the seven physicians named above, as well as a total of 61 physicians, all affiliated with NCH, are listed in the Voted Best/Best Doctors

2015-2016 documentation submitted by the applicant. NCH asserts that only five percent of doctors in America earn this prestigious honor, decided by impartial peer review.

NCH provides CVs for Dr. Burke and Dr. Rossi noting that Dr. Burke has various board certifications, including the American Board of Surgery and the American Board of Thoracic Surgery Diplomate. Dr. Rossi has board certification with the American Board of Pediatrics and Board of Pediatric Cardiology.

- 1. 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.**

According to NCH, the pediatric heart transplant surgeon to be recruited will dually serve as program director of the Pediatric Heart Transplant Program. The applicant indicates that this individual will ideally be mid-career. NCH contends having the reputation, resources and wherewithal to attract top talent from all over the world.

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

NCH indicates a medical staff of more than 650 physicians and more than 3,500 employees, offering more than 40 pediatric specialties and subspecialties and is Florida's only freestanding pediatric trauma center.

NCH reiterates its seven Heart Program cardiologists/cardiac surgeons making the 2015-2016 Best Doctors in America® list (see Item E.2.b.1 of this report). The applicant states that it performs more pediatric cardiac surgeries and has more acutely-ill pediatric cardiac patients than any other hospital in Florida, including the four existing pediatric heart transplant providers. NCH lists 13 other characteristics that the applicant states is evidence of its experience in the special needs of children (CON application #10421, pages 90 – 92).

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

NCH states that due to the complexity and chronically ill condition of transplant patients, nurses and nurse practitioners must have specific training and experience. NCH asserts that it will have a staff of nurses and nurse practitioners with the level of expertise to care for its pediatric cardiac transplant patients. NCH contends that to the extent that nurses with such experience already work at NCH, these nurses will be utilized. Further, NCH contends that additional staff with transplant experience will be recruited. The reviewer notes no existing nurse/nurse practitioner staff are named and no nurse/nurse practitioner CVs are provided.

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

NCH states having a blood supply and will have sufficient blood on hand to accommodate heart transplant patients on a long-term basis. NCH states that it maintains relationships with blood banks in the south Florida region that are capable of meeting the needs of its transplant patients on a long-term basis.

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

NCH asserts that nutritionists with expertise in the nutritional needs of transplant patients will be a member of the multidisciplinary team that cares for each pediatric cardiac transplant patient. NCH maintains that nutritional assessment and diet counseling services will be furnished by a qualified dietician available to all transplant patients. NCH states and the reviewer confirms that Schedule 6A of the application indicates 8.5 FTEs for dietician in years one, two and three of the proposed program. The reviewer notes that there are 0.2 FTEs incrementally each year for a nutritionist for the proposed project. The reviewer notes no existing nutritionist/dietician staff are named and no nutritionist/dietician CVs are provided.

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

NCH states it will provide respiratory therapists with expertise in the needs of pediatric transplant patients and already has two respiratory therapists on staff with expertise with transplant patients. NCH also states that its respiratory therapists have experience in providing care to pediatric transplant patients prior to the proposed program's initiation, as necessary. The reviewer notes no existing respiratory therapist staff are named and no respiratory therapist CVs are provided.

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

NCH indicates that there will be social workers, psychologists, psychiatrists and other individuals skilled in the special needs of children and performing comprehensive psychological assessments, counseling patients/parents/caregivers, providing assistance with financial arrangements and making arrangements for use of community resources. NCH also indicates that social workers, psychologists, psychiatrists and financial counselors will be part of the patient's multidisciplinary team and their input and guidance will play a significant role in the selection committee process. The applicant indicates that it already has social workers, psychologists and psychiatrists on staff who evaluate certain patient populations, including bone marrow transplant recipients.

NCH states and the reviewer confirms that Schedule 6A of the application indicates 18.4 FTEs for social workers in years one, two and three of the proposed program with an incremental 0.2 FTEs for each year for psychologists, pursuant to the program. The reviewer notes no existing social workers/psychologist/psychiatrist staff are named and no social workers/psychologist/psychiatrist CVs are provided.

- 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.**

NCH states that it will comply with this criterion.

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 distances to the nearest four Florida pediatric heart transplant providers, from the proposed location for CON application #10421.

Driving Distances in Miles – CON application #10421 Variety Children’s Hospital, Inc., d/b/a Nicklaus Children’s Hospital and Florida Pediatric Heart Transplantation Providers					
Facility	Nicklaus Children’s Hospital	Jackson Memorial Hospital	Memorial Regional Hospital	All Children’s Hospital	UF Health Shands Hospital
Nicklaus Children’s Hospital		9.1	26.7	262.3	341.1
Jackson Memorial Hospital	9.1		19.4	261.7	333.8
Memorial Regional Hospital	26.7	19.4		250.4	319.8
All Children’s Hospital	262.3	261.7	250.4		151.2
UF Health Shands Hospital	341.1	333.8	319.8	151.2	

Source: www.Mapquest.com

The chart above illustrates that from the proposed CON application #10421, the nearest pediatric heart transplant provider (Jackson Memorial Hospital) is 9.1 miles with the second nearest provider 26.7 miles away. This indicates that the two operational OTSA 4 pediatric heart transplantation providers are within 26.7 miles of the proposed project. Item E. 1. a. of this report has previously shown that for the five-year period ending June 30, 2015, Service Area 4 pediatric heart

transplant providers, collectively, had the lowest volume of the three operational service areas. The third nearest provider is 262.3 miles and the most distant and the highest volume provider statewide is 341.1 miles. OTSA 4 is the only service area with more than one operational pediatric heart transplant provider and if the proposed project is approved, OTSA 4 would have three providers.

NCH contends that the fact there are two pediatric heart transplant programs in south Florida should not preclude the approval of the proposed project. NCH also contends that while JMH is located in OTSA 4 and is counted in the number of programs located in OTSA 4--it does not serve the area and should not be counted. NCH asserts that neither Memorial Regional Hospital nor JMH have the underlying cardiac surgical volume or the acutely ill cardiac patients in their respective hospitals to generate the volume of an All Children's Hospital program.

NCH states that in Miami-Dade County, very few patients are listed which itself indicates an access issue. NCH further states that of those who have been listed, there is a lower transplant rate in Miami-Dade County than in the broader service area. NCH asserts that for CY 2012, 2013 and 2014, OTSA 4 pediatric heart transplant candidates that are being listed are not receiving a transplant in OTSA 4 or within Florida (see below).

Pediatric Heart Transplant Candidates and Transplant Recipients Service Area 4 Pediatric Residents CY 2012-2014			
Resident County	CY 2012	CY 2013	CY 2014
CANDIDATES			
Broward	5	5	1
Collier	1	0	1
Miami-Dade	1	2	5
Monroe	0	0	0
Palm Beach	1	1	0
Total	8	8	7
TRANSPLANT RECIPIENTS			
Broward	3	4	1
Collier	0	0	1
Miami-Dade	3	1	1
Monroe	0	0	0
Palm Beach	1	0	1
Total	7	5	4
PERCENT OF WAITLIST WHO RECEIVED TRANSPLANT			
Broward	60.0%	80.0%	100.0%
Collier	0.0%	--	100.0%
Miami-Dade	300.0%	50.0%	20.0%
Monroe	--	--	--
Palm Beach	100.0%	0.0%	--
Total	87.5%	62.5%	57.1%

Source: CON application #10421, page 106

The applicant reiterates outmigration from CY 2012-2014, high volumes of pediatric cardiac surgeries at NCH (CY 2014) and MCIs for heart transplants (CY 2012-2014), to estimate the expected pediatric heart transplants (CY 2014).

- 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.**

NCH provides Agency licensure and Variety Children’s Hospital’s accreditation by The Joint Commission. The reviewer notes that the applicant’s license (issued by the Agency) expired on January 15, 2016. However, Agency records indicate that on November 17, 2015, the Agency issued the applicant a new license, effective January 16, 2016 which will expire on January 15, 2018.

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Below is a brief list the applicant's stated 13 achievements. Where provided by the applicant, the reviewer includes the portion of the application where the achievement or recognition is documented:

- NCH has more pediatric programs ranked among "America's Best" by U.S. News & World Report in 2011-2012, 2012-2013 and 2014-2015 than any other Florida hospital. In addition, two NCH programs are ranked among the top 10 in the nation. NCH is the only hospital in Florida with programs included among the top 10 in pediatric subspecialties assessed by U.S. News.
- NCH is one of only three pediatric hospitals in the nation and the only one in Florida to have all three of its ICUs receive either a Gold Beacon Award or Silver Beacon Award from the American Association of Critical Care Nurses.
- The Heart Program at NCH provides care for more children with congenital heart disorders than any other hospital in Florida and is consistently ranked among the best programs in the nation for cardiology and heart surgery.
- NCH's bone marrow transplant program is accredited by the prestigious FACT-Foundation for the Accreditation of Cellular Therapies.
- NCH's Brain Institute is the first and largest pediatric neuroscience collaboration in the nation. The NCH Brain Institute is ranked eighth in the nation in pediatric neurology and neurosurgery and no other program in the southeastern U.S. ranks higher.
- NCH's NICU is ranked as one of the top 10 programs in the nation in neonatology and no other program in Florida ranks higher.
- NCH's Cancer Center is the largest provider of pediatric cancer services in Florida.
- NCH's Research Institute is one of the largest providers of pediatric research in the region. The Institute has earned full reaccreditation from the Association of Human Research Protection Programs and is the first pediatric facility in Florida and one of the few in the nation to achieve this standing.
- NCH LifeFlight® Critical Care Transport team provides transport of critically ill children from referring hospitals to NCH critical care units.
- For the third time in a row, NCH has been designated an Association of American Nurses Credentialing Center (ANCC) Magnet facility, the nursing profession's most prestigious institutional honor. NCH was the fifth pediatric hospital in the nation to achieve this recognition.

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- The ANCC awarded its 2015 Magnet® Prize to NCH in recognition of NCH’s Humpty Dumpty Falls Prevention Program (developed at NCH) with NCH being the first children’s hospital internationally to receive this Award. The Prize was presented at the ANCC National Magnet Conference®.
- NCH is a 2015 recipient of the “NDNQI Press Ganey Award for Outstanding Nursing Quality”. NCH was the highest ranking hospital in the pediatric hospital category.
- NCH is ranked among the top 125 training organizations by Training magazine and has been included in the ranking since 2006.

The reviewer notes other awards and recognitions issued to NCH (CON application #10421, Tab 18 - Quality Achievements). NCH discusses recognition as a Florida Blue/Blue Distinction Center® for delivering high quality bone marrow transplant care as part of the Blue Distinction Center’s for Specialty Care® program.

NCH discusses having been recognized as one of the “Healthiest Companies in America” by Interactive Health. The applicant also discusses having received (in 2014) three Kids Crown Awards that pertain to its outpatient centers.

The applicant provides a description of its Performance Improvement (PI) Plan. According to NCH, the mission, vision, value, strategic and service excellence statements of NCH guide and direct the PI Plan and activities. The PI Plan is stated to systematically monitor, analyze and improve patient outcomes and services. Additionally, the PI Plan is stated to provide the framework for a collaborative approach to improve performance in a systematic, coordinated and continuous manner to enhance patient safety and achieve optimal health outcomes. NCH states that the proposed program will be incorporated into the regularly updated PI Plan. NCH includes the PI Plan, with Appendices A through D, last updated December 19, 2014.

Agency complaint records indicate, for the three-year period ending November 19, 2015, Nicklaus Children’s Hospital, the parent’s sole hospital, had three substantiated complaints. A single complaint can encompass multiple complaint categories. The substantiated complaint categories were Emergency Access, EMTALA and resident/patient/client rights (one compliant each).

- 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.**

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.

Below is an analysis of the audited financial statements of Variety Children's Hospital where the short-term and long-term measures fall on the scale (highlighted in gray) for the most recent year.

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Variety Children's Hospital, Inc.		
	Dec-14	Dec-14
Current Assets	\$181,354,766	\$142,974,135
Total Assets	\$1,020,717,134	\$958,278,455
Current Liabilities	\$110,577,855	\$102,655,251
Total Liabilities	\$434,934,491	\$418,072,845
Net Assets	\$585,782,643	\$540,205,610
Total Revenues	\$597,116,794	\$550,721,019
Excess of Revenues Over Expenses	\$37,233,406	\$91,515,770
Cash Flow from Operations	\$62,372,387	\$57,652,557
Short-Term Analysis		
Current Ratio (CA/CL)	1.6	1.4
Cash Flow to Current Liabilities (CFO/CL)	56.41%	56.16%
Long-Term Analysis		
Long-Term Debt to Net Assets (TL-CL/NA)	55.4%	58.4%
Total Margin (ER/TR)	6.24%	16.62%
Measure of Available Funding		
Working Capital	\$70,776,911	\$40,318,884

Position	Strong	Good	Adequate	Moderately Weak	Weak
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 \$181,472,034 which includes \$1,893,034 for this project. The applicant indicates on Schedule 3 of its application that funding for the project will be provided by the applicant from available cash on hand.

The applicant provided a copy its December 31, 2014 audited financial statements. A letter of financial commitment from the applicant's executive vice president and chief financial officer was also included. These statements were analyzed for the purpose of evaluating the parent'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 table below shows the NCH's projected staffing for the proposed project in years one, two and three, ending June 30, 2018, June 30, 2019 and June 30, 2020, respectively. By the end of year two, NCH

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estimates an FTE increase in the nursing category and another FTE increase in this same category by the end of year three. In all the remaining categories, for all three years, the FTE counts remain constant. The table below accounts for FTEs to be added as a result of the proposed project, if approved.

Variety Children's Hospital d/b/a Nicklaus Children's Hospital CON application #10421 Pediatric Heart Transplantation Program Staffing Patterns			
	Year One Ending 6/30/2018	Year Two Ending 6/30/2019	Year Three Ending 6/30/2020
ADMINISTRATION			
Secretary	0.4	0.5	0.5
Financial Coordinator	0.7	0.4	0.4
PHYSICIANS			
Medical Director	0.2	0.2	0.2
Other: Transplant Surgeon	1.0	1.0	1.0
NURSING			
RNs (Patient Care)	5.4	7.7	9.6
Other: Transplant Coordinator	1.0	1.0	1.0
Other: Quality Accreditation Coordinator	0.5	0.5	0.5
ANCILLARY			
OR RN	0.5	0.5	0.5
Operating Room Technologists	0.5	0.5	0.5
Other: Nutritionist	0.2	0.2	0.2
Other: Psychologist	0.2	0.2	0.2
SOCIAL SERVICES			
Other: Social Worker	0.5	0.5	0.5
TOTAL	11.1	13.4	15.3

Source: CON application #10421, Schedule 6A

According to the applicant's Schedule 6A assumptions, the proposed project staffing schedule is based upon the anticipated patient activity and current levels of staffing in existence at NCH.

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.

The immediate and long-term financial feasibility of the project is tied to expected profitability. The purpose of our analysis for this section is to evaluate the reasonableness of the applicant's profitability projections and, ultimately, whether profitability is achievable for this project. Typically, our analysis includes an evaluation of net revenue per patient day (NRPD), cost per patient day (CPD) and profitability, where we compare the NRPD, CPD and profitability to actual operating results from related hospitals as reported on Florida Hospital Uniform Reporting System reports and adjust for inflation.

In this instance, however, the applicant did not provide projected revenue for the combined operations including the proposed project. Because the grouping data of like-hospitals reflects revenues and expense data for combined operations and not specific programs, any comparison for program-specific revenues to total/combined revenues making up the group averages would be invalid. As a result, net revenues and overall profitability cannot be analyzed.

However, staff notes that the applicant had \$181.4 million in current assets and \$62.4 million in cash flow from operations at December 31, 2014. With anticipated project costs of \$1.9 million and projected project operating expenses of \$3.3 million in year one and \$5.8 in year two, the applicant should be able to absorb all the costs of the project.

Conclusion:

This project appears to be financially feasible based on the low project cost and funding available to the applicant.

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

No. Due to the health care industry's existing barriers in consumer-based competition, this project will not likely foster the type competition generally expected to promote quality and cost-effectiveness.

General economic theory indicates that competition ultimately leads to lower costs and better quality. However, in the health care industry there are several significant barriers to competition:

Price-Based Competition is Limited - Medicare and Medicaid account for 41.2 percent of hospital charges in Florida, while HMO/PPOs account for approximately 45.9 percent of charges. While HMO/PPOs negotiate prices, fixed price government payers like Medicare and Medicaid do not. Therefore, price-based competition is limited to non-government payers. Price based competition is further restricted as Medicare reimbursement in many cases is seen as the starting point for price negotiation among non-government payers. In this case, 48.5 percent of patient days are expected to come from Medicare and Medicaid with 40.2 percent from HMO/PPOs.

The User and Purchaser of Health Care are Often Different – Roughly 87.1 percent of hospital charges in Florida are from Medicare, Medicaid, and HMO/PPOs. The individuals covered by these payers pay little to none of the costs for the services received. Since the user is not paying the full cost directly for service, there is no incentive to shop around for the best deal. This further makes price-based competition irrelevant.

Information Gap for Consumers – Price is not the only way to compete for patients, quality of care is another area in which hospitals can compete. However, there is a lack of information for consumers and a lack of consensus when it comes to quality measures. In recent years there have been new tools made available to consumers to close this gap. However, transparency alone will not be sufficient to shrink the information gap. The consumer information must be presented in a manner that the consumer can easily interpret and understand. The beneficial effects of economic competition are the result of informed choices by consumers.

In addition to the above barriers to competition, a study presented in The Dartmouth Atlas of Health Care 2008 suggests that the primary cost driver in Medicare payments is availability of medical resources. The study found that excess supply of medical resources (beds, doctors, equipment, specialist, etc.) was highly correlated with higher cost per patient. Despite the higher costs, the study also found slightly lower quality outcomes. This is contrary to the economic theory of supply and demand in which excess supply leads to lower price in a competitive market. The study illustrates the weakness in the link between supply

and demand and suggests that more choices lead to higher utilization in the health care industry as consumers explore all alternatives without regard to the overall cost per treatment or the quality of outcomes.

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.**

The proposed project is not reported to involve construction or renovation.

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

Below is a chart to account for the applicant’s and the district’s Medicaid and charity care percentages for fiscal year 2014 provided by the Agency’s Florida Hospital Uniform Reporting System (FHURS).

**Medicaid and Charity Care for
Variety Children’s Hospital, Inc.
d/b/a Nicklaus Children’s Hospital (CON application #10421)
Compared to the District for FY 2014**

Applicant	Medicaid and Medicaid HMO Days	Charity Percentage Service	Combined Medicaid and Charity Care
Nicklaus Children’s Hospital*	37.40%	0.05%	37.45%
District 11 Average	22.78%	4.24%	27.02%

Source: Fiscal Year 2014 Agency for Health Care Administration Actual Hospital Budget Data

Note: * For this review, Nicklaus Children’s Hospital’s fiscal year ended 12/31/2014

The table below illustrates Nicklaus Children’s Hospital’s FY 2015-2016 low-income pool (LIP) and Disproportionate Share Hospital (DSH) participation, as of December 10, 215.

CON Action Number: 10421

Variety Children’s Hospital, Inc. d/b/a Nicklaus Children’s Hospital (CON application #10421) LIP and DSH Program Participation for FY 2015-2016		
Applicant/Program	Annual Total Allocation	Year-to-Date Total Allocation As of December 10, 2015
Nicklaus Children’s Hospital/LIP	\$4,558,131	\$1,147,034
Nicklaus Children’s Hospital/DSH	\$396,663	\$98,440

Source: Florida Agency for Health Care Administration, Division of Medicaid, Office of Program Finance

NCH states having a long history providing health services to the medically indigent. NCH indicates that in FY 2013 and 2014, ending December 31, NCH provided \$2,327,848 and \$1,193,660 in charity care, respectively, representing 2.1 and 2.5 percent of its net patient revenue. NCH maintains that in addition to charity care, the applicant provided \$106,941,948 in conventional Medicaid and \$134,616,815 to patients under Medicaid Managed Care in 2014.

According to Schedule 7A, NCH intends to provide in the proposed pediatric heart transplantation program 63.0 percent Medicaid, 37.0 percent commercial insurance and 0.0 percent Self-Pay both in year one (ending June 30, 2018) and in year two (ending June 30, 2019), total annual patient days. For the proposed program for year three (ending June 30, 2020) NCH estimates 62.0 percent Medicaid, 38.0 percent commercial insurance and 0.0 percent self-pay, total annual patient days. The applicant does not offer charity care patient days allotted to the proposed program, according to Schedule 7A or the Schedule 7A notes. The reviewer notes that Schedule 7A notes indicate that the proposed transplant program revenues are by inpatient and outpatient classification. These notes further indicate that the applicant’s estimates were based on evaluating the historical experience of NCH’s complex cardiac patient charges, payor mix and anticipated utilization.

The reviewer notes that statewide during the 12-month period ending June 30, 2015, there were 18 Medicaid/Medicaid Managed Care patients that received pediatric heart transplantation.⁴ NCH offers no Medicaid or charity care patient day condition(s) regarding the proposed project.

⁴ Based on the Agency’s Florida Center for Health Information and Policy Analysis hospital discharge data

F. SUMMARY

Variety Children's Hospital d/b/a Nicklaus Children's Hospital (CON application #10421) proposes to establish a pediatric heart transplantation program at NCH, in Miami, Miami-Dade County, OTSA 4. NCH is the sole hospital operated by MCHS.

Project costs total \$1,893,034. These costs include equipment, project development and start-up costs. There is no reported construction or renovation associated with the project.

Need:

Need is not published by the Agency for pediatric heart 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.

NCH contends that the proposed project is necessary to ensure transplant candidates have timely access to transplantation services and other pre- and post-transplantation evaluative, therapeutic and clinical services. The applicant offers several factors as justifying need for the proposed project:

- NCH performs more cardiac surgeries on the pediatric population than any other hospital in Florida. Cardiac transplantation is inevitable for many of the patients who currently undergo complex heart surgery in infancy.
- NCH has a greater number of complex cardiac patients with diagnoses that most frequently are the underlying disease/disorders that indicate a need for heart transplantation in infants and children than any other hospital in Florida.
- NCH performed 362 pediatric cardiac catheterizations in CY 2014 which exceeds the Agency's minimum criteria of 200 catheterizations during the preceding year.
- NCH performed 207 pediatric open heart surgeries in CY 2014 which exceeds the Agency's minimum criteria of 125 open heart surgeries during the preceding year – 53 of the 207 were performed on infants 30 days old and younger.
- The only other pediatric heart transplant program in Miami-Dade County is virtually nonexistent with as many as two pediatric heart transplant cases a year. This provider has not transplanted a single patient from Miami-Dade County or from OTSA 4 in recent years.
- The only other pediatric heart transplant center in OTSA 4 is a low volume program and has only transplanted two Miami-Dade County residents in recent years

- 100 percent of NCH's potential cardiac transplant patient population either leaves their NCH continuum of care to be transplanted outside Miami-Dade County and often outside of Florida, or they do not obtain a transplant at all because they cannot leave the area
- NCH's complex cardiac pediatric patients are some of the most complex pediatric patients in Florida. As such, it is particularly important for them, and their families, to have continuity of care during this critical period of their management. There is a great potential harm in changing institutions for heart transplantation, including availability of medical records, family unfamiliarity with physicians and staff, staff unfamiliarity with a sick and complicated patient, and the challenges of reoperation after prior cardiac surgery

The Agency notes one Lee County resident in-migrated to OTSA 4 for a pediatric heart transplant and no OTSA 4 resident outmigrated from OTSA 4 for pediatric heart transplantation for the 12 months ending June 30, 2015.

The Agency indicates that OTSA 4 has relatively low but stable pediatric heart transplant volume for the four-year period ending June 30, 2015 and no outmigration for the 12-month period ending June 30, 2015, therefore it is reasonable to conclude that a third provider in OTSA 4 would likely reduce already relatively low volumes at the existing pediatric heart transplantation provides in OTSA 4.

Quality of Care:

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 transplant program. Demonstrated quality of care measures through numerous awards and recognitions are shown. 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, is accredited by The Joint Commission and is a quality provider.

Agency complaint records indicate that the parent's (MCHS's) sole hospital, NCH, had three substantiated complaints for the three-year period ending November 19, 2015.

Financial/Cost:

- Funding for this project and the entire capital budget should be available as needed
- This project appears to be financially feasible based on the low project cost and funding available to the applicant
- This project is not likely to have a material impact on competition to promote quality and cost-effectiveness

Medicaid/Indigent Care:

According to the Agency's 2014 FHURS Data Report, NCH provided 37.40 percent of its total annual patient days to Medicaid/Medicaid HMO patients and 0.05 percent to charity care patients in FY 2014.

The applicant participates in the LIP program and the DSH program. NCH's annual total LIP allocation for FY 2015-2016 was \$4,588,131, with a total allocation of \$1,147,034 as of December 10, 2015. For the same fiscal year, NCH's annual total DSH allocation was \$396,663, with a total allocation of \$98,440, as of the same date.

According to Schedule 7A, NCH intends to provide in the proposed pediatric heart transplantation program 63.0 percent Medicaid, 37.0 percent commercial insurance and 0.0 percent Self-Pay both in year one (ending June 30, 2018) and in year two (ending June 30, 2019), total annual patient days. For the proposed program for year three (ending June 30, 2020) NCH estimates 62.0 percent Medicaid, 38.0 percent commercial insurance and 0.0 percent Self-Pay, total annual patient days. The applicant does not offer charity care patient days allotted to the proposed program, according to Schedule 7A or the Schedule 7A notes.

NCH offers no Medicaid and no charity care patient day conditions regarding the proposed project.

G. RECOMMENDATION

Deny CON #10421.

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