

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

**A. PROJECT IDENTIFICATION**

**1. Applicant/CON Action Number**

**The Nemours Foundation  
d/b/a Nemours Children's Hospital/CON #10471**  
10140 Centurion Parkway North  
Jacksonville, Florida 32256

Authorized Representative: Deborah Platz, Esq.  
Enterprise Vice President &  
General Counsel  
(904) 587-4505

**2. Service District/Subdistrict**

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

**B. PUBLIC HEARING**

A public hearing was requested and held on behalf of Shands Teaching Hospital and Clinics, at 10:00 a.m., on Tuesday, January 10, 2017 at the Health Council of East Central Florida (HCECF), Inc., 5931 Brick Court, Suite 164, Winter Park, Florida 32792. The public hearing was conducted by the HCECF.

Below is a brief summary of the comments and presentations made by the speakers.

Nemours presented first, with Josh Wilson, Public and Community Relations Manager for Nemours introducing everyone. Dana Bledsoe, President of Nemours Children's Hospital in Orlando gave an overview of the history of Nemours and its journey in Florida.

Three mothers of pediatric patients spoke next. One mother spoke about the financial burdens associated with pediatric heart transplants, including bankruptcy. She also discussed the necessity to maintain as much normalcy and routine as possible when a health crisis strikes a family, including a strong support system that can only be found at home. Another mother spoke about her positive experience with Nemours and being part of its family advisory council—that Nemours allowed family’s enormous input on every aspect of the hospital. Another mother noted that the standard of care at Nemours is exceptional.

Marlin Hutchens, representing the American Heart Association, spoke supporting the proposed transplant programs. Speaking specifically about heart disease, he stated that in order to fight the disease more access points and research was needed, including an access point in Lake Nona. Marni Stahlman, President and CEO of Shepherd’s Hope in Orlando spoke next. Ms. Stahlman spoke about the health care crisis in Orange County, specifically that Florida ranks 40<sup>th</sup> out of 50 states for care of children and that there are 36,000 uninsured children in Orange County alone. She stated that Nemours assisted in providing staff (physicians) to perform 300 physicals to children in August allowing children to attend school.

David Odahowski, President and Chief Executive Officer of the Edyth Bush Charitable Foundation, stated that his foundation supports the proposed transplant programs and stated that his foundation was offering financial support of the programs as well. He stated that the foundation funds community health and supports increasing the level of care to the families and children of Central Florida.

Dr. Gul Dadlani, Chief of Pediatric Cardiology at Nemours, stated his appreciation for the significant interest in pediatric cardiology that was displayed by the attendance at the requested public hearing. He spoke specifically regarding access to services—and that Central Florida children don’t have access to pediatric transplant services in the region. He maintains that Nemours could provide the necessary access. Mr. John Rendle, Director of Ancillary Services at Nemours, spoke about Nemours’ commitment and concentration on patient-centered care. He noted that the hospital recently opened a comprehensive medical rehabilitation unit for pediatric patients. Mr. Rendle asserted that the proposed transplant programs would be successful.

Dr. Peter Wearden, a congenital cardiothoracic surgeon and department chair of the Division of Cardiovascular Surgery at Nemours, echoed Dr. Dadlani’s sentiment about the significant interest in pediatric

cardiology generated by the public hearing. He stated his belief that the applications for the proposed services were very strong. Dr. Wearden noted that the existing programs in Florida are quite accomplished but that families facing transplants have significant burdens (financial, social and psychological) that can be alleviated by having services closer to home within their support network. He noted that the proposed services would have an integrated practice unit with direct overlap of the personnel for the three proposed programs. He indicated that the pediatric cardiology program has been quite successful (64 open heart surgeries with no mortality). Dr. Wearden also noted that Nemours has the largest Cystic Fibrosis clinic in the State of Florida but one of the lowest rates for lung transplantation in the nation. He also indicated that organs are leaving the state for transplantation in other areas of the nation.

Another mother spoke of her experience with a diagnosis of a congenital heart condition. She spoke of the financial burdens for her family as well as the day-to-day hardships. She also spoke of her distressing experiences with how the diagnosis was delivered to her family. She fully supported Nemours proposed services.

Mr. Michael Glazer, Esquire, of Ausley McMullen spoke next in opposition of the proposed applications on behalf of UF Health Shands Hospital (Gainesville Florida—Alachua County) and Johns Hopkins All Children's Hospital (St. Petersburg Florida—Pinellas County). Mr. Glazer also submitted a written letter opposing the project by the Public Health Trust of Miami-Dade County as well as written materials from UF Health Shands Hospital and Johns Hopkins All Children's Hospital. Mr. Glazer presented some legal points on the merits of the application:

- The applicant does not meet the basic threshold requirements since the pediatric cardiac program was only implemented in June of 2016 even though their settlement agreement granting the Certificate of Need for pediatric cardiac services allowed services to begin as early as July 2014.
- Forecasted procedures are extremely aggressive and can only be achieved through cannibalization of existing programs including UF Health and Johns Hopkins All Children's.
- While the application cites several times that there are not pediatric transplant services in the service area, the applicant ignores the provision of 59C-1.008, Florida Administrative Code that states that the existence of unmet need will not be based solely on the absence of a health service.

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- Orange County residents are reasonably proximate to transplant services.
- Nemours is does not meet the requirements to be a teaching or research hospital.
- There are only 41 pediatric lung transplant programs in the nation, 36 states do not have any and Florida has two programs.
- The application is institution-specific not service area-specific.
- Approval of the three applications might actually limit accessibility and deny care to pediatric patients in the State of Florida.

Dr. Bill Pietra, Chief of Pediatric Cardiology at UF Health Shands, spoke next indicating that a particular volume of patients creates opportunities in quality and treatment for pediatric cardiology. He notes that as volumes fall, a program is less likely to transplant higher acuity patients as the risk for mortality increases significantly when a program has less than 10 transplant patients. In addition, Dr. Pietra maintained that the argument regarding access is false as technological improvements have succumbed to impediments in distance. Dr. Pietra also stated that congenital heart issues do not end at age 18 and programs with a full continuum of care (both pediatric and adult transplant programs) have better results.

Dr. Jeffrey Jacobs, thoracic and cardiac surgeon at Johns Hopkins All Children's Hospital, indicated that there is a documented relationship between outcomes and programmatic volumes for pediatric heart transplantation. He stated that no need for another program exists in the State of Florida. Dr. Jacobs maintained that another provider will have a negative impact (dilution) on existing providers which will prove ultimately harmful to the pediatric population. He maintains that low volume providers are risk adverse and less likely to transplant pediatric patients with high-risk profiles. Dr. Jacobs asserted that diluting volumes among an additional provider will limit access to high risk patients as well as limit the capacity to develop treatments at the existing providers.

Ms. Jennifer Rackley, a Pediatric Heart and Lung Coordinator and Registered Nurse at UF Health Shands, stated that outcomes at Shands are some of the best in the United States due to the volume of the program and that the patients have access to both pediatric and adult services as a pediatric matures to adulthood. She noted that transplants happen to the entire family not just the patient. Ms. Rackley concluded by stating that competition has the ability to hurt the quality of care for the pediatric population.

Dr. Jay Fricker, a pediatric cardiologist at UF Health Shands, spoke next and indicated that the relationship between volume and quality is so significant that UF Health Shands has had every transplant program in the state transfer patients to the facility. Dr. Fricker noted his belief that the application is premature, as Nemours has not yet met minimal standards that were set up by the now defunct Pediatric Cardiac Care Advisory Council within the Department of Health.

Mr. Phil Blank, Esquire, representing Orlando Health and Arnold Palmer Children's Hospital, spoke next. He stated that there is no compelling reason to approve the three applications and that the applicant does not meet the applicable statutory or rule criteria for new pediatric transplant programs. Further, Mr. Blank noted that the applicant does not present any information on why the Agency should waive the criteria for the minimum threshold for pediatric cardiac services identified in rule. Mr. Blank maintained that the applicant does not have an established research program under the rule criteria. Mr. Blank concluded by stating, "denying the applicant is the right thing to do, not the easy thing to do." Mr. Blank also submitted written opposition at the hearing on behalf of Orlando Health and Arnold Palmer Hospital for Children.

Dr. William DeCampi, a thoracic and cardiac surgeon associated with Arnold Palmer Hospital, spoke next indicating that Nemours has put together a good structure and processes but has not produced outcomes. Dr. DeCampi indicated that the application is premature and inappropriate—that the applicant must first demonstrate quality outcomes for its existing cardiac services before adding transplant services. He also cited the failure of pediatric cardiovascular services at St. Mary's Medical Center which resulted in pediatric mortality. Dr. DeCampi concluded by asserting that the proposed services were based on a hope and a projection of a successful program. Dr. Nykanen, a pediatric cardiologist associated with Orlando Health, echoed Dr. DeCampi's sentiments. He stated that he was concerned about the proposed program's sustainable outcomes. Dr. Nykanen also noted that there is a paucity of staffing resources for these programs which can affect volume and outcomes for transplant procedures. He maintained that it is not difficult to contact UF Health Shands staff and that the Shands program has no financial impediments and produces great outcomes. Dr. Nykanen concluded by noting that quality and mistakes are defined by the balance between access and outcomes.

Nemours presented a short rebuttal starting with Dr. Wearden who maintained that the application stands on its own merits and that volume data, the teaching requirement and the research requirement are addressed within the application. Dr. Wearden noted that incremental costs are also addressed within the application and that the proposed services are extensions of the existing programs. Dr. Wearden noted that in 2017, there is no learning curve and that we should not accept the status quo when it comes to the improvement of accessibility of care for pediatric patients and their families.

Steven Ecenia, Esquire of Rutledge-Ecenia representing Nemours spoke last. He stated that the application meets all the requirements for an application submitted under not normal circumstances. Mr. Ecenia maintained that the service area is desperately underserved with the closest program 88 miles away. In addition, Mr. Ecenia asserted that the opposition materials submitted do not contain any information that impugn the merits of the Nemours applications.

Mr. Ecenia contended he has never seen any evidence that dilution of procedures has had any effect on the quality of care at an existing health care provider. He also questioned the motivation of Orlando Health's involvement in the public hearing and suggested that UF Health Shands and Johns Hopkins All Children's are just "preserving their own self-interest without regard to the needs or wants of the residents of the service area." Mr. Ecenia concluded by stating that on balance the application meets all statutory criteria and that it would be shameful for the state to deny it.

### **Letters of Support**

The applicant includes 27 signed and three unsigned (a total of 30) unduplicated letters of support spread among CON application #10471. Of these 30 support letters, 25 are of an OTSA 3 origin, two originate from OTSA 1 and OTSA 2 (each) and one is from out-of-state (from the parent's facility in Wilmington, Delaware). The reviewer notes that these 30 support letters are duplicates of the 30 support letters included in co-batch companion **CON applications #10472 and #10473**. Also, the reviewer notes that of these 30 support letters, 10 are from area physicians, with eight of these indicating affiliation with the applicant. The reviewer further notes that the support letters are generally of a form letter variety though some have individually composed portions, many with some recurring themes, as briefly summarized below:

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- The new transplant programs at Nemours will fill a gap in the availability of pediatric organ transplant programs in central Florida, ensuring life-saving care for pediatric patients
- Increasing geographic access to care in central Florida will remove one less burden for families struggling with severe and/or terminal illnesses for their children, often too critically ill and too weak to travel to other hospitals to receive transplant services
- Residents of central Florida do not have access to pediatric heart, pediatric lung and pediatric heart/lung transplant services without the added burden of travel far outside of the Orlando region
- The proposals will give the community the best quality of care while alleviating geographic or financial barriers of families in desperate need of transplant services
- Nemours has an excellent track record of providing quality and financially accessible health care services to Orlando, central Florida and the entire state
- Nemours Children's Hospital in Orlando will utilize the resources of its affiliate (Nemours Alfred I. DuPont Hospital for Children in Delaware) to fully implement the proposed transplantation programs
- Nemours Children's Hospital currently meets the operational standards for transplant procedures and has many experienced physicians and staff already available to provide care to these critical children
- There is a great need for this service in the region
- Currently there are close to 40 pediatric patients waiting for the respective transplants in the State of Florida yet there are very few pediatric heart, lung and heart/lung transplant programs in Florida and none in Nemours' OTSA
- The heart, lung and heart/lung transplant programs will be seamlessly incorporated into the existing Nemours Children's Hospital in Lake Nona
- Resources at UF Health Shands Hospital (OTSA 1) are extended. Their wait times are long and pediatric cardiac intensive care unit (PCICU) is typically at admission capacity

Some support letters are noted from the following, indicating an OTSA 3 origin unless otherwise indicated):

- Victor M. Torres, Jr. (15th District), State Senator, The Florida Senate
- Jason Brodeur (District 28) and Rene "Coach P" Plasencia (District 50), State Representatives, The Florida House of Representatives
- Orange County Public Schools - Superintendent

- Orange County Board of County Commissioners
  - Orange County Mayor
  - Commissioner, District 4
- City of Orlando
  - Commissioner, District 1
  - Orlando Fire Chief
- Florida Department of Health
  - Administrator, Health Officer in Brevard County
  - Health Office and Director in Orange County
  - Acting Health Officer in Seminole County
- U. S. Department of Veterans Affairs, VA Medical Center-Orlando, Medical Center Director
- University of Central Florida, Vice President for Medical Affairs and Dean, College of Medicine
- American Heart Association/Greater Orlando-Senior Vice President, Central Region
- Tavistock Group, Senior Managing Director
- HCA – North Florida Division/Regional Vice President-Orlando Market (OTSA 1)
- Wolfson Children’s Hospital, Hospital President (OTSA 1)
- Lakeland Regional Health, Executive Vice President/Chief Operating Officer (OTSA 2)

The reviewer notes that CON application #10471 provides excerpts of seven letters of support.

### **Letters of Opposition**

There were no letters of opposition received by the Agency as of the omissions deadline date.

## **C. PROJECT SUMMARY**

**The Nemours Foundation d/b/a Nemours Children’s Hospital (CON application #10471)** also referenced as NCH or the applicant, a not-for-profit Class 2 hospital, affiliated with Nemours Children’s Health System (NCHS), proposes to establish a new pediatric heart transplantation program at NCH, 13535 Nemours Parkway, Orlando, Florida 32827, Orange County, OTSA 3. The parent, NCHS, headquartered in Jacksonville, Florida operates one hospital in Florida and one hospital in Wilmington, Delaware. NCHS offers pediatric only health services and spans five states – Delaware, Pennsylvania, New Jersey, Maryland and Florida.

According to NCHS, “No better setting could be found than a well capitalized, with a mission limited to pediatric health care, existing experience in pediatric transplantation, a long standing history in the local area and state and a new state of the art, nationally recognized hospital to offer these critically needed high acuity services to the children of this region of Florida”.

In this same batching cycle, NCH also submits applications for a new pediatric heart and lung transplantation program (**CON application #10472**) and a new pediatric lung transplantation program (**CON application #10473**).

Nemours Children’s Hospital is a 100-bed specialty hospital, licensed for 90 acute care beds, two Level II neonatal intensive care unit (NICU) beds and eight Level III NICU beds. NCH has the following non-operational but CON approved pediatric programs (listed from most recently to least recently approved):

- CON #10167 – nine-bed comprehensive medical rehabilitation (CMR) unit
- Exemption (E)#120009 – 10-bed child/adolescent psychiatric unit

NCH does not have statutory teaching hospital designation and is not currently CON approved for any inpatient transplantation services.

Project costs total \$715,425. These costs include equipment, project development and start-up costs. Notes to Schedule 1 of this application indicate that costs shown on Schedule 1 for each of the co-batched/companion applications (**CON applications #10471, #10472 and #10473**) are duplicative and mutually exclusive. The notes further indicate that the costs cover the development of the proposed thoracic transplant program and no additional costs will be incurred should the Agency approve one, two or all three of the simultaneously filed applications. There is no reported construction or renovation associated with the project.

The proposed pediatric heart transplantation program, if approved, is expected to be licensed on February 17, 2017, with initiation of service on January 1, 2018. The Agency notes that pursuant to Rule 59C-1.010(5)(a), Florida Administrative Code, the Agency shall publish its notice of intent. Pursuant to Rule 59C-1.010(5)(b), Florida Administrative Code, if there is no challenge to all or any part of the Agency decision

embodied in the State Agency Action Report within 21 days after the publication of the notice of intent, consistent with Rule 59C-1.012, Florida Administrative Code, the State Agency Action Report shall become the final order of the Agency. The review notes that the required timeframes, as described above, do not allow for licensure as of February 17, 2017.

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

- The Nemours Foundation d/b/a Nemours Children's Hospital conditions this application on the development of a comprehensive pediatric thoracic transplantation program including heart, lung, and heart and lung transplantation. This condition will be measured by a Nemours Children's Hospital Transplantation Committee report submitted annual to AHCA upon initiation of the program.

The Agency notes that the above condition is identical to the condition proposed for co-batched/companion **CON applications #10472 and #10473**.

NOTE: Should the project be approved the applicant's condition(s) 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. The reviewer notes that pursuant to 59C-1.008 (2) (e) 3.—the existence of unmet need will not be based solely on the absence of a health service, health care facility, or beds in the district, subdistrict, region or proposed service area.

OTSA 3 has not CON approved or operational pediatric heart transplant program. OTSA 1 and OTSA 2 each have one pediatric heart transplantation program and OTSA 4 has two pediatric heart transplantation programs. Data reported to the Agency by the local health councils for the 12 months ending June 30, 2016 show the following pediatric heart transplant utilization, by facility, service area and district:

Florida Pediatric Heart Transplantation Program Utilization July 2015 – June 2016			
Hospital	Service Area	District	Total Procedures
UF Health Shands Hospital	1	3	12
Johns Hopkins All Children’s Hospital	2	5	9
Memorial Regional Hospital	4	10	11
Jackson Memorial Hospital	4	11	3
<b>TOTAL</b>			<b>35</b>

Source: Florida Pediatric Organ Transplantation Program Utilization data published September 30, 2016

As shown in the table above, for the 12 months ending June 30, 2016, UF Health Shands Hospital (Alachua County) provided 12 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, 2016.

Florida Pediatric Heart Transplantation Utilization 12-Month Reporting Periods Ending June 30, 2012 to June 30, 2016								
Service Area	County	Facility	12-Month Reporting Periods July 1 to June 30					Total
			2012	2013	2014	2015	2016	
1	Alachua	UF Health Shands Hospital	7	13	4	17	12	<b>53</b>
2	Pinellas	Johns Hopkins All Children’s Hospital	4	6	13	10	9	<b>42</b>
4	Broward	Memorial Regional Hospital	2	5	3	4	11	<b>25</b>
4	Miami-Dade	Jackson Memorial Hospital	3	1	2	1	3	<b>10</b>
<b>Total</b>			<b>16</b>	<b>25</b>	<b>22</b>	<b>32</b>	<b>35</b>	<b>130</b>

Source: Florida Need Projections Utilization Data for Adult and Pediatric Transplant Programs issued September 2012 – September 2016

During the five-year period, OTSA 4 providers, in aggregate, had the lowest volume of pediatric heart transplants (35 procedures or 26.92 percent), OTSA 2 had the second highest volume (42 procedures or 32.31 percent) and OTSA 1 had the highest volume (53 procedures or 40.77 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 list<sup>1</sup>. See the organ by waiting timetable below.

<sup>1</sup> As of December 2, 2016 per the OPTN website @ <http://optn.transplant.hrsa.gov>. The age range for this data base is 0-17 years.

**Organ Procurement and Transplantation Network (OPTN)  
Current Florida Wait List Registrants  
Based on OPTN Data as of December 8, 2016**

	<b>Heart</b>
Total	36
< 30 Days	4
30 to < 90 Days	8
90 Days to < 6 Months	9
6 Months to < 1 Year	3
1 Year to < 2 Years	0
2 Years to < 3 Years	5
3 Years to < 5 Years	3
5 or More Years	4

Source: <https://optn.transplant.hrsa.gov/data/view-data-reports/state-data/> on December 8, 2016

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.

**Florida Pediatric Heart Donors Recovered  
January 1, 2011-December 31, 2015  
Based on OPTN Data as of December 2, 2016**

<b>Pediatric</b>	<b>2016*</b>	<b>2015</b>	<b>2014</b>	<b>2013</b>	<b>2012</b>	<b>2011</b>
All Donor Types	26	33	38	45	33	36
Deceased Donor	26	33	38	45	33	36
Living Donor	0	0	0	0	0	0

Source: <https://optn.transplant.hrsa.gov/data/view-data-reports/state-data/> on December 8, 2016

Note: \* For 2016, January 1 through October 31, 2016

As shown above, there were 33 Florida pediatric heart donors in 2015. Florida Center for Health Information and Transparency data indicates there were a total of 30 pediatric heart transplants and 11 pediatric heart implant assist device procedures performed at Florida hospitals for the 12 months ending June 30, 2016. 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, 2016. The reviewer notes that this comparison contemplates two different timeframes, one being fiscal year (FY) and one being CY.

Agency data indicates that all 30 of the pediatric patients (under 15 years of age) receiving heart transplants performed in Florida in the 12 months ending June 30, 2016 were Florida residents<sup>2</sup>. OTSA 3 residents accounted for five of the 30 procedures, or 16.67 percent. Below is a chart to account for these totals.

<sup>2</sup> There were 35 total pediatric heart transplant procedures reported to the local health councils for the 12 months ending June 30, 2016. Some variation in the patient data is to be expected.

**Pediatric Heart Transplants at Florida Hospitals  
by Patient Residence  
12 Months Ending June 30, 2016**

<b>Service Area</b>	<b>Transplants Performed</b>	<b>Percent of Total</b>
1	9	30.00%
2	8	26.67%
3	5	16.67%
4	8	26.67%
Unknown	0	0.00%
<b>Total</b>	<b>30</b>	<b>100.0%</b>

Source: Florida Center for Health Information and Transparency database for 12 months ending June 30, 2016. MS-DRGs 001 and 002 (excluding heart implant assist devices). In this table, the Agency rounded to the nearest 1/10<sup>th</sup> of one percent to attain a 100.0 percent total

The Agency notes that OTSA 3 residents had the fewest pediatric heart transplant procedures of any OTSA in Florida and migrated at a rate of 100.0 percent beyond their home service area for the 12 months ending June 30, 2016. This out-migration would be due to the fact there is no pediatric heart transplantation provider in OTSA 3.

The reviewer notes that for the 12 months ending June 30, 2016, OTSA 3 residents presented the lowest demand for pediatric heart transplantation of any OTSA, according to Agency inpatient discharge data. Local health council data for the five-year period ending June 30, 2016 indicates that procedures have generally trended upward, overall, statewide. The reviewer notes that for the five-year period ending June 30, 2016, statewide, local health council data indicates that pediatric heart transplant procedures increase a low of 16 (12 months ending June 30, 2012) to a high of 35 (12 months ending June 30, 2016). Again, due to no pediatric heart transplantation provider being in OTSA 3, there is no OTSA 3 pediatric heart transplantation provider volume trending data to consider, as any residents would be required to out-migrate for this service and no residents would in-migrate to OTSA 3 for the same reason. The reviewer notes that considering there is no CON approved or authorized pediatric heart transplantation provider in OTSA 3, no OTSA 3 pediatric heart transplantation provider volume could be adversely impacted by approval of the proposed project.

The Agency notes that for the five-year period ending June 30, 2016, the implantation of pediatric heart assist devices has had a decreasing impact on pediatric heart transplantation volume. For the 12 months ending June 30, 2012, statewide, pediatric heart assist devices accounted for 52.94 percent (nine of 17 procedures) of total pediatric heart transplant/assist discharges. For the 12 months ending June 30, 2016,

statewide, pediatric heart assist devices accounted for 33.33 percent (10 of 30 procedures) of total pediatric heart transplant/assist discharges. The data does not indicate a correlation that pediatric heart assist device implantation procedures have reduced or lessened the rise in pediatric heart transplantations.

The chart below overall trends relatively constant for pediatric heart assist procedures compared to a rising pediatric heart transplant volume, statewide, for the five-year period ending June 30, 2016. 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, 2016.

**Pediatric Heart Transplant and Pediatric Heart Assist Implant Discharges  
All Florida Hospitals  
Five Years Ending June 30, 2016**

<b><i>Year Ending June 30</i></b>	<b><i>Pediatric Heart Transplants</i></b>	<b><i>Pediatric Heart Assist</i></b>	<b><i>Total Pediatric Heart Transplant/ Assist Discharges</i></b>
<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>
<i>2016</i>	<i>30</i>	<i>10</i>	<i>40</i>

Source: Florida Center for Health Information and Policy Transparency 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 for the period from July 1, 2011 through December 31, 2015. These ICD-9 codes changed to 02HA0QZ, 02HA0RS, 02HA0RZ, 02HA3QZ, 02HA3RS, 02HA3RZ, 02HA4QZ, 02HA4RS and 02HA4RZ, effective January 1, 2016 and were therefore effective for six months of this five-year review period (January 1, 2016 to June 30, 2016). These code conversions occurring in the beginning of CY 2016 could have slightly impacted the pediatric heart transplant and the pediatric heart assist implantation totals for the 12-months ending June 30, 2016

The Agency notes that while percentage increases may appear substantial, total procedures per year have been relatively modest overall, particularly for pediatric heart assist procedures. The highest year-over-year increase in the five-year period was a rise of 14 pediatric heart transplantation procedures (statewide) for the 12 months ending June 30, 2015. The highest year-over-year increase in the five-year period was a rise of four pediatric heart assist implant procedures (statewide) for the same 12-month period (ending June 30, 2015).

NCH contends it has taken a novel approach to development of a comprehensive thoracic transplant program by combining three types of transplants in one program. NCH also maintains that, from a clinical and operational standpoint, it makes sense to combine these programs from the following reasons:

- Overlapping diagnoses result in the need for these organs to be transplanted
- The same clinical and medical staff are required to perform and support transplant of these organs
- The same facilities and equipment are needed to support transplant of these organs before, during and after transplant
- Performing multiple organ transplant types increases case volume and therefore:
  - Viability and quality of the program
  - Efficiently uses costs resources
- Performing multiple organ transplant types increases community outreach and education for more patients with related diagnoses

NCH contends that unique features of NCH enhance the rationale for developing and operating three transplant types together including:

- NCH's Integrated Case Model is established with a configuration of resources where all three proposed types of transplant would occur within the same clinical department.
- NCH already has in place and/or is currently recruiting the vast majority of needed clinical expertise to the clinical department that will provide these transplant services.
- NCH has the resources through The Nemours Foundation to support the development of the program and the ongoing operation of the multi-organ transplant program (typically financially draining to most hospitals).
- With the exception of the transplant cardiologist (heart) and transplant pulmonologist (lung), there is direct clinical overlap of all clinical professionals caring for the patients. This includes the surgical and OR team, the anesthesia team, the ICU team and all other ancillary teams included but not limited to: respiratory therapy, social work, child life, physical/occupational therapy, psychology and pharmacy. There is also direct overlap, with the exception of the modality of biopsy, in the diagnosis and management of rejection. The infrastructure for the management of transplant programs in terms of organ procurement coordination and meeting all state, federal and insurer regulatory requirements are identical.

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- All patients and their treatment plans will be discussed at a weekly multi-disciplinary care conference. This conference will be attended by surgeons, cardiologists, pulmonologists, psychologists, pharmacists and transplant coordinators amongst others. The overlap between specialists and the interaction between the heart and lung at health and in the disease state is a preferable way to approach discussion of these patients. Additionally, the expertise of the transplant cardiologist and transplant pulmonologist are directly transportable to each other's patient particularly in the areas of post-operative management, treatment of immune suppression and rejection. Heart/lung transplantation by necessity requires both specialists.
- With the economy of resources and the improvement of care in such a multidisciplinary approach, it is only logical for a center with the financial and human capacity to transplant both heart and lungs to not offer the three programs that would truly be a benefit to pediatric patients in the region.

NCH asserts that the development of the proposed comprehensive thoracic transplant program is a natural progression for NCH's existing resources and the next step in NCH meeting its development goals to become a world-class pediatric hospital, with a top tier pediatric and congenital cardiothoracic program. NCH additionally asserts to complement the cardiac and pulmonary services already operating both in Orlando and at its other centers throughout Florida.

According to NCH, certain "not normal" circumstances affect **CON application #10471** which are offered below:

- Florida does not have an approved pediatric heart/lung transplant program in the state.
- Florida's only two approved pediatric lung transplant programs have not performed any lung transplants in the last two reporting years.
- There are no pediatric heart transplant or lung transplant programs in OTSA 3 where NCH is located.
- Florida has no other comprehensive, multi-organ thoracic transplant program for pediatric patients.
- Florida has no other pediatric comprehensive, multi-organ thoracic transplant program that is part of an integrated delivery system such as Nemours offers.
- NCH will offer a unique, dedicated model of cardiothoracic care – a model developed at Nemours' Alfred I. Dupont Hospital for Children in Wilmington, Delaware. The key and unique element of this Model of Care is a unified team of cardiac clinical and administrative

professionals who serve children with cardiac problems in dedicated facilities (the “Cardiac Team”). The Cardiac Team only cares for children with cardiac diagnoses. As such, the Cardiac Team of anesthesiologists, surgeons, cardiologists, nurses and other support personnel do not “float” to other hospital floors or departments as in a typical hospital setting. The dedicated model of cardiac care allows the Cardiac Team to develop highly specialized knowledge and relationships to provide the best treatment protocols for patients with cardiac conditions. Again, NCH and Nemours will bring this unique, dedicated model to the new proposed transplantation program.

- NCH has developed state-of-the-art facilities and innovative clinical pathways for the care of the most complex pediatric thoracic patients.
- NCH has already and will continue to bring new opportunities for research in pediatric cardiology, cardiac surgery and pulmonary medicine particularly clinical translational and basic research into the relationships between childhood obesity and cardiac conditions.
- Nemours operates a regional network of clinics in Florida with primary locations in Pensacola, Jacksonville and Orlando that will operate in partnership with NCH for the appropriate regional referral of patients in Florida for pediatric cardiothoracic care.
- NCH can reduce the out-migration of pediatric thoracic transplant patients from the Orlando area to other parts of the State as well as the out-migration of these patients to other out-of-state transplant programs. Similarly, NCH will reduce the out-migration of organs donated in Florida to other states ensuring that Florida recipient patients are first priority for organs donated in Florida.
- NCH has in place the infrastructure, facilities and resources to seamlessly add thoracic transplant services to its existing comprehensive cardiac surgery program. Additional staff are already being recruited to this program. As a result, the project will require minimal incremental capital costs. Total project costs are therefore estimated to be \$715,425.

Using the Florida Population Estimates and Projections by District 2010-2030 (issued February 2015), NHC indicates that the pediatric population (under age 15) in OTSA 3 is projected to grow from 718,958 in 2016 to 768,532 in 2021 (6.9 percent). The applicant maintains that this same population is expected to grow at a faster rate than the State as a whole (4.39 percent). See the exhibit below.

**Nemours Children’s Hospital  
Pediatric Population (Under 15) for OTSA 3 / 2016-2021**

Area	2016	2021	Percent Change
Brevard	86,765	88,956	2.53%
Indian River	21,299	22,023	3.40%
Lake	53,633	57,379	6.98%
Martin	20,261	20,178	-0.41%
Okeechobee	7,815	7,661	-1.97%
Orange	252,247	276,944	9.79%
Osceola	65,286	73,457	12.52%
Seminole	79,383	83,250	4.87%
St. Lucie	54,461	59,195	8.69%
Volusia	77,808	79,489	2.16%
<b>OTSA 3 Total</b>	<b>718,958</b>	<b>768,532</b>	<b>6.90%</b>
State Total	3,444,040	3,595,389	4.39%

Source: CON application #10471, Vol. I, page 71, Exhibit 13

Using Agency inpatient hospital database records (2014-2015) and Winstat 2013 (according to <http://www.winstat.com/>, WinSTAT® is the statistics Add-In for Microsoft® Excel), NCH states that there were six to eight pediatric residents of OTSA 3 that received heart transplants between 2013 and 2015 at Florida hospitals. See the exhibit below.

**Nemours Children’s Hospital  
Pediatric (0-14) Heart Transplant from OTSA 3  
2013-2015**

County	2013	2014	2015
Brevard	2	2	0
Indian River	0	1	0
Lake	0	0	2
Martin	0	0	0
Okeechobee	0	0	0
Orange	2	3	1
Osceola	0	2	1
Seminole	0	0	0
St. Lucie	1	0	1
Volusia	1	0	3
<b>Total</b>	<b>6</b>	<b>8</b>	<b>8</b>

Source: CON application #10471, Vol. I, page 101, Exhibit 37

NCH contends and the Agency concurs that patients seeking pediatric heart transplantation in OTSA 3 have no choice but to travel distances to access other Florida heart transplant programs. NCH points out that this incurs more costs and stress to families of the pediatric transplant patients.

The applicant discusses that congenital heart defect (CHD) and dilated cardio myopathy (DCM) are the two most common diagnoses resulting in pediatric heart transplant patients and the age ranges with which CHD and DCM commonly occur. The applicant also discusses some historical pediatric heart transplantation data in Florida. The applicant also

discusses national heart transplantation data, the total number of hearts recovered, the total registrations in Florida and the total transplants in Florida (2013-2016). NCH stresses that using UNOS OPTN Data as of November 18, 2016, from 2013 to 2016, there are significant numbers of donated pediatric hearts from Florida that are either being used out-of-state or not being used at all for patient transplantation. NCH emphasizes that only 33 of the 190 recovered hearts were transplanted in Florida to pediatric patients or just 17.3 percent (of total recovered hearts), with 157 either not used or used out-of-state. NCH contends that the proposed project will help ensure that Florida patients are making the best use of hearts donated by residents of Florida by providing greater outreach and education. See the exhibit below.

**Nemours Children's Hospital  
Use of Pediatric (0-14) Hearts Recovered for Transplant in Florida / 2013-2016**

	Organ Recovery				Hearts Not Used or Used Out-of-State
	Number of Hearts Recovered	Pediatric (0-14) Transplants in Florida	Transplants Outside of Florida	Total Hearts Transplanted	
2013	64	6	26	32	58
2014	46	10	13	23	36
2015	44	8	14	22	36
2016	36	9	9	18	27
<b>Total</b>	<b>190</b>	<b>33</b>	<b>62</b>	<b>95</b>	<b>157</b>

Source: CON application #10471, Vol. I, page 100, Exhibit 36

NCH further stresses that using a Scientific Registry of Transplant Recipients (SRTR), TransLife 2015 Report, from January 1, 2014 to December 31, 2015, TransLife's region realized 47 heart transplants but expected 58 (CON application #10471, Vol. I, page 102, Exhibit 39). Per NCH, comparatively, in 2015, 120 hearts were authorized for donation, 39 were recovered and only 26 were transplanted (CON application #10471, Vol. I., page 103, Exhibit 40). NCH contends that most importantly, close to half of the recovered hearts in TransLife's counties were relocated out-of-state and out-of-transplant region rather than matched with one of the many patients in need within Florida.

According to NCH, based on national use rates and Florida pediatric population estimates, as well as availability of donor organs in-state, the applicant projects to perform four heart transplant in the first year of operation (2018) and eight in the second year (2019). NCH maintains that these projections assume that a greater number of local patients in OTSA 3 will register for transplantation when given access at NCH and that some patients currently registering in other parts of Florida or out-of-state would register closer to home. See the Exhibit below.

**Nemours Children’s Hospital  
Projected NCH Heart Transplants**

	Year One - 2018	Year Two - 2019
Statewide Use Rate (2013-2016)	7.00	
Highest OTSA Use Rate (2013-2016)		9.24
OTSA Population (0-14)	738,323	748,200
Projected OTSA 3 Demand	5.17	6.91
Projected NCH Capture of OTSA 3	3	6
Additional Florida Cases	1	1
Out of State Cases	0	1
<b>Total NCH Heart Transplants</b>	<b>4</b>	<b>8</b>

Source: CON application #10471, Vol. I, page 105, Exhibit 42

The applicant provides the diagnostic groups that will be served by the proposed program. See the table below.

**Nemours Children’s Hospital  
Typical Clinical Diagnoses for Transplants**

Heart	Lung	Heart/Lung
Cardiomyopathy	Cystic Fibrosis	Eisenmenger’s Syndrome
Congenital Heart Disease	Idiopathic PulmonaryFibrosis	Congenital Heart Disease
Coronary Artery Disease	Idiopathic Pulmonary Hypertension	Pulmonary Fibrosis
Ehlers Danlos Syndrome	Alpha-1-Antitrypsin Deficiency	Pulmonary Hypertension
Pulmonic Stenosis	Inhalation Burns/Trauma	Transplant failure/rejection
Valvular Heart Disease	Transplant failure/rejection	
Transplant failure/rejection		

Source: CON application #10471, Vol. I, page 46, Exhibit 9

- 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 it will have all of the resources necessary for the provision of proposed comprehensive thoracic transplant services. NCH highlights Michael A. Bingler, MD, FACCE, FSCAI, Director, Interventional Cardiology and Gul H. Dadlani, MD, Division Chief, Pediatric Cardiology.

On January 11, 2017, the reviewer notes that according to the website: [http://findaprovider.nemours.org/?FreeText:Doctors name=Bingler](http://findaprovider.nemours.org/?FreeText:Doctors%20name=Bingler) and the website: [http://findaprovider.nemours.org/?FreeText:Doctors name=Dadlani](http://findaprovider.nemours.org/?FreeText:Doctors%20name=Dadlani), Dr. Bingler and Dr. Dadlani, respectively, are on staff at the applicant's address.

CON application #10471, Vol. I, Attachment G includes a curriculum vitae (CV) for both Dr. Bingler and Dr. Dadlani. According to his CV, Dr. Bingler is certified by the American Board of Pediatrics and is subspecialty boarded in Pediatric Cardiology. According to his CV, Dr. Dadlani is certified by the American Board of Pediatrics, with a Pediatric Cardiology subspecialty.

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

NCH indicates that Steve Lichtenstein, MD, CCM, Chief, Cardiac Anesthesiology, is available to serve as anesthesiologist for all transplantation procedures. NCH also indicates that Dr. Lichtenstein has experience with both pediatric open heart surgery and heart/lung transplantation. NCH states that it is in the process of hiring additional similarly qualified anesthesiologists to supplement the Cardiac Center staffing.

On January 11, 2017, the reviewer notes that according to the website: [http://findaprovider.nemours.org/?FreeText:Doctors name=Lichtenstein](http://findaprovider.nemours.org/?FreeText:Doctors%20name=Lichtenstein), Dr. Lichtenstein is on staff at the applicant's address.

CON application #10471, Vol. I, Attachment G includes a CV for Dr. Lichtenstein. According to his CV, Dr. Lichtenstein is certified by the American Board of Anesthesiology and among other affiliations and associations was former Director of Cardiovascular and Transplant Anesthesiology, Children's Hospital of Wisconsin.

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

NCH discusses its cardiac ICU (CICU) and states having eight patient rooms with seven private and one semi-private, totaling a nine-bed capacity. NCH maintains that the CICU is located one floor above the Perioperative Suite and has a negative pressure isolation room and a positive pressure room on opposite sides of the

unit. According to the applicant, the inpatient rooms that comprise the CICU were part of the original hospital construction completed in 2012 and are designed to be operationally flexible for patient acuity. Architectural details are provided (CON application #10471, Vol. II, Attachment T).

**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 applicant states that this criterion is not applicable. NCH further states that this standard does not specifically reference pediatric heart transplant programs and is therefore not applicable nor is this standard reasonable for a pediatric heart transplant program.

The Agency notes that as previously stated, there are currently no OTSA 3 pediatric heart transplantation providers and hence, no OTSA 3 providers that have 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, 2016. As stated previously, for the 12 months ending June 30, 2016, of the statewide total of 30 pediatric heart transplants performed, the OTSA with the fewest number of residents receiving this procedure (five of 30 or 16.67 percent) was OTSA 3 residents.

NCH contends that the criterion is not consonant with recent research and professional practices regarding pediatric heart transplantation and was developed at a time when the limited experience with pediatric heart transplantation dictated higher volumes. NCH also contends that according to the International Society of Heart and Lung Transplant (ISHLT), the vast majority (73 percent) of the 186 pediatric heart transplant programs worldwide only perform an average of one to four procedures per year

(CON application #10471, Vol. 1, page 129, Exhibit 47). According to NCH, only a few pediatric heart transplant centers in the world would meet this standard for providing 24 heart transplants per year.

- (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.**

NCH states that this standard does not specifically reference pediatric heart transplant programs, nor is it reasonable for a pediatric heart transplant program. The applicant contends that while a projection of 12 heart transplants in program year two may be reasonable for an adult program, this is not reasonable for a pediatric heart transplantation program.

The applicant provides an exhibit to estimate a total of four pediatric heart transplantations in year one (2018) rising to eight by year two (2019), with a total of 12 pediatric thoracic transplants annually by year two. The reviewer provides an asterisk for each separately submitted proposal among the co-batched/companion applications.

**Nemours Children’s Hospital  
NCH Projected Transplant Volume**

	<b>Year One</b>	<b>Year Two</b>
Pediatric Heart Transplant*	4	8
Pediatric Lung Transplant**	2	3
Pediatric Heart/Lung Transplant***	1	1
Total Thoracic Transplants	7	12

Source: CON application #10472, Vol. I, page 110, Exhibit 46

NOTE: \* CON application #10471

\*\* CON application #10473

\*\*\* CON application #10472

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

NCH concedes that it does not yet meet these volumes noted since the inception of its cardiac surgery program and cardiac catheterization. However, the applicant states that these programs are well on their way to meeting this volume within a reasonable time from start-up of this program. NCH discusses cardiac catheterizations performed from July 2016 through November 2016 and that NCH is expected to exceed 200 cardiac catheterization procedures for CY 2017.

NCH discusses pediatric cardiac catheterizations cases by Florida hospitals from July 1, 2015 to June 30, 2016. Using the Agency's Florida Need Projections for Pediatric Open Heart Surgery Programs and Pediatric Cardiac Catheterization, issued September 30, 2016, the applicant points out that both UF Health Shands Hospital and Memorial Regional Hospital provided far less than the minimum of 200 cardiac cases. The applicant also comments that this is particularly notable for Shands as the largest volume provider of heart transplantation and in addition, that Jackson is notably the lowest volume pediatric heart transplant provider in the state. NCH asserts that this would therefore not correlate between cardiac catheterization volume and heart transplant volume nor is it necessarily true that cardiac catheterization volume is an indicator of quality outcomes for heart transplantation. See the exhibit below.

**Nemours Children's Hospital  
Pediatric Cardiac Catheterization Cases by Hospital**

<b>Hospital</b>	<b>Cases</b>
Nicklaus Children's Hospital	475
Baptist Medical Center Jacksonville/UF Health Jacksonville	298
Johns Hopkins All Children's Hospital	250
Jackson Memorial Hospital	224
Florida Hospital	211
Arnold Palmer Medical Center	201
UF Health Shands Hospital	145
Memorial Regional Hospital	141
St. Joseph's Hospital	3
<b>Total</b>	<b>1948</b>

Source: CON application #10471, page 132, Exhibit 49

The reviewer confirms that the case totals in the exhibit above are consistent with the stated Agency publication.

NCH indicates from June through November 2016, NCH performed 57 open heart surgery procedures, which equates to 114 procedures on an annualized basis. Per NCH, this first six-month period includes the start-up period. Similar to the applicant's comment

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previously about being on pace to exceed 200 cardiac catheterization procedures for CY 2017, the applicant states being on a pace to exceed 125 open heart surgery procedures for CY 2017.

NCH discusses pediatric heart transplant cases by Florida hospitals from July 1, 2015 to June 30, 2016. Using the Agency’s Florida Need Projections for Pediatric Open Heart Surgery Programs and Pediatric Cardiac Catheterization, issued September 30, 2016, the applicant comments that Jackson only performed 49 pediatric open heart surgery cases, “far below” the required 125 caseload. NCH also comments that All Children’s and Shands exceeded the 125 caseload by two and 10 cases during the reporting year. The applicant points out that these two facilities are the highest volume heart transplant providers in the state. Additionally, NCH comments that Memorial performed 147 pediatric open heart surgery cases but is the second lowest volume provider of heart transplantation. NCH asserts that there is, therefore, not a correlation between open heart surgery volume and heart transplant volume nor would it appear that open heart surgery volume is necessarily an indicator of quality outcomes for heart transplantation. See the exhibit below.

**Nemours Children’s Hospital  
Pediatric Open Heart Surgery Caseload by Provider**

<b>Hospital</b>	<b>Cases</b>
Nicklaus Children’s Hospital	193
St. Joseph’s Hospital	159
Memorial Regional Hospital	147
Florida Hospital	138
UF Health Shands Hospital	137
Johns Hopkins All Children’s Hospital	127
Baptist Medical Center Jacksonville/UF Health Jacksonville	119
Arnold Palmer Medical Center	110
Jackson Memorial Hospital	49
<b>Total</b>	<b>1,179</b>

Source: CON application #10471, page 133, Exhibit 50

The reviewer confirms that the case totals in the exhibit above are consistent with the stated Agency publication.

NCH requests that the Agency consider the following “not normal” circumstances regarding the proposed project in consideration of this criterion:

- There is no pediatric heart transplant program in OTSA 3
- OTSA pediatric population growth is faster than the State of Florida

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- Patients and their families from OTSA 3 that are in need of heart transplant must travel significant distances and often relocate to other cities pre-, during and post-transplant which is a significant cost burden and additional stress during a difficult time
- Without local access to a pediatric heart transplant program, there may be patients in need of transplantation that are reluctant to register for such care given the burden of travel
- There is a net export of donated pediatric hearts from the State of Florida
- NCH will offer a unique comprehensive thoracic transplantation program that will combine the services of heart transplantation with lung and heart/lung transplantation, which would be the only program of its kind in Florida
- There are no similar volume rules for lung and heart/lung transplantation
- Pediatric cardiac programs always have significantly lower surgical and catheterization volumes than adult cardiac catheterization programs
- NCH is a mission driven organization that has consistently developed novel approaches to pediatric care in Florida working toward the goal of bringing a top tier, world-class dedicated pediatric hospital to Florida
- There is no correlation between the volume experience or quality outcomes of existing pediatric heart transplant programs and the arbitrary minimum open heart surgery and cardiac catheterization caseloads prescribed in this rule

The reviewer notes that the “not normal” circumstances provided above differ from the previously stated “not normal” circumstances (CON application #10471, Vol. I, pages five and six and pages 67 and 68) and differ also from the unique features provided to justify the proposed project (CON application #10471, Vol. I, pages 51 and 52). The reviewer also notes that while the applicant provides justification for why this criterion has not been met and presents not normal circumstances for consideration, the criterion has not been met.

c. **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 that it has a comprehensive team of providers/ specialists who can care for pediatric transplant patients and their families on a 24-hour basis. NCH also states being already committed to an integrated approach to medical care and this commitment extends to these transplant services and will include care prior to, during and after transplantation as well as outpatient care.

NCH discusses its Department of Cardiovascular Services, its Cardiac Care Service Line, its CICU, the Pediatric Transplant Team and related pediatric transplantation topics (CON application #10471, Vol. I, pages 116 through 118).

- (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 a relationship between Nemours and TransLife has been established which will provide NCH acquisition, management and the appropriate handling of organs for transplantation.

NCH provides a letter of support for all three co-batched/ companion applications from David DeStefano, Executive Director, TransLife Organ & Tissue Donation Services (CON application #10471, Vol. II, Attachment I). This support letter states that TransLife agrees to work with Nemours to develop systems to facilitate the transplanted gift, including those set forth by the Agency regarding organ procurement and transplantation, pursuant to Rule 59C-1.044(3)(b), Florida Administrative Code.

The reviewer notes that no executed, draft or shell contractual agreement between the applicant and TransLife is included in the application.

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

NCH states that it has an established and operational ICU unit for pediatric patients that includes facilities for prolonged reverse isolation. NCH states and the reviewer confirms that the applicant's existing facilities were described previously in the application. The applicant again references CON application #10471, Vol II, Attachment T.

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

NCH maintains that the Transplant Care Team will meet formally every week to review all patients, both pre- and post- transplant. The applicant maintains that recommendations for assessment and treatment will be made. NCH asserts that there will also be a monthly quality review meeting to discuss all transplant cases from a systems standpoint. NCH comments that Quality Assurance and Process Improvement (QAPI) outcomes and measures will be reviewed at this meeting. The applicant states that periodically, at least annually, it will report to the hospital wide Performance Improvement and Patient Safety Committee.

NCH indicates that after the decision to proceed with transplant is made, patients will be listed with UNOS and that candidates are prioritized by UNOS based on severity. NCH discusses the family consent process. The applicant also discusses potential recommendations other than transplant (such as left ventricular assist device-LVAD, as well as other options). LVAD is pointed out as a potential bridge to transplantation. NCH points out that whatever the outcome of the Transplant Team meeting, the patient and family will be notified by the transplant coordinator, prepared and educated. The applicant references CON application #10471, Vol. II, Attachment R-Protocols and Policies for Thoracic Transplantation Program.

NCH maintains that it is developing specific patient care protocols for the proposed comprehensive thoracic transplant program and that they apply to the three co-batched/ companion proposals. NCH

states developing a patient and family handbook guide and that all patients and families are to receive this book upon registration for transplantation at NCH.

NCH highlights the 15-page Heart Transplantation Discharge Education (Teaching Booklet) utilized by Alfred I. Dupont Hospital for Children in Delaware (CON application #10471 Vol. II, Attachment L). NCH maintains that it will utilize this and other existing information, policies and protocols from the Nemours Foundation's Delaware hospital where appropriate and relevant in this new transplant program in Orlando.

- (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 states that NCH is working to develop protocols for patient care including pre-hospital, in-hospital and post-discharge care as well as patient selection criteria for maintenance and evaluation. The applicant again references CON application #10471, Vol. II, Attachment R-Protocols and Policies for Thoracic Transplantation Program. NCH states and the reviewer confirm that this attachment includes extensive protocols for each of the three co-batched CON applications. According to NCH, these protocols will continue to be developed and refined to be ready for implementation upon approval of the proposed thoracic transplant center.

- (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 working to develop protocols for post transplantation for long-term management of transplant patients. NCH indicates that the protocols include clinic visits post transplantation for monitoring and testing, an immunization schedule, safe practices of immunosuppressed patients and reconditioning of "status I" patients. The applicant mentions evaluative procedures for acute and long-term management of transplantation patients and again references CON application #10471, Vol II, Attachment R. According to NCH, these protocols

will continue to be developed and refined to be ready for implementation upon approval of the proposed thoracic transplant program.

- (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 states that it is a designated pediatric acute care hospital and is fully stocked with inventory for in-patient, emergency and surgical procedures. According to the applicant, this inventory list is similar to a list of equipment necessary for transplant procedures. The applicant references CON application #10471, Vol. II, Attachment S-Transplantation Program Equipment List/Equipment for Procurement, Organ Preservation and Perfusion of Hearts and Lungs. NCH indicates that cadaveric organs will be procured by the NCH procuring transplant surgeon in conjunction with TransLife. The applicant further discusses the procurement and perfusion process.

- (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 states that it has an existing contractual Master Services Agreement with the Mayo Clinic to provide pathology services not available at NCH. NCH also states that, "As noted elsewhere NCH also has a contractual agreement with OneBlood, Inc., for blood banking services". The applicant maintains that at its Jacksonville, Florida location, Mayo Clinic has various typing services and among other designations, Mayo Clinic holds American Society of Histocompatibility and Immunogenetics (ASHI), tissue typing laboratory accreditation (ASHI #01-4-MN-03-1). The reviewer notes that CON application #10471 does not include these stated contractual agreements/accreditations. According to the applicant, NCH has begun discussion with both of these organizations to add to transplant tissue typing services to the existing agreements and also states that these relationships would be finalized prior to initiating transplant services.

NCH provides a letter of support for the heart and the lung co-batched application from Donald D. Doddridge, President and CEO, OneBlood, Inc. (CON application #10471, Attachment J). The reviewer notes that this support letter includes, among other statements that, “We are committed to supply the increase of blood products needed for added procedures”. However, no executed, draft or shell contractual agreement between the applicant and OneBlood is included in the application.

The reviewer notes that CON application #10471, Vol. II, Attachment K-Pathology Letter of Support includes two support letters from physicians (chairs) of Nemours/Department of Pathology and Laboratory Medicine that indicate that the hospital’s physicians in these departments have extensive experience in providing laboratory support for transplant surgery.

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

The applicant maintains that the laboratory medicine section of the Department of Pathology and Laboratory Medicine hours of operation are 24 hours a day, seven days a week. The applicant also maintains that if testing is not performed in-house, the specimen is referred to an appropriate reference laboratory. NCH indicates having a preferred provider relationship with the Mayo Clinic and also indicates having a close relationship with Florida Hospital for certain laboratory services. The reviewer again notes that CON application #10471 does not include a contractual agreement with Mayo Clinic and also notes no copy of a contractual agreement with Florida Hospital for the delivery of pathology services.

NCH indicates that the NCH Department of Pathology and Laboratory Medicine is staffed with four pathologists, all with more than 20 years of experience in high complexity multidisciplinary care and all four are certified by the American Board of Pathology. The applicant states that its laboratory holds clinical laboratory license by the Agency, however, the reviewer notes that a copy of the stated laboratory license is not included in the application.

According to NCH, its laboratory meets or exceeds all Clinical Laboratory Improvement Act (CLIA) and that the laboratory is accredited by the College of American Pathologists (CAP). The reviewer notes that the application does not include any CLIA or CAP accreditations or certifications.

NCH asserts that the Blood Bank and Transfusion Services are contracted services with OneBlood, Inc., that will perform all testing transfusion services and supply all of the blood products used at NCH. The applicant also comments on other services provided by OneBlood. NCH asserts that the Blood Bank is inspected by the American Association of Blood Banks (AABB) and by the US Food and Drug Administration (FDA).

NCH discusses two specific laboratory analyzers (CON application #10471, Vol. I, page 123). The applicant asserts that in term of laboratory requirements for transplantation services, the NCH clinical and pathologic laboratories, and the blood banking laboratory operated by OneBlood provide all necessary services for a transplantation program, including the monitoring of drug levels.

**(10) Blood banking facilities.**

NCH asserts that the Blood Bank and Transfusion Services are contracted services with OneBlood, Inc., that will perform all testing transfusion services and supply all of the blood products used at NCH. The applicant also comments on other services provided by OneBlood. NCH again states that the Blood Bank is inspected by the AABB and by the FDA.

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

NCH states having established basic training policies and procedures for all physicians and staff members of the hospital. The applicant indicates that the policies and procedures are being modified for current and new staff working in the transplantation program to meet the specific care requirements of transplant patients. NCH references the extensive CON application #10471, Vol. II, Attachment R-Protocols and Policies for Thoracic Transplantation Program.

NCH contends that the staff NCH expects to work in the transplantation program have previous experience working with pediatric or special care transplant patients. NCH provides job descriptions of all the job positions available through the transplantation program and the experience of the proposed staff members (CON application #10471, Vol. II, Attachment H).

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

NCH references CON application #10471, Vol. II, Attachment R-Protocols and Policies for Thoracic Transplantation Program/Pediatric Post-Transplant Patient and Family Handbook: A Guide for Patients and Families. The reviewer notes this 11-page handbook has the following major headings:

- Objectives
- Resources
- Teaching methods
- Evaluation methods

In addition, topics in the guide include:

- Going home
- Medications
- Transplant related complications
- Staying healthy
- Food safety
- Storing and traveling with medications
- Activity restrictions and limitations
- Infection
- Rejection
- Follow-up

d. **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 states that Peter Wearden, MD, will be the primary transplantation surgeon and program director for the proposed program. The applicant includes a curriculum vitae or CV and the additional information for Dr. Wearden. On January 12, 2017, the reviewer notes that according to the website: <http://findaprovider.nemours.org/?FreeText:Doctorsname=Wearden&latlng=0,0&sortDirection=asc>, Dr. Wearden is on staff at the applicant's address.

The applicant maintains that there is a recruitment strategy and sample job description in order to hire an additional transplantation surgeon. The reviewer notes that CON application #10471, Vol. II, Attachment H includes a job description for a transplant program medical director, among other job descriptions specific to the proposed project. The reviewer also notes that this job description indicates that five years of clinical experience in transplantation is required.

The applicant does not respond to the requirement to have a physician with one-year experience in the management of infectious diseases in the transplant patient shall be a member of the transplant team. However, on January 12, 2017, the reviewer notes that according to the website: <http://findaprovider.nemours.org/?Specialties=24&CustomField=21%3bYes>, the applicant has three physicians on staff at its address with infectious disease specialty.

- (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.**

NCH reiterates Peter Wearden, MD, PhD. Please see item E.2.b., immediately above.

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

NCH states that staff presented in CON application #10471, Vol. I, Attachment G are current employees of NCH and will be available to the transplantation program following approval. The applicant indicates it has developed a recruitment strategy and job description for positions that will need to be filled to fully staff the transplantation program, many of whom are already in the process of being recruited to be part of NCH's existing programs. NCH again reiterates that CON application #10471, Vol. II, Attachment H includes job descriptions for a transplant program medical director, among other job descriptions specific to the proposed project.

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

According to NCH, staff presented in CON application #10471, Vol. I, Attachment G are current employees at NCH and will be shared with the transplantation program following approval. NCH states it has developed a recruitment strategy and job description for positions that will need to be filled to fully staff the transplantation program. NCH references CON application #10471, Vol. II, Attachment H for job descriptions for new staff that will be hired to support the thoracic transplant program. The reviewer inspected both the referenced attachments.

The reviewer notes that Attachment G provides mostly physician CVs, with the exception of the following two CVs:

- Michael A. Maymi, RN, BSN, MSN, Doctorate of Nursing Practice, Lead Cardiac ICU Acute Care Nurse Practitioner
- Anthony Lee Roller, BSN, MSN, ARNP, Cardiac ICU Nurse

The reviewer notes that Attachment H provides a job description for the following additional transplantation program staff, presented in the order they are provided in the attachment:

- Heart transplant coordinator
- Transplant program medical director
- Nutritionist (clinical dietitian transplant program)
- Respiratory therapist
- Pediatric psychologist
- Child life specialist
- Social worker

**(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 that it has a fully stocked blood bank facility onsite to compliment the transplantation program and other programs at NCH that utilize blood transfusions procedures. NCH maintains that it has an established agreement with OneBlood to provide additional blood bank reserves at the occasion that the Nemours supply is not sufficient.

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

The applicant maintains that it has multiple nutritionists already employed and will continue to hire nutritionists with transplant experience to support increasing patient volumes of the pediatric thoracic transplant program. The applicant again references its Attachment H for the sample clinical dietitian job description. NCH indicates that while the current cadre of nutritionists is more than capable of caring for transplant patients, NCH intends to recruit one nutritionist with specific transplant experience. The reviewer notes no existing nutritionist/dietician staff are named and no nutritionist/dietician CVs are provided. However, the reviewer notes that Schedule 6A of the application includes a 1.0 FTE for nutritionist (transplant program).

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

NCH maintains having current staff members qualified to meet the respiratory needs of transplantation patients and will also recruit

additional respiratory therapists with transplant experience as part of its ongoing recruitment of staff to meet the hospital's increasing patient volume. NCH indicates that while the current cadre of respiratory therapists is more than capable of caring for transplant patients, some having done so at other centers, NCH intends to recruit a transplant respiratory therapist to oversee training and quality. The reviewer notes no existing respiratory therapist staff members are named and no respiratory therapist CVs are provided. However, the reviewer notes that Schedule 6A of the application includes a 1.0 FTE for transplant respiratory therapist.

**(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 states having currently budgeted for and already recruiting for a transplant psychologist to support the existing cardiac program. The applicant again references Attachment H of the application. NCH also states that it will recruit one FTE social worker and one FTE child list specialist specifically for the transplant program. The reviewer notes that these statements are consistent with the applicant's Schedule 6A (see item E.3.c. of this report). The reviewer also notes that no existing social workers/psychologist staff are named and no social workers/psychologist CVs are provided. However, the applicant includes job descriptions for these positions (CON application #10471, Vol. II, Attachment H).

**e. 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 plans to submit data regarding each transplantation program to the Agency along with other statistical information within 45 days of the end of each calendar quarter.

**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 #10471.

Driving Distances in Miles The Nemours Foundation d/b/a Nemours Children's Hospital and Florida Pediatric Heart Transplantation Providers					
Facility	Nemours Children's Hospital	Johns Hopkins All Children's Hospital	UF Health Shands Hospital	Memorial Regional Hospital	Jackson Memorial Hospital
Nemours Children's Hospital		105	125	211	225
Johns Hopkins All Children's Hospital	105		151	250	262
UF Health Shands Hospital	125	151		320	334
Memorial Regional Hospital	211	250	320		19
Jackson Memorial Hospital	225	262	334	19	

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

The chart above illustrates that from the proposed CON application #10471, the nearest pediatric heart transplant provider (Johns Hopkins All Children's Hospital) is 105 miles, with the second nearest provider (UF Health Shands Hospital) being 125 miles away. As previously indicated, OTSA 3 has no operational or CON approved pediatric heart transplantation provider.

The applicant discusses travel challenges for patients and families in need of pediatric transplantation services, as proposed. Using Google Maps October 2016, NCH states that it summarizes the mileage from the city center of each county in OTSA 3 to the existing transplant provider currently offering heart and or lung transplant services. The applicant provides an exhibit (CON application #10471, Vol. I, page 75, Exhibit 15-Analysis of Travel Distance for Pediatric Transplant Patients in OTSA 3 to Existing Providers). The reviewer notes that the applicant inaccurately includes Palm Beach County and does not include Lake County and Volusia County in its Exhibit 15. Therefore, the reviewer notes that the applicant does not include the full complement of OTSA 3 counties (not

including Lake County and Volusia County) and incorrectly adds an OTSA 4 county (Palm Beach County) in its Exhibit 15. Further, the applicant offers no explanation for this county listing discrepancy.

Regarding availability, NCH reiterates that there are few pediatric transplant programs in the State of Florida and few focus solely on pediatric patients. NCH emphasizes and the Agency has previously shown that Miami-Dade County (OTSA 4) and Alachua County (OTSA 1) are Florida's only operational pediatric heart transplantation and pediatric lung transplantation provider locations. The applicant indicates that these facilities are two to five hours away from residents of OTSA 3, which impose significant personal and financial hardships on patient's families. NCH comments that that the proposed project is centrally located in OTSA 3 and that it would enhance availability to these life-saving services.

The reviewer notes that the applicant discusses efficiency (CON application #10471, Vol. I, page 136). According to Nemours, the proposed project will be incorporated seamlessly into the existing hospital structure. Also, Nemours states that it will utilize several of its existing employees to staff the proposed program, that the proposed unit will be housed in the existing hospital space and that this will all help minimize the overall cost of the proposed project. The Agency notes that efficiency is not a statutory rule criteria, pursuant to Section 408.035(1)(a) and (b), Florida Statutes (referenced above).

Regarding accessibility, NCH reiterates that OTSA 3 resident lack access to a pediatric heart and lung transplant program in OTSA 3. NCH maintains that the proposed project will clearly enhance geographic access to care and will also enhance financial access, as the applicant indicates that NCH serves patients without regard to ability to pay and will extend these same policies to transplant recipients. The reviewer notes that NCH offers no Medicaid or charity care patient day condition regarding the proposed project.

Regarding extent of utilization of existing health care facilities, NCH reiterates that one objective of the proposal is the increase the number of heart transplants performed in Florida, rather than have Florida residents travel to other states and in addition, to ensure that organs donated in Florida are transplanted in Florida for residents.

**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 a mission statement (CON application #10471, Vol. I, page eight):

“To provider leadership, institutions and services to restore and improve the health of children through care and programs not readily available, with one high standard of quality and distinction regardless of the recipients financial status.’

According to NCH, this mission is achievable because of the following core components:

- Unified hospital and physician practice as one entity
- Integrated system of clinical care that is supported by a critical mass of subspecialty pediatric physicians
- Educational partnership and programs for teaching and education of staff including graduate medical, allied health and nursing professions
- Pediatric research
- Exclusively pediatric focus at all times
- All components assembled in one location, under one strategy
- Endowed foundational support that permits the prioritization of pediatric care
- Investment in a Comprehensive Electronic Health Record (EHR) and other state of the art electronic medical systems
- Data warehouse

Further, NCH provides values (CON application #10471, Vol. I, page eight):

Excel~Respect~Serve~Honor~Learn

NCH indicates being a leader in research and improvement of quality of care for pediatric patients and that this quality is affirmed not only through a consistent granting of “Full Accreditation Status” from the Joint Commission, but more impressively through the recognized success of not only meeting but in most cases exceeding the National Patient Safety Goals. According to the applicant, Joint Commission surveyors have particularly commented on Nemours’ success in this area year after year. The reviewer notes that the applicant does not provide Joint Commission accreditation documentation.

CON application #10471, Vol. II, Attachment U-Articles and Other Documentation includes December 6, 2016 correspondence indicating that Leapfrog Group has designated NCH as one of three top children's hospitals in Florida<sup>3</sup>. According to NCH, the hospital provides quality of care through the development of numerous quality and safety initiatives. Below is a brief description of NCH's four stated quality initiatives that the applicant indicates are not available at any other providers in District 7:

- Pedi-QS – The national Pediatric Quality System adopted by the Joint Commission as a prototype to improve care for children in a measurable way. (The reviewer notes that asthma, medication safety, attention deficit and cystic fibrosis are highlighted)
- Nemours Clinical Measurement Program (NCMP) – This integrated clinical information from various sources into a system of computerized data and NCMP works with specialties of Nemours in order to demonstrate, using the electronic medical record, how care coordination and safe clinical practices can be achieved.
- Nemours Biomedical Research – Designed to improve the health of children through translational research programs that move discoveries rapidly from bedside to practice and community.
- Electronic Health Record – This provides another avenue to achieving both clinical quality and safety.

NCH indicates that the proposed Quality and Safety Plan for Nemours is provided in Attachment P. The reviewer notes that CON application #10471, Vol. II, Attachment P is titled "Utilization Management Documentation and Policies".

Agency complaint records indicate, for the three-year period ending December 9, 2016, Nemours Children's Hospital, the NCHS' sole Florida hospital, had no substantiated complaints.

The applicant demonstrates it is a quality provider.

<sup>3</sup> The reviewer notes that there are only three Class 2 licensed children's hospitals in the State of Florida: Johns Hopkins All Children's Hospital (OTSA 2), Nemours Children's Hospital (OTSA 3) and Nicklaus Children's Hospital (OTSA 4). The reviewer also notes that page four of six of the referenced attachment indicates the following three Florida facilities as children's hospitals: Nemours Children's Hospital, Golisano Children's Hospital of Southwest Florida and Orlando Health Arnold Palmer Hospital for Children. The Agency licenses Nemours Children's Hospital as a Class 2 hospital. However, Golisano Children's Hospital of Southwest Florida is licensed under a Class 1 affiliate facility (Lee Memorial Hospital) and Arnold Palmer Medical Center is licensed as a Class 1 facility. Therefore, the reviewer notes that while The Leapfrog Group may designate these latter two facilities as children's hospitals, the Agency does not license them as Class 2 facilities.

- 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 The Nemours Foundation and Subsidiaries (parent of the applicant) where the short-term and long-term measures fall on the scale (highlighted in gray) for the most recent year.

<b>The Nemours Foundation and Subsidiaries</b>		
	<b>Dec-15</b>	<b>Dec-14</b>
Current Assets	\$385,478,734	\$246,489,650
Total Assets	\$1,840,228,636	\$1,749,776,693
Current Liabilities	\$161,437,333	\$137,547,433
Total Liabilities	\$766,272,790	\$782,111,585
Net Assets	\$1,073,955,846	\$967,665,108
Total Revenues	\$1,140,156,048	\$1,059,480,664
Excess of Revenues Over Expenses	\$47,106,219	\$48,241,188
Cash Flow from Operations	\$81,032,179	\$52,637,230
<b>Short-Term Analysis</b>		
Current Ratio (CA/CL)	2.4	1.8
Cash Flow to Current Liabilities (CFO/CL)	50.19%	38.27%
<b>Long-Term Analysis</b>		
Long-Term Debt to Net Assets (TL-CL/NA)	56.3%	66.6%
Total Margin (ER/TR)	4.13%	4.55%
<b>Measure of Available Funding</b>		
Working Capital	\$224,041,401	\$108,942,217

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

**Capital Requirements and Funding:**

On Schedule 2 the applicant indicates capital projects totaling \$133,620,728, which includes \$715,425 for this project. The applicant indicates on Schedule 3 of its application that funding for the project will be provided by the parent company from available resources as an equity investment.

The applicant provided a copy of the December 31, 2015 audited financial statements for its parent. The applicant also provided a copy of a letter of financial commitment from The Nemours Foundation’s senior vice president and chief financial officer. 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 Schedule 6A table below shows the NCH’s projected staffing for the proposed project in year one (ending December 31, 2018) and year two (ending December 31, 2019). The table below accounts for FTEs to be added as a result of the proposed project, if approved.

<b>The Nemours Foundation d/b/a Nemours Children’s Hospital Pediatric Heart Transplantation Program Staffing Patterns</b>		
	<b>Year One Ending 12/31/2018</b>	<b>Year Two Ending 12/31/2019</b>
<b>ADMINISTRATION</b>		
Financial Coordinator	1.0	1.0
Administrative Assistant	1.0	1.0
<b>PHYSICIANS</b>		
Program Director	1.0	1.0
Surgeon	1.0	1.0
Cardiologists	4.0	4.0
Pulmonologist	1.0	1.0
Cardiac-Intensivist	1.0	1.0
Anesthesiologist	1.0	1.0
<b>NURSING</b>		
Advance Practice Nurse	3.0	3.0
Transplant Care Coordinator	2.0	2.0
<b>ANCILLARY</b>		
Social Worker (MSW)	1.0	1.0
Child Life Specialist	1.0	1.0
Transplant Psychologist	1.0	1.0
Nutritionist (Transplant Program)	1.0	1.0
Transplant Respiratory Therapists (1)	1.0	1.0
<b>TOTAL</b>	<b>21.0</b>	<b>21.0</b>

Note: (1) Existing respiratory therapists will be trained by the Transplant Respiratory Therapist  
Source: CON application #10471, Schedule 6A

Notes to Schedule 6A indicates that due to the relatively small number of transplant cases, the staffing is not expected to change over the two-year projection period. These same notes also indicate that positions and FTEs are based on the hospital’s existing cardiac surgery program and the experience of the pediatric thoracic transplant program at the Alfred I. DuPont Children’s Hospital in Delaware.

**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 applicant was compared to its own 2015 fiscal year end operating results. The data was then inflated using the CMS Market Basket, 3rd Quarter, 2016. Net revenue per patient day, cost per patient day, and operating margin per patient day that fall near the inflated values are considered reasonable projections. Below is the result of our analysis.

	PROJECTIONS PER APPLICANT		NEMOURS FY 2015 DATA INFLATED TO 2019 PPD		
	Total	PPD	PPD	Difference	% Difference
Net Revenues	170,079,302	7,373	10,065	-2,692	-26.7%
Total Expenses	23,836,916	9,069	15,468	6,579	-42.0%
Operating Income	-38,271,099	-1,703	-4,525	2,822	-62.4%
Operating Margin	-22.71%		<b>Comparative Group Values</b>		
	Days	Percent	Actual	Difference	% Difference
Occupancy	23,067	63.20%	31.90%	31.30%	98.1%
Medicaid/MDCD HMO	15,760	68.30%	69.10%	-0.08%	-1.2%
Medicare	104	0.45%	0.47%	-0.02%	-4.3%

Projected net revenues per patient day fall well below the applicant’s inflated net revenue per patient day and may be understated. Total operating expenses per patient day are also well below the applicant’s inflated total operating expenses per patient day and may not be attainable. Operating income is well above the operating income that the applicant experienced in their FY 2015 fiscal year. It should be noted that the hospital is relatively new, opening in 2012. Occupancy percentage for FY 2015 was low at 31.9 percent. The low occupancy is the primary causal factor for the high net revenue, expenses and operating income per patient day. As the occupancy increases, these indicators should decrease as evidenced by the FY 2019 projections.

The parent company had \$385.5 million in current assets, \$224.0 million in working capital and \$81.0 million in cash flow from operations at December 31, 2015. With anticipated project costs of \$715,425 and projected project operating expenses of \$3.8 million in year one and \$6.7 million in year two, the applicant should be able to absorb all the costs of the project.

**Conclusion:**

This project will have negligible impact on the applicant due to the small costs and revenues associated with the project compared to the overall revenue and expenses of the applicant.

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

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

**Conclusion:**

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

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

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 (FY) 2015 provided by the Agency's Florida Hospital Uniform Reporting System (FHURS).

**Medicaid and Charity Care for  
The Nemours Foundation d/b/a Nemours Children’s Hospital  
Compared to the District for FY 2015**

<b>Applicant</b>	<b>Medicaid and Medicaid HMO Days</b>	<b>Charity Percentage Service</b>	<b>Combined Medicaid and Charity Care</b>
Nemours Children’s Hospital*	69.1%	0.2%	69.3%
<b>District 7 Average</b>	17.5%	5.7%	23.2%

Source: Fiscal Year 2015 Agency for Health Care Administration Actual Hospital Data  
Note: \* For this review, Nemours Children’s Hospital’s FY ended 12/31/2015.

According to the Agency’s Division of Medicaid, Office of Program Finance, NCH did not participate in FY 2015-2016 in either the low-income pool (LIP) or the Disproportionate Share Hospital (DSH) programs. Further, NCH has not participated in either LIP or DSH in FY 2016-2017, through December 8, 2016.

NCH states that it ensures financial access to all patients in need of its services from primary care to outpatient care to the most clinically complex inpatient care. NCH includes CON application #10471, Vol. II, Attachment O-Financial Accessibility Documentation. The reviewer notes that this attachment includes a financial assistance program policy and an uninsured discount program policy. According to the applicant, NCH accepts all patients regardless of ability to pay.

Below is the applicant’s projected transplant volumes and payor mix for co-batched/companion **CON applications #10471, #10472 and #10473**. The reviewer provides an asterisk for each separately submitted proposal among the co-batched/companion applications.

**The Nemours Foundation d/b/a Nemours Children’s Hospital**

	<b>Year One</b>		
	<b>Medicaid</b>	<b>Commercial Non-Medicaid</b>	<b>Total</b>
Pediatric Heart Transplants*	2	2	4
Pediatric Lung Transplants**	1	1	2
Pediatric Heart and Lung Transplants***	--	1	1
<b>Total Thoracic Transplants</b>	3	4	7
	<b>Year Two</b>		
	<b>Medicaid</b>	<b>Commercial Non-Medicaid</b>	<b>Total</b>
Pediatric Heart Transplants*	4	4	8
Pediatric Lung Transplants**	1	2	3
Pediatric Heart and Lung Transplants***	--	1	1
<b>Total Thoracic Transplants</b>	5	7	12

Source: CON application #10471, Vol. I, page 146, Exhibit 53

NOTE: \* CON application #10471  
 \*\* CON application #10473  
 \*\*\* CON application #10472

According to Schedule 7B, NCH intends to provide in the proposed pediatric heart transplantation program 50.0 percent Medicaid and 0.0 percent Self-Pay both in year one (ending December 31, 2018) and in year two (ending December 31, 2019), total annual patient days. The applicant does not offer charity care patient days allotted to the proposed program, according to Schedule 7B or the Schedule 7B notes. Schedule 7B notes indicate that the expected payor mix as shown in Schedule 7B is due to the small number of cases projected and the experience of other Florida pediatric thoracic providers.

The reviewer notes that statewide during the 12-month period ending June 30, 2016, there were 20 Medicaid/Medicaid Managed Care patients that received pediatric heart transplantation.<sup>4</sup> NCH offers no Medicaid or charity care patient day conditions regarding the proposed project.

**F. SUMMARY**

**The Nemours Foundation d/b/a Nemours Children's Hospital (CON application #10471)** proposes to establish a new pediatric heart transplantation program at NCH, in Orlando, Orange County, OTSA 3. NCH is the sole hospital in Florida operated by NCHS.

In this same batching cycle, NCH also submits applications for a new pediatric heart and lung transplantation program (**CON application #10472**) and a new pediatric lung transplantation program (**CON application #10473**).

Project costs total \$715,425. These costs include equipment, project development and start-up costs. Notes to Schedule 1 of this application indicate that costs shown on Schedule 1 for each of the co-batched applications (**CON application #10471, #10472 and #10473**) are duplicative and mutually exclusive. The notes further indicate that the costs cover the development of the proposed thoracic transplant program and no additional costs will be incurred should the Agency approve one, two or all three of the simultaneously filed applications. There is no reported construction or renovation associated with the project.

<sup>4</sup> Based on the Agency's Florida Center for Health Information and Transparency hospital discharge data

**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. Pursuant to 59C-1.008 (2) (e) 3.— the existence of unmet need will not be based solely on the absence of a health service, health care facility, or beds in the district, subdistrict, region or proposed service area.

The Agency notes that the five OTSA 3 residents that received a pediatric heart transplant in the 12-month period ending June 30, 2016 out-migrated to another OTSA to receive this service. No OTSA 3 pediatric heart transplantation provider volume could be adversely impacted by approval of the proposed project.

NCH requests that the Agency consider the following “not normal” circumstances in the review of the application:

- There is no pediatric heart transplant program in OTSA 3.
- OTSA pediatric population growth is faster than the State of Florida.
- Patients and their families from OTSA 3 that are in need of heart transplant must travel significant distances and often relocate to other cities pre-, during and post-transplant which is a significant cost burden and additional stress during a difficult time.
- Without local access to a pediatric heart transplant program, there may be patients in need of transplantation that are reluctant to register for such care given the burden of travel.
- There is a net export of donated pediatric hearts from the State of Florida.
- NCH will offer a unique comprehensive thoracic transplantation program that will combine the services of heart transplantation with lung and heart/lung transplantation, which would be the only program of its kind in Florida.
- There are no similar volume rules for lung and heart/lung transplantation.

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- Pediatric cardiac programs always have significantly lower surgical and catheterization volumes than adult cardiac catheterization programs.
- NCH is a mission driven organization that has consistently developed novel approaches to pediatric care in Florida working toward the goal of bringing a top tier, world-class dedicated pediatric hospital to Florida.
- Additionally, there is no correlation between the volume experience or quality outcomes of existing pediatric heart transplant programs and the arbitrary minimum open heart surgery and cardiac catheterization caseloads prescribed in this rule.

The Agency notes that opposition discussed and provided written documentation at the public hearing on the relationship between outcomes (quality and mortality) and programmatic volumes for pediatric cardiac services, including heart transplantation. Opposition indicated that the dilution of the volumes of procedures at existing facilities by the entrance of a low-volume provider might limit access to pediatric heart transplant services in the state as well as diminish the ability for existing facilities to develop treatments for these patient populations.

NCH maintains taking a novel approach to development of a comprehensive thoracic transplant program by combining three types of transplants in one program. The applicant indicates that, from a clinical and operational standpoint, it makes sense to combine these programs for the following reasons:

- Overlapping diagnoses result in the need for these organs to be transplanted
- The same clinical and medical staff are required to perform and support transplant of these organs
- The same facilities and equipment are needed to support transplant of these organs before, during and after transplant
- Performing multiple organ transplant types increases case volume and therefore:
  - Viability and quality of the program
  - Efficiently uses costs resources
- Performing multiple organ transplant types increases community outreach and education for more patients with related diagnoses

The Agency finds that the applicant did not demonstrate the applicable criteria specified in Section 408.035, F.S. and Rule 59C-1.044, F.A.C., including the applicant's failure to demonstrate special circumstances that would merit approval of the proposed project or the need for the proposed service. In addition, the applicant's pediatric cardiac services (pediatric

open heart and pediatric cardiac catheterization) were not operational in the calendar year preceding the November 2016 application deadline for this batching cycle. The applicant did not include documentation of patient caseloads for calendar 2015 required by 59C-1.044 (6) (b) 4., Florida Administrative Code, for an application to establish a new pediatric heart transplantation program.

**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 indicated. Policies and protocols to accommodate the proposed project are in place or are in development and will be complete prior to initiation of service. The applicant is Agency licensed and indicates being accredited by The Joint Commission.

Agency complaint records indicate that the parent's (NCHS) sole Florida hospital, NCH, had no substantiated complaints for the three-year period ending December 9, 2016.

The applicant is a quality provider.

**Financial/Cost:**

- Funding for this project and the entire capital budget should be available as needed
- This project will have negligible impact on the applicant due to the small costs and revenues associated with the project compared to the overall revenue and expenses of 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 2015 FHURS Data Report, NCH provided 69.1 percent of its total annual patient days to Medicaid/Medicaid HMO patients and 0.2 percent to charity care patients in FY 2015.

NCH did not participate in FY 2015-2016 in either the LIP or the DSH programs. Further, NCH has not participated in either LIP or DSH in FY 2016-2017, through December 8, 2016.

According to Schedule 7B, NCH intends to provide in the proposed pediatric heart transplantation program 50.0 percent Medicaid and 0.0 percent self-pay both in year one and in year two, total annual patient days. The applicant does not offer charity care patient days allotted to the proposed program, according to Schedule 7B or the Schedule 7B notes.

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

**G. RECOMMENDATION**

Deny CON #10471.

**AUTHORIZATION FOR AGENCY ACTION**

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

DATE: \_\_\_\_\_

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