

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

A. PROJECT IDENTIFICATION

1. Applicant/CON Action Number

**Orlando Health, Inc. d/b/a Arnold Palmer Medical Center/
CON #10518**

1414 Kuhl Ave., MP 2
Orlando, Florida 32806

Authorized Representative: R. Erick Hawkins
SVP, Strategic Management
(321) 841-3088

2. Service District/Subdistrict

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

B. PUBLIC HEARING

A public hearing was requested and held on behalf of Shands Teaching Hospitals and Clinics (UF Health), Johns Hopkins All Children's Hospital (JHACH) and Nemours Children's Hospital (NCH) at 1 p.m., on Monday, January 8, 2018 at the Southwest Library Community Room, 7255 Della Drive, Orlando, Florida 32812. The public hearing was facilitated by Mr. Ken Peach, Executive Director of the Health Council of East Central Florida.

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

After introductions were completed, Mr. Cary J. D'Ortona, COO of Arnold Palmer Medical Center (APMC), spoke first, offering an overview of the facility. He noted that the facility's cardiac program has consistently been recognized. Mr. D'Ortona indicated that APMC is ready to take the next step and prepared to hear concerns from all parties and address them accordingly.

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A parent of a pediatric cardiac patient that was treated at APMC reiterated their letter of support. The parent spoke about the quality of care and support they received at APMC and his strong support of the existing program and the staff. Another patient and their parent spoke about the quality of care received at APMC, expressing their gratitude to the staff. The parent also mentioned that congenital heart conditions are life-long conditions requiring a life-long relationship with doctors.

Dr. David Nykanen, Chief of Cardiology and Director of the Cath Lab, introduced himself and his background. He spoke of APMC's deliberate plan to develop a strong, measured, quality pediatric cardiac program—specifically with the goal to develop a program with no morbidity due to the ramp-up of the program.

He noted that the pool of patients at APMC are skewed to the most complex neonates due to the large Neonatal Intensive Care Unit (NICU) at APMC and its significant maternal/fetal program. Dr. Nykanen indicated that APMC has a medium volume program in terms of pediatric surgery but with high quality scores according to the STS database (#77 in volume). He asserted that the program looked at what was working at high-volume, high-quality pediatric cardiac programs and applied it to the program at APMC resulting in some of the best outcomes with some of the most complex cases. Dr. Nykanen praised the administration at APMC because the pediatric cardiology program is very expensive and does not provide a significant financial return on investment.

Dr. Nykanen indicated that OTSA 3 is growing rapidly, specifically citing the influx of residents from Puerto Rico in the wake of Hurricane Maria. In terms of the proposed service, he asserts that need for pediatric hearts transplant in OTSA 3 should be provided by the most experienced provider in the OTSA—APMC. He stated that APMC's pediatric cardiology program is now at a stage to service the needs of the community having put processes in place and having built the foundation for the program. Dr. Nykanen indicated that the additional required staff will be recruited once the CON is approved.

He asserted that APMC had no criticisms of UF Health Shands, a current provider of pediatric heart transplant services in Florida and noted that the program produces excellent outcomes. Dr. Nykanen noted that traveling long distances to a provider is not convenient for a patient and can prove to be impossible depending on economic circumstances. He contended that travel can also be harrowing to heart failure patients in need of transplantation and can potentially be fatal.

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Dr. William DeCampli, thoracic and cardiac surgeon at APMC, spoke next noting his appreciation of APMC's relationship with existing transplant centers. He indicated that the proposed new pediatric heart transplant program must be able to answer three questions:

- Are there enough cases in OTSA 3 to forecast a new program?
- Why does OTSA 3 need a pediatric heart transplant program?
- Why should that program be APMC?

He notes that in calendar year (CY) 2016, Shands reported 18 transplants with 40 to 50 percent coming from OTSA 3. Therefore, Dr. DeCampli indicates that there are at a minimum six to nine transplant-appropriate patients in OTSA 3. In terms of forecasting for a new program, Dr. DeCampli indicates that the number of eligible candidates for a pediatric heart transplant in OTSA 3 is greater than the number of pediatric transplants performed on residents in OTSA 3—noting that there is a real tendency to manage a health issue locally than to arrange with a remote institution for transplantation (both medically and surgically). He also notes that APMC has measures in place to increase the donor pool—and projected available transplant patients in OTSA 3 from 10 to up to 30.

In terms of accessibility in OTSA 3, Dr. DeCampli indicates that transplant services should be looked at like trauma. He stated that transportation of the patient pool for pediatric heart transplants is risky and significantly difficult logistically—and cited two cases specifically. He also notes that follow-up care, particularly in the first year, can produce morbidity through an opportunistic infection or acute failure. Dr. DeCampli asserts that distance sets up a barrier for compliance and a local transplant center in OTSA 3 can deter compliance issues and decrease morbidity.

Dr. DeCampli contends that APMC has a proven, prolonged track record of very good outcomes—without that record, a program should not be awarded to a facility. He notes the record of achievement of the pediatric cardiology program at APMC which had six deaths when 24 were predicted (2.2 percent morbidity at APMC compared to 3.1 percent nationally in 2017) with 28 percent of patients in Stat 4 or Stat 5 category.

Karen Putnal, Esquire, counsel to APMC, presented some arguments she contended weighed in favor of approval of the proposed application:

- The Agency must apply the statutory and rule criteria as written and consistently apply those criteria.
- APMC meets the need forecast of 12 pediatric heart transplants.
- APMC's historic facility volume of pediatric cardiac surgeries (page 37 of CON application #10518).

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- Cites prior cases and final orders.
- Statistical demonstration on a facility-specific basis of pediatric cardiac surgeries as there is a correlation between a facility's pediatric surgery volume and number of pediatric transplants.
- The application identifies "not normal circumstances" which speak for themselves.
- There are no providers of pediatric heart transplant services in OTSA 3.
- APMC has an excellent history of the ability to provide quality of care.
- APMC has the financial wherewithal to implement the program.
- Approval will enhance both geographic access and programmatic access to residents of OTSA 3.
- In terms of competition, the Agency cannot consider centers that are not located within OTSA 3.
- APMC's large NICU and large birth volume is a large pool of pediatric patients without access to a pediatric heart transplant program in OTSA 3.
- Innovation at an existing program is not a factor that should be considered and is discriminatory toward the OTSA 3 population.
- Establishes need under the statutory and rule criteria and should be approved.

On behalf of Nemours Children's Hospital (NCH), Kathy Platt, a health care planner, presented next. She noted that literally one year ago, APMC opposed NCH's pediatric heart transplant program and provided direct contradictory statements from those presented one year ago, such as:

- One year ago, APMC indicated that there was no need for a new pediatric heart transplant program.
- One year ago, APMC indicated that the rapidly increasing population did not merit a new program in OTSA 3.
- One year ago, APMC indicated the transportation issue did not merit a new program in OTSA 3.
- One year ago, APMC stated that NCH's projections were unreasonable, but APMC's projections are higher and reasonable.
- One year ago, APMC maintained that 59C-1.044 (6)(b)3. Florida Administrative Code, was relevant to pediatric programs but now it is not.
- One year ago, APMC indicated that UF Health and All Children's volume should be considered but Ms. Putnal now states that those facilities should not be considered.
- One year ago, APMC noted that there were no not normal circumstances.
- One year ago, APMC indicated that NCH could not be approved because its volume did not meet the need threshold but now APMC

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states that the OTSA 3 pediatric surgery volume cannot be examined in its entirety.

- APMC has presented new data in its application meeting the pediatric need threshold for pediatric cardiac surgeries that does not match previously reported local health council data, even though they had the ability to correct this data prior to the submission of CON application #10518.
- NCH notes that in its examination of APMC's data regarding pediatric open heart surgeries, and found that they only performed 87 in CY 2017.
- The Agency should consider APMC's previous lack of implementation for a pediatric bone marrow transplant program awarded in 2014— with no transplants having been performed in three years.
- NCH has superior elements than APMC, including NCH's already approved lung transplant program and a complete surgical team in place.

Dr. Peter Wearden, Director and Chair of The Nemours Cardiac Center at NCH, stated that the submission of CON application #10518 is disingenuous, discouraging but gratifying as well—as APMC has experienced an epiphany and changed positions to accept that the OTSA needs a transplant center after testifying against NCH's application one year ago. He questioned some of the data presented by Dr. DeCampi and Dr. Nykanen, pondering why APMC is a low-volume pediatric cardiac surgery program when it has such a strong NICU and maternal-fetal program. He noted that one would expect a much busier pediatric cardiac surgery program than APMC experiences with such assets in place.

Dr. Wearden also questioned the motives in denying and opposing the NCH application and why the status quo is good enough, although he conceded that the status quo is pretty good. He maintained that the state should not accept the status quo—the state should not create situations where the status quo and the oldest and mature program is always favored over a superior model. Dr. Wearden noted, with encouragement from his counsel, his significant credentials and that NCH had recruited a “Super Bowl”-level team to perform transplants with him—with 87 percent of his staff having experience with him personally, performing 122 surgeries since June 2016 with no mortality.

He notes that the rule criteria the state utilizes for volume is archaic and perhaps a residual vestige from adult programs. Dr. Wearden maintains that the volume criteria has no basis in scientific fact. He also notes that there are no volume requirements for liver, kidney or lung transplants.

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With regards to the proposed APMC program, he cites his respect of both of the APMC doctors that testified but stated that Dr. DeCampli has not performed a transplant in 14 years and Dr. Nykanen has not performed a transplant in 18 years. Additionally, he noted that a member of the APMC team most recently participated in a transplant eight years ago.

Dr. Wearden concluded by noting his depressed state in the weekend preceding the public hearing and that he dreamed as a major-league surgeon that the state would think bigger and better than it has in the past by allowing the highest caliber program to perform pediatric heart transplants. Dr. Wearden celebrated the NCH organization. He cited that he must have been naïve, he did not expect to have to fight with his colleagues and the state in order to provide “desperately needed” services to the children of Florida. He finished by considering the following motivations for new pediatric heart transplant programs:

- “Is it ego?”
- “Is it competition?”
- “Is it politics?”
- “Is it rules that don’t make sense?”
- “Is it because we want what is best for these children and families in their desperate time of need?”

Mr. Steven Ecenia, Esquire, counsel to NCH, testified next and noted that he was particularly upset by the change of position by APMC from a year ago and admonished Dr. Nykanen and Dr. DeCampli for their changed stances and “hiding the ball” in expectation of submittal of their own application. Mr. Ecenia read into the record a statement from the 2017 public hearing on NCH’s proposed pediatric heart transplant program, noting APMC’s position that there were no programmatic issues in OTSA 3. He also admonished Ms. Putnal’s testimony in the public hearing for incorrect statements regarding NCH—noting that NCH is the program of choice in the area currently for pediatric cardiac surgery. Mr. Ecenia contends that APMC cannot maintain a consistent position regarding pediatric heart transplant programs in OTSA 3.

Mr. Michael Glazer, Esquire, counsel for UF Health Shands and JHACH, presented a historical overview of UF Health’s pediatric heart transplant program. Mr. Glazer indicated that there seemed to be an “arms race” in Orlando regarding pediatric heart transplants. He noted that adding a new pediatric heart transplant program will not add new patients. Mr. Glazer indicated that the forecasted volume presented by APMC is not credible and can only be achieved by cannibalizing other existing pediatric heart transplant programs.

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Mr. Glazer indicated that there was no evidence presented by the applicant that the population of OTSA 3 or any particular patient is underserved. He noted that APMC touts itself as a destination hospital, maintaining that if it is okay to travel to APMC it must be okay to travel from it as well. He notes the relative proximity of Gainesville to Orlando. Mr. Glazer indicates that transportation is not a reason to justify a new program and that ECMO transport is done routinely.

Dr. Bill Pietra, Chief of Pediatric Cardiology at UF Health Shands, spoke next, noting at the start of his testimony that he has no issue in the expertise at any program represented at the hearing. He expressed concerns that another program will work against the residents of the State of Florida by diluting the volumes at existing programs and leaving the state devoid of a robust program. He indicated that small-volume programs (less than ten a year) that lose one patient a year are considered sub-standard—thereby influencing decisions and forcing a child that is too high-risk to be turned down to be listed for a transplant. Dr. Pietra notes that a robust program increases programmatic access to all residents with congenital heart failure.

Ms. Jeannie Ausbrak, social worker at UF Health Shands, spoke next. She notes that travel is a burden but the lack of a center of excellence is a bigger burden for a critically ill child. She testified to the services available at UF Health, including services available for children and families with lack of transportation. She indicated that location alone is not the deciding factor for most families with a child with a significant illness.

Dr. Jay Fricker, a pediatric cardiologist at UF Health Shands, spoke next about UF Health. He noted that robust programs train the next transplant surgeons while advancing the science of transplantation, immunology and infectious disease. Dr. Fricker indicated that transplantation is a tough business and another program would require a huge team and huge investment. He notes that Dr. Wearden could be a pioneer in the science because he was at one of the three centers for pediatric heart transplants in the country, before there was such a proliferation of pediatric heart transplant programs in the country which does not advance the science. He stated that the CON unit can do what it wants to do and that it will do what it wants to do—noting that decisions have been pretty poor overall.

Dr. DeCampli provided a rebuttal, noting a number of points:

- One year ago, APMC was happy with the status quo. At the time, APMC thought long and hard regarding its response to NCH's application and felt comfortable with the concern APMC expressed about a brand new program that lacked cohesion to bring up a new transplant program.

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- APMC is committed to improving care to the pediatric population diagnosed with congenital heart failure.
- While NCH was first in line, health care is not a candy store. He indicated that it is not prudent to hire a team until a CON has been acquired. He maintains that APMC will have no issue recruiting the team within 12 months of CON approval.
- A number of arguments have centered around a “robust” program, regionalizing transplantation to perhaps one program. Dr. DeCampli maintains that this would ignore access issues and might be classified as self-serving. He states that a regionalized program is unacceptable.
- He advocated that advancement of the science could be achieved through collaboration between institutions and advancing the field through multi-institutional collaboration increasing access to multiple centers.
- OTSA 3 has been underserved by its lack of a transplantation program. It is time that the service area has one that is local to residents in a facility with a proven record and proven outcomes, APMC.
- Hopes that the state will take into consideration the commitment, dedication and deliberate application of excellent outcomes in order to apply principles to the development and execution of a successful pediatric heart transplant program.

Written Materials

On behalf of **JHACH**, **Jonathan M. Ellen, MD** (President, CEO and Physician-in-Chief), **Jeffrey P. Jacobs MD**, FACS, FACC, FCCP (Professor of Surgery and Pediatrics, Johns Hopkins University) and **Alfred Asante-Korang MD**, MRCP (UK), FACC (Medical Director of Transplant Cardiology and Heart Failure, JHACH) submitted letters in opposition to CON application #10518.

Jonathan M. Ellen, MD, opposes the proposal in consideration of the historical services provided at JHACH, a pediatric heart transplant provider in OTSA 2. Dr. Ellen states that the proposal should be denied because pediatric transplantation programs are among the most quaternary services and the number of pediatric transplants that are performed in Florida and nationwide is extremely small. Moreover, Dr. Ellen states that very few hospitals should be authorized to perform pediatric heart transplants and existing hospitals with pediatric heart transplant programs are well-positioned across the state. Dr. Ellen determines that the addition of an additional pediatric heart transplant provider will dilute quality which is a concern that prevails over the convenience of travel.

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Dr. Ellen also notes that as a result of existing referral relationships, much of pre- and post-operative care for patients can be managed in consideration of patients' travel needs. Dr. Ellen also states that despite Orlando Health, Inc.'s historical provision of pediatric cardiac services, existing providers are equipped to see patients for a wide range of services. JHACH's proximity and capacity to serve residents of the Orlando area is underscored. The attrition of highly specialized staff from existing pediatric transplant programs as a result of recruitment to the APMC program is also expected to have an adverse impact on quality as the workforce will be diluted.

Jeffrey P. Jacobs MD states that denial of the proposal is warranted for the following reasons:

- Pediatric cardiac surgical outcomes are now better than ever.
- Variation in pediatric surgical outcomes exist.
- An inverse association between pediatric cardiac surgical volume and mortality exists that becomes increasingly important as case complexity increases.
- Heart transplants are all low volume high complexity operations that require repetition of critical volume-related skills in order to maximize the opportunity for success.
- Given the low volume of pediatric thoracic organ transplants performed annually in the United States and in Florida, and the number of existing pediatric thoracic organ transplantation programs in Florida, the need to create a new program for thoracic organ transplantation in Florida simply does not exist. In fact, the creation of such a new program would actually harm children in need of thoracic organ transplantation in Florida by diluting complex procedures at any individual program and therefore decreasing quality.

Alfred Asante-Korang, MD, discusses how the existing number of pediatric heart transplant programs and the low volume of pediatric thoracic organ transplants performed annually in the United States and in Florida do not support the addition of a pediatric heart transplant program. Dr. Asante-Korang describes the distribution of transplant programs per million and notes that the number of Florida's pediatric heart transplant programs per million exceeds the average ratio of transplant programs per million in states with similar populations to the State of Florida.

Dr. Asante-Korang underscores JHACH's provision of care to children with the highest risk of cardiac transplantation, especially during times where other providers would not accept these cases. JHACH's transplant outcomes and mortality records are also highlighted. Dr. Asante-Korang further elaborates on JHACH's capacity to reserve high-risk and complex pediatric transplant patients by noting that JHACH has among the

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highest rates of transplantation in the country—with a significant portion listed as Status 1a, which designates the highest priority by severity of illness. In the absence of sufficient volume, Dr. Asante-Korang indicates that access may be restricted as the program would need to be conservative in the type of cases accepted.

The written document concludes by reiterating that JHACH's history demonstrates the need to ensure that existing programs have the volumes to ensure substantial experiences and support of higher risk patients. JHACH maintains that the proposed services is not anticipated to increase or ensure access in the region or state.

Nemours Children's Hospital (NCH) submitted written documents in opposition to CON application #10518. The arguments leveraged against approval of the proposal enumerate the project's lack of conformity with statutory criteria in Rule 59C-1.044(4) and (6), Florida Administrative Code, statements in opposition to the project are also contextualized with arguments APMC provided against a previous pediatric heart transplant application submitted by NCH, congenital heart surgery public reporting supplied to the Society of Thoracic Surgeons (STS) and arguments APMC presented against "Not Normal Circumstances" warranting approval of CON application #10471. NCH discussed APMC's lack of implementation of a pediatric bone marrow transplantation program (CON #10218). NCH also provides a summary of criteria which are stated to demonstrate the determinants by CON application #10471 should be approved over CON application #10518.

Specific criticisms to CON application#10518 include:

- Questioning the utilization projections forecasted in the second and third years of operation
- The absence of documentation of the number of transplants that will be performed within the definition of pediatric patients (under age 15)
- APMC fails to meet the open heart surgery requisite threshold
- Discrepancies in data supplied to the Local Health Council and the Society for Thoracic Surgeons from 2013 – 2016.

NCH indicates that an individual facility's volume of procedures performed are not indicative of need for transplants within a service area, particularly where there are other cardiac surgery providers in the service area. Opposition maintains that if the Agency intends for the volume thresholds for pediatric cardiac catheterizations and open heart

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surgeries in the rule to be an indicator of need for heart transplant in OTSA 3, those minimum volume thresholds have been met for January – December 2016. The reviewer notes that the Agency examines an application for a new pediatric heart transplant services for documentation that the applicant met the threshold for pediatric cardiac procedures pursuant to Rule 59C-1.044(4)(a)4, Florida Administrative Code.

NCH maintains that OTSA 3 has met the 200 cardiac catheterization volume threshold in every year since 2011 and underscores the growth in catheterization volume in the service area over the last four years. NCH also notes that OTSA 3 has met the 125 open heart surgery threshold volume since 2011. Tables summarizing these volumes are included below:

Trends in Pediatric Cardiac Catheterizations Performed for Central Florida Providers						
Facility	Jan. - Dec. 2011	Jan. - Dec. 2012	Jan. - Dec. 2013	Jan. - Dec. 2014	Jan. - Dec. 2015	Jan. - Dec. 2016
Arnold Palmer	229	211	155	250	179	225
Florida Hospital	0	37	68	138	242	292
Nemours	0	0	0	0	0	65
Total Area 3	229	248	223	388	421	582

Source: Nemours Children’s Hospital Opposition Statement, Page 9

Trends in Pediatric Open Heart Surgeries Performed for Central Florida Providers						
Facility	Jan. - Dec. 2011	Jan. - Dec. 2012	Jan. - Dec. 2013	Jan. - Dec. 2014	Jan. -Dec. 2015	Jan. - Dec. 2016
Arnold Palmer	138	118	155	114	98	99
Florida Hospital	0	25	68	118	120	125
Nemours	0	0	0	0	0	57
Total Area 3	138	143	223	232	218	281

Source: Nemours Children’s Hospital Opposition Statement, Page 9

Opposition challenges APMC’s assertion that the lack of a pediatric heart transplant program in OTSA 3 causes patients and families to travel significant distances to other existing providers for care.

Nemours concludes that APMC’s cardiac surgery mortality data does not compare favorably with the STS national database and that cardiac surgery mortality rates have “declined” (NCH, Opposition Statement, page 14). Charts summarizing these trends are included below:

Arnold Palmer STS Mortality Data				
STAT Category	2013	2014	2015	2016
Cat 1	2.2%	0.0%	0.0%	0.0%
Cat 2	0.0%	0.0%	0.0%	4.4%
Cat 3	7.7%	0.0%	0.0%	0.0%
Cat 4	5.0%	5.6%	5.3%	10.0%
Cat 5	0.0%	0.0%	0.0%	33.3%

Source: Nemours Children’s Hospital Opposition Statement, Page 14

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Arnold Palmer STS Mortality Data Compared to National Database		
STAT Category	Arnold Palmer	National STS Database
Cat 1	0.0%	0.4%
Cat 2	4.4%	1.5%
Cat 3	0.0%	2.4%
Cat 4	10.0%	6.0%
Cat 5	33.3%	14.4%
Overall	5.6%	2.8%

Source: Nemours Children’s Hospital Opposition Statement, Page 14

Peter D. Wearden MD, PhD, Director and Chair of The Nemours Cardiac Center at NCH also provided a testimony in opposition to CON application #10518. Wearden opposes the application and challenges the assertion that approval of the project should be merited based on APMC’s history as a pediatric heart surgery program. Dr. Wearden maintains that APMC did not identify need for a pediatric heart transplant program until after the submission and opposition to the NCH application. Dr. Wearden also notes that the APMC Cardiac Program is a low-volume program and questions if APMC has the capacity to meet the needs of the community in relation to complex congenital disease.

A specific criticism of note discussed in the testimony is the purported need of patients requiring Extracorporeal Membrane Oxygenation (ECMO) and their capacity to be served in OTSA 3 in the absence of a pediatric transplant provider. Dr. Wearden discusses APMC’s claims that ECMO patients cannot be transferred and notes that from experience patients on ECMO are routinely transferred to centers up to hundreds of miles away.

Dr. Wearden additionally challenges the expertise and experience of physicians cited as potential transplant providers for the proposal.

The testimony concludes with a description of NCH’s history as a pediatric cardiac provider and the organization’s investments and professional affiliations.

On behalf of **Shands Teaching Hospital and Clinics, Inc. d/b/a UF Health Shands Hospital (UF Health)**, Edward Jimenez, Chief Executive Officer at UF Health submitted a letter opposing approval of an additional pediatric heart transplant program. He notes that UF Health is an existing pediatric heart transplant provider in OTSA 1.

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Mr. Jimenez provides a summary of the provision of services, personnel and resources available to pediatric patients at UF Health in addition to the facility's distinctions and quality performance record. UF Health is identified among the top 10.0 percent of congenital heart surgery programs in the nation as a result of its three-star rating in the STS Congenital Heart Surgery Database Report. Mr. Jimenez maintains that in data from the Scientific Registry for Transplant Recipients, UF Health was identified as having the lowest risk adjusted one-year mortality in the country for the period covered by January 2017.

Mr. Jimenez maintains that there is no need for an additional pediatric heart transplantation provider and comments on the accessibility of existing programs proximity to the counties in OTSA 3. He notes that travel needs are characterized as an issue that families and patients factor into their treatment needs. UF Health is highlighted for its capacity to accommodate patients that travel for all types of care. The addition of an another provider is expected to dilute the volume of patients needed to maintain quality and undermine the efficient distribution of limited specialized health care resources according to Mr. Jimenez.

Shands Teaching Hospital and Clinics, Inc. d/b/a UF Health Shands Hospital (UF Health) and Johns Hopkins All Children's Hospital (JHACH) also provided a joint opposition statement to CON application #10518. Themes expressed in the opposition statement echo arguments provided in the statements provided from representatives of JHACH and UF Health individually.

The joint statement expressed that there is no need for an additional pediatric heart transplant provider and the proposal will not increase access to heart transplant services for pediatric residents of OTSA 3 or the State of Florida. UF Health/JHACH expect for implementation of the proposal to result in a decrease in the efficiency and effectiveness of existing pediatric heart transplant programs reducing the volume at existing programs and ultimately eroding the existing quality of care as well as overall access to services—particularly to high-risk patients. Opponents of the APMC application indicate that the additional program is not warranted to meet any health planning objectives or anticipated population growth.

Opposition to the proposal is summarized below:

- There is no need for the proposed new project.
- The result of the proposed program will be dilution of the volume performed at existing programs.
- The project is not consistent with Agency Rules.
- The applicant fails to identify “not normal” conditions that support the approval of the proposed project.

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- With volume/outcome linkages for this service, the establishment of a new program will adversely impact patient outcomes.
- There is no need for an additional pediatric heart transplant program in Florida or in OTSA 3.
- APMC uses an erroneous need approach that fails to account directly for use rates and population growth. The applicant's need approach fails to provide a statistically predictive link between open heart surgeries and heart transplants.
- APMC's approach to establish a ratio between so-called "most-frequent indicators for transplant inpatients" at existing programs and their annual number of transplants is not based on sufficient evidence to establish a predictive link between identified diagnoses and a heart transplant. There is even less evidence that the average performance of the four existing long-established transplant programs over the past three calendar years is a reliable predictor of the prospective future performance of a new program by its second year of operation.
- APMC does not meet the required minimum pediatric open heart surgery volume established as set forth in Rule 59C-1.044, Florida Administrative Code
- ECMO patients in OTSA 3 do not constitute a "not normal" circumstance.
- Travel issues are unavoidable for heart transplant patients and are not evidence of need.

An attachment authored by **Biagio Pietra, MD** (Division Chief, Congenital Heart Center, UF College of Medicine - Chief of Pediatric Cardiology), provides an assessment of the state of transplantation in the State of Florida, conclusions in the attachment include:

- Adding a heart transplant center to the state will not increase availability of donor organs.
- Transplant centers typically provide support to those with access issues in order to overcome perceived barriers in accessing care.
- Hazard function increases in patients at centers performing less than 10 pediatric heart transplants in a year—in general hazard function increases as program volumes decrease.

Letters in opposition to the proposal are provided from the following individuals on behalf of UFHealth's Congenital Heart Center:

- F. Jay Fricker, M.D. (Gerold L. Schiebler Scholar Chair, Pediatric Cardiology)
- Biagio A. Pietra, M.D. (Division Chief, Congenital Heart Center, UF College of Medicine-Chief of Pediatric Cardiology)
- Mark S. Bleiweis, M.D. (Professor – Departments of Surgery and Pediatrics, Director – Congenital Heart Center)
- Jennifer Rackley, MSN, ARNP, CPNP – AC

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- Jean Osbrach, LCSW, Social Work Manager
- Timothy Bantle, RRT (ECMO Coordinator, UF Health – Cardiopulmonary Services)

Themes expressed in opposition to the proposal include:

- The correlation between volume and quality/outcome of the pediatric patient with congenital heart disease requiring surgery is documented in medical literature. The volume of congenital heart surgical procedures performed also correlates with the number of pediatric heart transplant procedures done in those centers also performing heart transplants. The addition of another center will decrease the number of heart transplant procedures done at existing centers. Opening another center will shift the referral of the most complex patients to the most experienced centers, without the benefit of caring for the less complex pediatric patient referred for heart transplant. New programs will opt to take the less complicated patient to assure that their program will have optimal outcomes.
- SRTR “risk adjustment” outcomes for pediatric heart transplant recipients.
- Infants and children who receive heart transplantation surgery need lifelong care and eventually could need re-transplantation and care by physicians who treat adults. The Congenital Heart Center at the University of Florida has a comprehensive program to care for the pediatric heart recipient as they reach adolescence and adulthood.
- Heart transplantation in infants and children is relatively new therapy with constantly evolving new and innovative therapies to extend their life. Survival after transplant is still limited and research in the areas of improved immune suppression is vital if we ever reach the goal of allograft intolerance and normal life expectancy. Advances in these areas will only be accomplished in an academic center with high volume at an institution committed to cardiovascular and immunology research.
- Centers with high volume caring for the complex patient will be the institutions that train the next generation of transplant physicians.
- The argument of convenience for follow-up is not a valid reason for opening a sixth center in Florida. Our patients can attest to the issue of quality versus convenience when dealing with complex pediatric cardiovascular disease, including heart transplantation.
- There is no benefit to people living in the State of Florida to justify another pediatric heart transplant center, in fact, too many centers will be detrimental to the overall quality of care and access to services within the state.

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- UF Health provides services that keep transplant families intact during the process of transplant and patient management. In addition to comprehensive medical care given to each child, services offered include: crisis counseling, marital counseling, grant-funded housing assistance, grant-funded family daily expenses, insurance counseling, assessment for noncompliance, mental health issues and transitions to adult programs.
- The transportation of patients on ECMO can be performed safely and is not a valid reason for approving APMC's CON application.

An attachment with descriptions of CardioHelp System, heart-lung support system accompanies the opposition letter is provided by the ECMO Coordinator at the UF Health-Cardiopulmonary services.

Letters of Support

Letters of support for the proposal were submitted on behalf of local health providers and institutions, state representatives, patients and community members, community service organizations, civic institutions and members of local government.

Letters of support speak favorably of the proposal in light of the following:

- Quality of APMC's health services and personnel
- The lack of accessibility of pediatric heart transplant services within the community and service area
- The travel burdens, geographic barriers and medical risks associated with having to travel outside of the service area for care
- The project's capacity to expand and enhance access to critically needed medical and surgical cardiac services for children
- The project's capacity to meet the needs of the most critical pediatric patients living in the transplant region
- The need for pediatric heart transplant and left-ventricular devices in central Florida
- The anticipated growth in the population that will precipitate increased need for access to pediatric heart transplant services in central Florida.

The reviewer notes that a number of letters of support submitted by health providers identified a professional affiliation with the applicant and that form letters were present among the support letters.

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Support letters are noted from the following individuals and institutions:

- Linda Stewart, District 13, Florida State Senator
- Jason Brodeur, District 28, Florida House of Representatives
- Mike Miller, District 47, Florida House of Representatives
- Teresa Jacobs, Mayor, Orange County
- Buddy Dyer, Mayor, City of Orlando
- Patty Sheehan, Commissioner, Orlando City Council, District 4
- Victoria P. Siplin, Vice-Mayor/Commissioner, Orange County, District 6
- Kathryn Vroman, President & CEO, Make-A-Wish Central and Northern Florida
- Roderick S. Williams, Fire Chief, City of Orlando – Fire Department
- George A. Ralls, MD, FACFP, Deputy County Administrator, Director of Health & Public Safety, Medical Director, Orange County EMS System
- Stephanie Garris, JD, CEO, Grace Medical Home
- Margaret Brennan, RN, MSSL, President/CEO, Community Health Centers
- Kevin M. Sherin, MD, MPH, Local Health Officer and Director, Florida Department of Health – Orange County
- Donna J. Walsh, MPA, BSA, RN, Health Officer, Florida Department of Health - Seminole County

C. PROJECT SUMMARY

Orlando Health, Inc. d/b/a Arnold Palmer Medical Center

(CON application #10518) also referred to as APMC or the applicant is an existing provider in District 7, Subdistrict 2, Orange County, seeking to establish a pediatric heart transplant program in OTSA 3. Orlando Health, Inc. currently operates the following hospitals in Orange County, Florida (Subdistrict 7-2).

- Arnold Palmer Medical Center
 - 364 Acute Care Beds, 90 Level II NICU Beds, 52 Level III NICU Beds
- Dr. P. Phillips Hospital
 - 237 Acute Care Beds
- Orlando Health
 - 835 Acute Care Beds, 53 Comprehensive Medical Rehabilitation Beds
- South Seminole Hospital
 - 126 Acute Care Beds, 62 Adult Psychiatric Beds, 8 Child/Adolescent Beds, 10 Substance Abuse Beds

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APMC is also a provider of pediatric inpatient cardiac catheterization and pediatric open heart surgery and was approved on March 12, 2014 for a pediatric bone marrow transplant program. Upon submission of CON application #10518, the approved pediatric bone marrow transplant program had not performed its first surgery.

The total project cost for the proposal is \$1,544,594. The total project cost includes land cost, building cost, equipment cost, project development costs and start-up costs. Schedule 9 of the application indicates that the project involves 1,100 gross square feet (GSF) of renovation construction totaling to \$348,745.

Schedule 10 of the application forecasts the issuance of licensure in November 2018 and initiation of service in October 2019.

APMC notes that it is a statutory teaching hospital as are all other hospitals in Subdistrict 7-2 operated by Orlando Health, Inc.

The conditions approval of the project to the following Schedule C condition(s):

Orlando Health, Inc. d/b/a Arnold Palmer Medical Center will promote and foster outreach activities for pediatric cardiology services, which will include the provision of pediatric general cardiology outpatient services at satellite locations within Organ Transplant Service Area 3.

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

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.

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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 Bianca Eugene, analyzed the application in its entirety with consultation from the financial analyst Derron Hillman of the Bureau of Central Services, who evaluated the financial data. Scott Waltz of the Office of Plans and Construction, reviewed the application for conformance with architectural criteria.

E. CONFORMITY OF PROJECT WITH REVIEW CRITERIA

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

1. Fixed Need Pool

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

There is no fixed need pool publication for pediatric heart transplant programs. Therefore, it is the applicant's responsibility to demonstrate the need for the project, including a projection of the expected number of pediatric heart transplants that will be performed in the first years of operation. OTSA 3 does not have an operational or approved pediatric heart transplant program. Pursuant to Rule 59C-1.008(2)(e) 3 Florida Administrative Code—the existence of unmet need will not be based solely on the absence of a health service, health care facility, or beds in the district, subdistrict, region or proposed service area.

Data reported to the Agency by the local health councils for the 12 months ending June 30, 2017 show the following pediatric heart transplant utilization, by facility, OTSA and district:

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Florida Pediatric Heart Transplantation Program Utilization July 2016 - June 2017			
Hospital	Service Area	District	Total Procedures
UF Health Shands Hospital	1	3	9
Johns Hopkins All Children's Hospital	2	5	7
Memorial Regional Hospital	4	10	4
Jackson Memorial Hospital	4	11	1
Total			21

Source: Florida Pediatric Organ Transplantation Program Utilization data published September 29, 2017

Below is a five-year chart to account for pediatric heart transplantation utilization, by OTSA, county and facility, for the five-year period ending June 30, 2017:

Florida Pediatric Heart Transplantation Utilization 12-Month Reporting Periods Ending June 30, 2013 to June 30, 2017								
Service Area	County	Facility	12-Month Reporting Periods July 1 to June 30					Total
			FY 12/13	FY 13/14	FY 14/15	FY 15/16	FY 16/17	
1	Alachua	UF Health Shands Hospital	13	4	17	12	9	55
2	Pinellas	Johns Hopkins All Children's Hospital	6	13	10	9	7	45
4	Broward	Memorial Regional Hospital	5	3	4	11	4	27
4	Miami-Dade	Jackson Memorial Hospital	1	2	1	3	1	8
		Total	25	22	32	35	21	135

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

It is noted that unlike other hospital programs, transplant services are reliant upon donors and patients are often placed on waiting lists. Utilization data, whether current or historic, is primarily an indication of the number of donors. Although wait lists are an indicator of need, without available donors, they are not by themselves a predictor of utilization.

The reviewer notes that the Organ Procurement Transplantation Network (OPTN), the national database of patient waiting lists for organ transplantation in the United States, shows 31 pediatric patients in Florida currently registered on the heart transplantation waiting list¹. See the organ by waiting time table below.

¹ As of December 8, 2017 per the OPTN website @ <http://optn.transplant.hrsa.gov>. The age range for this data base is 0-17 years.

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Organ Procurement and Transplantation Network (OPTN) Current Pediatric Heart Transplant Wait List Registrants as of Jan. 17, 2018	
Time on Waiting List	Number of Registrants
< 30 Days	4
30 to < 90 Days	1
90 Days to < 6 Months	7
6 Months to < 1 Year	5
1 Year to < 2 Years	4
2 Years to < 3 Years	0
3 Years to < 5 Years	5
5 or More Years	5
All Time Total	31

Source: <http://optn.transplant.hrsa.gov/latestData/rptData.asp>, as of January 17, 2018

Donor/patient matches are also a factor in transplant services. The chart below contains the most recent five-year volume of heart donations recovered in the State of Florida from donors aged 0-17.

Hearts Recovered from Donors Aged 0-17 January 1, 2013 – December 31, 2017					
	2017*	2016	2015	2014	2013
All Donor Types	24	30	33	38	45
Deceased Donor	24	30	33	38	45
Living Donor	0	0	0	0	0

Source: <http://optn.transplant.hrsa.gov/latestData/rptData.asp>, as of *January 17, 2018

As shown above, there were 24 Florida pediatric heart donors in 2017 (CY 2017).

Florida Center for Health Information and Transparency data indicates there were a total of 26 pediatric heart transplants and 18 pediatric heart implant assist device procedures performed at Florida hospitals for the 12 months ending June 30, 2017 (FY 16/17).

The following table reflects the number of pediatric heart transplants performed (excluding heart assist devices) for the twelve months ending on June 30, 2017.

Pediatric Heart Transplants by Patient Residence 12 Months Ending June 30, 2017		
Service Area	Transplants Performed	Percent of Total
1	8	30.77%
2	8	30.77%
3	3	11.54%
4	6	23.08%
Unknown	1	3.85%
Total	26	100.0%

Source: Florida Center for Health Information and Transparency database for 12 months ending June 30, 2017, MS-DRGs 001 and 002 (excluding heart implant assist devices). In this table, the Agency rounded to the nearest tenth to attain a 100.0 percent total

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Pediatric Heart Transplant and Pediatric Heart Assist Implant Discharges All Florida Hospitals Five Years Ending June 30, 2017			
Year Ending June 30	Pediatric Heart Transplants	Pediatric Heart Assist	Total Pediatric Heart Transplant/Assist Discharges
2013	25	7	32
2014	19	7	26
2015	33	11	44
2016	30	10	40
2017	26	18	44

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

The Agency notes that Rule 59C-1.044(2)(c), Florida Administrative Code defines a pediatric transplantation patient as a patient under the age of 15 years.

Orlando Health indicates that there are no existing pediatric heart transplant (PHT) providers within OTSA 3, nor are there any prior approved PHT programs pending licensure. According to the applicant, patients residing within OTSA 3 who may be clinically eligible for PHT services must leave OTSA 3 to receive or be wait-listed for transplant services, which creates impediments to access, particularly for those patients for whom transport poses significant risk.

The applicant states that its parent company, Orlando Health, Inc., has a long and distinguished history of providing quality care to all populations served by its facilities. Orlando Health expects to utilize its quality resources and clinical criteria and standards in response to agency rule preferences in order to ensure the highest quality care for the proposal. APMC maintains that Orlando Health uses a variety of state and national quality benchmarks to measure and ensure quality, licensure and certification standards, the Joint Commission and CMS measures. APMC underscores its historical role as “one of the most trusted names in children’s health care worldwide since 1989”. The reviewer notes that a description of pediatric specialties available at APMC is included on pages 6-7 of the application.

Orlando Health states that the application demonstrates that approval of the proposal will enhance access to a high quality cardiac program for PHT services for residents of OTSA 3. APMC maintains that the proposal satisfies the statutory and rule criteria for approval. Pursuant to 408.035(1), Florida Statutes and Rule 59C-1/044(6)(b), Florida Administrative Code, the applicant attests to “not normal circumstances” for which approval of the proposal is merited.

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APMC states that the proposal demonstrates that:

- There is no operational or approved PHT program in OTSA 3.
- Analyses of relevant data establish that APMC will perform a minimum of 12 heart transplants per year within two years of CON approval.
- The application seeks approval for a PHT program only and does not seek approval of an adult heart transplant program therefore the minimum volume criteria set forth in 59C-1.044(6)(b)3 is not applicable.
- The annual duplicated cardiac catheterization patient caseload at APMC was at or exceeded 200 for the calendar year preceding the CON application deadline and the duplicated cardiac open heart surgery caseload was at or exceeded 125 for the calendar year preceding the CON application deadline

The applicant states that at the baseline year for the measures indicated above, (2016) APMC performed 227 duplicated cardiac catheterizations on patients aged 0-14 in CY 2016 and 240 duplicated cardiac catheterizations on patients aged 0-17 in CY 2016. APMC asserts that it performed 138 open heart surgeries on patient aged 0-14 in CY 2016 and 141 open heart surgeries on patients aged 0-17 in CY 2017. Orlando Health anticipates that a pending rule change may expand the pediatric age cohort up to age 21 for Medicaid designated transplant centers, thus expanding the eligible patient pool (Attachment 4, CON application #10518).

The reviewer notes that the applicant's data submitted to the local health council for CY 2016 shows that APMC performed 225 cardiac catheterizations and 99 open heart surgeries. The reviewer also notes that on February 6, 2018, APMC informed Mr. Ken Peach, Executive Director of the Health Council of East Central Florida, Inc., that APMC "correctly and fully reported its pediatric open heart surgery case volume to the Society for Thoracic Surgeons national database for the relevant time period...[but] inadvertently under-reported its utilization to the local health council. APMC discovered the source of the error as APMC's incorrect exclusion of pediatric OHS cases performed at APMC that do not involve cardio-pulmonary bypass but that meet the regulatory definition of "Pediatric Open Heart Surgery" as set forth in Rule 59C-1.032 (2)(f), Florida Administrative Code." The reviewer notes that the Agency amended Rule 59C-1.032(2)(f), Florida Administrative Code on July 30, 2017.

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Orlando Health additionally expects for the proposal to allow for APMC to provide pediatric ventricular assist devices (“VAD”) or mechanical pumps to support heart function and blood flow either as a bridge to transplant or as a destination therapy itself. The applicant notes that VAD services are only available at heart transplant centers. APMC discusses how having access to VAD significantly expands options for patients facing heart failure or potential heart failure while increasing the potential pool of patients who may be eligible for heart transplant as compared to the pool of patients eligible for heart transplant at a hospital that does not provide VAD.

The applicant describes how APMC has the largest neonatal intensive care unit (NICU) within the country which results in a disproportionate volume of newborns per year with complex forms of congenital heart disease. APMC attests to having extensive experience treating the most complex pediatric cardiology patients, within the past four years APMC documents having 33 NICU patients placed on ECMO and 11 cardiovascular intensive care unit (CVICU) patients placed on cardiac bypass or other heart assist device after surgery. Within this patient population, the applicant identifies a significant number of patients that are too sick to be transferred from APMC to another facility to receive a PHT. Orlando Health states that many of these patients do not get listed for a heart transplant since they likely would not survive the necessary transfer.

Orlando Health describes how patients are chemically paralyzed on ECMO, since slight movements can cause the cannula to shift and potentially cause death. APMC states that the risk of moving ECMO patients is so dire that when a patient is going to be taken off ECMO, the operation is performed at the patient’s bedside because it is too risky to move the patient down the hall to the operating room. The applicant maintains that patients on ECMO are only transported when immobility present as a risk factor for certain death. Despite having experience in treating patients with ECMO, the APMC states that transporting patients on ECMO carries significant risk of death. In many instances the applicant states that the risk of transporting a patient on ECMO to be listed for PHT is greater than the risk of waiting to see if the patient recovers on ECMO. APMC maintains that even with its nationally-recognized quality and extensive experience caring for these patients, the most fragile patients do not survive. The applicant asserts that it is impossible to predict the exact number of patients who would have survived, or, for those who did survive would have had enhanced outcomes if APMC had been able to offer PHT.

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Orlando Health posits that every child placed on ECMO or other heart assist device is a potential candidate for PHT as a life-saving procedure. APMC advances that even in the cases where transporting a patient on ECMO from APMC to a transplant facility may be an option, forcing a patient to accept the high and potentially fatal risks of this transport presents a major access issue.

The reviewer notes that the applicant does not provide data illustrating:

- The morbidity or mortality outcomes associated with ECMO patients overall.
- Disparities in health outcomes between patients not transferred on ECMO in comparison to patients transferred while on ECMO.
- The differences in outcomes of potential or identified PHT patients on ECMO who reside within or outside of an OTSA with a PHT program.
- The volume of patients on ECMO who are refused PHT services as a result of transport risks.
- Demonstrated adverse effects of out-migration on PHT patients who reside in OTSA 3 in comparison to PHT patients who reside in an OTSA with a PHT program.

The reviewer also notes that across all OTSAs there are invariable and inevitable geographic constraints for pediatric heart transplant patients as residents within an OTSA do not reside at equidistances to providers within the OTSA. As there are no geographic access standards for the locations of transplant providers within Rule 59C-1.044, therefore the introduction of a provider in OTSA 3 will not necessarily result in increased access to PHT services for residents of the service area.

The applicant maintains that a possible alternative solution to the exigency of rapid follow-up access is for a distant transplant center to provide a specialized outpatient center in the patient's OTSA, but notes that no existing PHT program in Florida has established any outpatient points of access to critical post-transplant care within OTSA 3. In the event that such clinics existed in OTSA 3, the excess risk to patients would not be completely mitigated because definitive diagnosis and treatment of these life-threatening events of acute care rejection or infection require inpatient management. According to the applicant, the inevitable transport to a distant PHT center, with all its inefficiencies, is still a risk and this will ultimately reflect in excess complications, extended hospitalizations, decreased quality of life and death in this fragile pediatric population. APMC maintains that these reflect "not normal circumstances" and impediments to access that warrant approval of the application.

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The reviewer notes that the applicant does not provide data demonstrating the occurrence or extent of the points noted above, there is no pediatric heart transplant provider in OTSA 3 and that Rule 59C-1.044(3)(a), Florida Administrative Code, state:

*(3) Coordination of Services. Applicants for transplantation programs, regardless of the type of transplantation program, shall have:
(a) 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*

Moreover the applicant states that the following reasons merit approval of the proposal at APMC:

- APMC has an extraordinary high birth volume. Annually, approximately 14,000 babies are born at Winnie Palmer Hospital, making it the busiest labor and delivery unit in the State of Florida and one of the busiest in the nation.
- APMC's high birth volume results in a high-volume comprehensive NICU program. More than 1,600 babies are admitted into the Alexander Center for Neonatology each year and more than 40,000 neonates have been successfully treated since the unit opened in 1975.
- APMC's 142-bed NICU is capable of the highest level of care for high-risk newborns and is one of the largest and most technologically advanced NICUs in the U.S., including a 20-bed state-of-the-art unit that is one of only a few in the U.S. dedicated exclusively to pediatric congenital heart care.
- APMC's CVICU, one of only a few in the United States-staffed 24/7 with an in-house cardiologist and other specialized doctors, providing a designated pediatric pharmacist, designated nursing staff, designated therapists and other dedicated resources to meet the specialized needs of pediatric patients, post-cardiac surgery. This results in the best outcomes for the patients.
- APMC also offers the only pediatric echo lab in central Florida accredited in transthoracic, transesophageal and fetal echocardiography.
- APMC provides weekly visits and 24/7 communication for the care and management of patients with single-ventricle heart defects between their first and second surgeries.
- The Fetal Cardiac Program works in tandem with Orlando Health's Adult Congenital Heart Program to offer care for a lifetime. With experience treating patients of all ages, APMC's pediatric cardiologists and pediatric cardiothoracic surgeons team with cardiologists and cardiac surgeons at the Orlando Health Heart Institute.

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The applicant maintains that APMC, in collaboration with its dedicated physicians, has established a solid foundation for a sustainable high quality PHT program that will enhance access for all residents of OTSA 3 and in particular for patients who currently lack access to this life-saving procedure. A description of Orlando Health’s teaching and research activities is provided on pages 16 – 34 of CON application #10518. Additional research activities are provided in Attachment 2 of the application.

Demand Within OTSA 3

The applicant notes that all OTSA 3 patients who receive PHT currently must leave the OTSA for treatment. APMC notes that during the period from 2012 – 2016, 22 children residing in OTSA 3 were treated at UF Health, eight at JHACH and one each at Jackson Memorial Hospital and Memorial Regional Hospital.

Hearts Provided by Florida Hospitals

APMC provides the following chart depicting organ procurement recoveries in the OPTN online database. The applicant notes that documentation of organ procurement recoveries in the OPTN online database only occurs when the organ is used by a recipient in an organ transplant and that organ harvests that do not result in transplantation are not counted.

Pediatric Heart Donations & Transplants in Florida Age 0 - 17 Years, CY 2014 - 2016				
Category	2014	2015	2016	Total
Total Resident Transplants	30	33	37	100
Resident Donor Recoveries	40	33	30	103
Florida Hearts Used in Florida Recipients	14	10	14	38
Florida Hearts Sent Outside Florida	26	23	16	65
Proportion of Florida Donor Hearts Leaving Florida	65%	70%	53%	63%

Source: CON application #10518, Page 42, <https://optn.transplant.hrsa.gov/data/view-data-reports/state-data/>

Based on this data, Orlando Health concludes that it is clear that the pool for heart donor recoveries is not dependent on the state resident for the purposes of transplantation and that over the three-year period the number of Florida heart recoveries exceeded the number of heart transplants.

APMC Service Area

The applicant provides population forecast summaries for different geographic regions by OTSA and within OTSA 3 that are reproduced in the following tables.

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Population by OTSA Age 0 -17 CY 2014 - 2016						
OTSA	Region	Population Estimates			3-Year Total	Percent Change
		2014	2015	2016		
1	North Florida	893,141	901,352	909,012	2,703,505	1.8%
2	West Florida	1,036,411	1,048,033	1,060,790	3,145,234	2.4%
3	Central Florida	846,624	857,597	869,445	2,573,666	2.7%
4	South Florida	1,299,055	1,304,437	1,311,055	3,914,547	0.9%
Total		4,075,231	4,111,419	4,150,302	12,336,952	1.8%

Source: CON application #10518, Page 43, UNOS transplant database: Florida Agency for Health Care Administration, Florida Population Estimates, February 2015

From the data above, Orlando Health highlights the forecasted increase in population size of the 0-17 population in OTSA 3 in relation to other OTSA providers. The applicant notes that in 2016, OTSA 3 represented 21.0 percent of the state’s pediatric population and by 2022 (year three of the proposed transplant program) the service area will increase by 7.2 percent from the 2017 population. A table depicting the current and forecasted estimates of the 17 and under population within OTSA 3 by county is provided on page 44 of CON application #10518.

APMC provides the inpatient origin profile for APMC cardiac services for patients 0 – 17 for CY 2014 – 2016 for the most recent three years of complete data. See the table below.

Cardiac Services Patient Origin Arnold Palmer Hospital, Ages 0-17 CY 2014 - 2016					
Service Area (OTSA)	CY 2014	CY 2015	CY 2016	Three-year Total	Three-Year Distribution
Orange (3)	67	85	76	228	35.3%
Seminole (3)	26	26	21	73	11.3%
Brevard (3)	17	25	22	64	9.9%
Osceola (3)	17	26	17	60	9.3%
Polk (2)	9	19	27	55	8.5%
Volusia (3)	17	17	14	48	7.4%
Lake (3)	15	7	17	39	6.1%
Service Area Total	168	205	194	567	87.9%
Other Florida	19	23	17	59	9.1%
Other States	6	6	7	19	2.9%
Total	193	234	218	645	100.0%
Profile by OTSA					
OTSA 1	8	11	10	29	4.5%
OTSA 2	12	21	30	63	9.8%
OTSA 3	166	193	171	530	82.2%
OTSA 4	1	3	0	4	0.6%
Other States	6	6	7	19	2.9%
Total	193	234	218	645	100.0%

Source: CON application #10518, APH internal data, “Cardiac Services” service-line, page 45

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The reviewer notes that Polk County is adjacent to but not within OTSA 3. The table reveals that 87.9 percent of patients aged 0-17 originate from the applicant's total service area, with the exclusion of Polk County patients (highlighted above), 79.4 percent of patients aged 0-17 receiving cardiac services originate from OTSA 3. The reviewer notes that cardiac services in this table are also not delineated by service type.

Need Methodology #1

Orlando Health uses a need methodology based on the ratio of transplants to cardiac surgeries at existing PHT centers. Based on data reporting to the STS, the applicant notes that within the Congenital (0-17) Cardiac Surgery National Database, APMC is 77th in volume of reported cases and maintains a "very low" overall four-year mortality of 2.2 percent which is significantly lower than the STS peer average of 3.1 percent. The applicant provides a summary of the report in Attachment 15 of the STS standard report Table 1 for the number of APMC operations for the past four years.

APMC additionally maintains that an error in reporting of pediatric open heart surgery volume occurred and provides a corrected table of its pediatric open heart surgery cases by hospital ages 0 – 17 based on corrected data based on STS data reporting and internal hospital records. The reviewer notes that pursuant to Rule 59C-1.033 (Pediatric Open Heart Surgery Program), Florida Administrative Code, the definition of a pediatric patient is "a person under 15 years of age", not up to age 17. The reviewer notes that the applicant submitted updated information for CY 2016 to the local health council on February 6, 2018 based on rule changes that were made on July 30, 2017. The reviewer notes that it appears from the letter addressed to Mr. Ken Peach that the applicant retrospectively applied the updated rule definition to CY 2016 data. The reviewer notes that a copy of the letter was not forwarded to the Agency by the applicant but by the local health council on February 7, 2018.

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Pediatric Open Heart Surgery Cases by Hospital Ages 0 - 17, January - December 2016			
Service Area	Hospital	Cases	Percent of Total
5	Nicklaus Children's Hospital	173	13.7%
5	Memorial Regional Hospital	170	13.4%
3	St. Joseph's Hospital	154	12.2%
4	Arnold Palmer Medical Center	148	11.7%
2	UF Health Shands Hospital	140	11.1%
4	Florida Hospital	125	9.9%
2	Baptist Medical Center Jacksonville	117	9.2%
3	Johns Hopkins All Children's Hospital	110	8.7%
5	Jackson Memorial Hospital	71	4.5%
4	Nemours Children's Hospital	57	11.1%
State Total		1,265	100.0%

Source: CON application #10518, Page 47 “Florida Need Projections for Pediatric Open Heart Surgery Programs and Pediatric Catheterizations Programs”, July 2019 Planning Horizon published by Agency for Health Care Administration, Society for Thoracic Surgeons, Data Quality Report, 2016. Highlighted values are incorrect. The reviewer notes that the applicant reports an additional 49 cases from the volume initially reported in the April 2017 Florida Need Projections for Pediatric Cardiac Catheterization Programs and Pediatric Open Heart Surgery Programs & Utilization Data for Pediatric and Adult Organ Transplantation Programs Publication.

APMC notes the volume of pediatric open heart surgery cases for other OTSA 3 providers was 121 at Florida Hospital and 57 at NCH from CY 2016, with NCH performing its first pediatric open heart surgery case on June 2, 2016.

Orlando Health maintains that the ratio of PHT to open heart surgery varies by hospital with larger PHT programs having higher ratios than the smaller transplant programs. For this reason, APMC forecasts a higher ratio of PHTs to pediatric open heart surgeries to occur at its facility. The applicant expects for some out-migration to occur at APMC where a small number of patients may go elsewhere for transplantation at the start of the PHT program which is subtracted from projected base volume. APMC predicts that while some in-migration of patients needing PHT surgery will occur from other OTSA 3 providers, the projects indicated below do not include in-migration. ²

APMC provides the following tables forecasting PHTs within the first three years of operations of the proposed program.

² The reviewer notes that on page 45 of CON application #10518, the applicant identified patients aged 0 – 17 from Polk County in OTSA 2 as a part of Arnold Palmer Hospital’s Cardiac Services Patient Origin Service Area Total

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Forecasted Pediatric Heart Transplants Arnold Palmer Hospital, Ages 0-17 CY 2020 - 2022				
	Base* 2017	Year One (2020)	Year Two (2021)	Year Three (2022)
OTSA 3 Population 0-17 (for reference only, population growth not considered)	881,645	918,938	932,199	945,201
Forecasted Cardiac Surgeries at APH* (average operations, 2014 - 2016)	167	167	167	167
Ratio of Transplant to Open Heart Surgery conversation rate		4%	7%	7%
Net Transplants Calculation, APH		6.7	11.7	11.7
Outmigration Rate		10%	0	0
Outmigration (Transplants)		-0.7	0	0
Net Transplants, Forecasted		6.0	11.7	11.7

Source: CON application #10518, Pages 48-49. "Florida Need Projections for Pediatric Open Heart Surgery Programs and Pediatric Catheterizations Programs", July 2019 Planning Horizon published by Agency for Health Care Administration; APH internal data; Florida Agency for Health Care Administration, Florida Population July 1 Estimates, February 2015. *Society for Thoracic Surgeons "Congenital Cardiac Surgery Database, Data Quality Report".

The applicant states that analysis of relevant data indicates a relationship between the number of PHTs performed and the volume of cardiac surgery cases performed as evidenced by the following table:

Pediatric Open Heart Surgery Cases and Heart Transplants by Hospital Ages 0 -17, January - December 2016				
OTSA	Hospital	Cardiac Surgeries	Transplants	Transplant as Percent of Cardiac Surgery
1	UF Health Shands Hospital	140	15	10.7%
2	Johns Hopkins All Children's Hospital	110	8	7.3%
3	Memorial Regional Hospital	170	7	4.1%
4	Jackson Memorial Hospital	71	4	5.6%
State Total		491	34	6.9%

Source: CON application #10518, Page 49. "Florida Need Projections for Pediatric Open Heart Surgery Programs and Pediatric Catheterizations Programs", July 2019 Planning Horizon published by Agency for Health Care Administration.

The applicant also provides a summary of historical open heart surgery data performed from 2014 – 2016 at APMC, which is indicated to demonstrate actual volumes of pediatric heart surgery cases at APMC. The reviewer notes that the chart below, including the notes that were included with it are confusing—noting that the applicant indicates that 2015 data should be corrected data but does not include other “corrected” data that it submitted to the local health council on February 6, 2018. In addition, the reviewer notes that the data collected by local health council should only include the 0-14 population while the applicant has shown previously that the STS data includes the 0-17 population.

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Historical Open Heart Surgery Data Arnold Palmer Hospital CY 2014 - 2016 *Corrected				
Data Source	2014	2015	2016	2014 - 2016 Average
Local Health Council	144	98*	99	144
Actual APH (STS Data)	157	195	148	167

Source: CON application #10518, Page 50. "Florida Need Projections for Pediatric Open Heart Surgery Programs and Pediatric Catheterizations Programs", July 2017 - 2019 Planning Horizons published by Agency for Health Care Administration; APH internal data as reported to the Society for Thoracic Surgeons, Data Quality Report, 2016. Note: * excluded nine patients in May and 14 patients in June; correct totals should be 121.

APMC maintains that this methodology results in conservative projected volumes of six, 12 and 12 during the first three years of operation which satisfy Rule 59C-1.044(6)(b)2, Florida Administrative Code.

Need Methodology #2 – Community Need Analysis

Orlando Health provides another need methodology which evaluates the ratio of PHT to principal diagnosis codes that are most frequent indicators for PHT. APMC states that this need methodology converts patients by diagnosis to PHT surgery cases. Medical and clinical staff at AMPC analyzed ICD-10 codes most likely to result in a PHT, identified as "Most Frequent Indicators". The reviewer notes that Attachment 3 of the application includes ICD-10 Diagnosis Code Predictors. The applicant applies these indicators to the patient case mix at the existing PHT centers allowing for a ratio to be developed between the most frequent indicators of patients and the ratio of PHTs. The applicant provides a table summarizing the most frequent indicators for transplant inpatients profiled by existing pediatric heart transplant providers (JHACH, UF Health, Memorial Regional Hospital and Jackson Health System) for pediatric patients aged 0-17, the derived average ratio for this metric for all four providers from 2014 – 2016 is .187 (CON application #10518, Page 51).

APMC additionally contextualizes this analysis to OTSA 3 pediatric open heart surgery providers in order to identify the potential pool of pediatric heart transplant eligible candidates, for which APMC forecasts an average of 82 potential PHT-eligible candidates per year based on the volume of pediatric open heart surgery cases performed at APMC, Florida Hospital and NCH from CY 2014 – 2016 (CON application #10518, page 52).

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The applicant provides the following volume forecast based on this analysis:

Pediatric Heart Transplant Projections, OTSA 3 Community Need (Ages 0 -17) CY 2020 - 2022				
	Base* 2017	Year One (2020)	Year Two (2021)	Year Three (2022)
OTSA 3 Population 0-17 (for reference only, population growth not considered)	881,645	918,938	932,199	945,201
Most Frequent Indicators for Heart Transplants at Community OHS Providers	82	82	82	82
Ratio of Transplant to Most Frequent Indicators conversion rate		10%	18%	18%
Net Transplants, Forecasted		8.2	14.8	14.8

Source: CON application #10518, Page 52. UNOS transplant database; APH internal data; Florida Agency for Health Care Administration, Florida Population July 1 Estimates, February 2015. *Base equals 3-year average of 2014 - 2016 data

Orlando Health states that the second methodology further demonstrates the reasonableness of APMC’s projections in light of Rule 59C-1.044(6)(b)2, Florida Administrative Code, relating to minimum number of PHT procedures by the end of the second year of operation.

The applicant provides the following table summarizing the forecasted APMC pediatric heart transplants using both methodologies and the average length of stay (ALOS) based on the more conservative forecast which is reproduced below:

Summary of Forecasted APMC Pediatric Heart Transplants Ages 0-17, CY 2020 - 2022			
	Year One 2020	Year Two 2021	Year Three 2022
Forecasted Pediatric Heart Transplants			
Need Methodology #1: APMC Based	6.0	11.7	11.7
Need Methodology #2: Community OTSA 3 Based	8.2	14.8	14.8
Forecasted APH Transplants	6	12	12
Average Length of Stay*	125	115	110
Patient Days Related to Performed Transplants	750	1,380	1,320

Source: CON application #10518, Page 53

An analysis of the forecasted ALOS is provided based on the ALOS of PHT cases across all existing providers for CY 2014 – 2016. The applicant maintains that these assumptions are reasonable and reflect reductions of stay gained through transplantation experience (CON application #10518, page 54).

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.

Orlando Health, Inc. identifies David Nykanen, MD as the current Director of Cardiology and the Pediatric Cardiac Catheterization Laboratory at The Heart Center at APMC. Orlando Health references Dr. Nykanen's board certifications in pediatrics, pediatric cardiology and interventional cardiology with a specialization in the hybrid OR. A copy of David Nykanen's CV is included in Attachment 6 of CON application #10518.

Per Florida Department of Health's MQA Search Tool, David Nykanen is a Medical Doctor with staff privileges at APMC and Orlando Regional Medical Center, Dr. Nykanen holds board certifications in Pediatrics and Pediatric Cardiology by the American Board of Pediatrics. Dr. Nykanen appears as a staff member on the Pediatric Cardiology team at The Heart Center at Arnold Palmer's website:

<https://www.arnoldpalmerhospital.com/physician-finder/david-gordon-nykanen-md>

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

APMC identifies Hamish M. Munro, MD as Clinical Associate Professor of Anesthesiology at the University of Central Florida College of Medicine and Director of Pediatric Cardiac Anesthesiology at The Heart Center at APMC. A summary of Dr. Munro's experience and credentials is provided and a copy of Dr. Munro's CV is included in Attachment 6 of CON application #10518.

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Per Florida Department of Health's MQA Search Tool, Hamish Munro is a Medical Doctor with staff privileges at APMC and Orlando Regional Healthcare System, Dr. Munro is board-certified in Anesthesiology by the American Board of Anesthesiology. Dr. Munro also appears as an anesthesiologist at The Heart Center at APMC's website: <https://www.arnoldpalmerhospital.com/physician-finder/hamish-m-munro-md>

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

Orlando Health indicates that as part of the proposal, APMC proposes to renovate and convert an older, open-design five-bed pediatric CVICU pod into two isolation rooms.

The applicant includes descriptions of the architectural plans for these proposed renovations in Schedule 9 of CON application #10518.

(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 maintains that this criterion is not applicable as there are no existing PHT providers in OTSA 3 and no other PHT program has been approved for this same service planning area.

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

The applicant provides the following table summarizing its need methodologies for the proposed project.

Summary of Forecasted APMC Pediatric Heart Transplants Ages 0-17 (CY 2020 - 2022)			
Forecasted Pediatric Heart Transplants	Year One (2020)	Year Two (2021)	Year Three (2022)
Need Methodology #1: APMC Based	6.0	11.7	11.7
Need Methodology #2: Community OTSA 3 Based	8.2	14.8	14.8
Forecasted APMC Transplants	6	12	12
Average Length of Stay	125	115	110
Patient Days Related to Performed Transplants	750	1,380	1,320

Source: CON application #10518, page 103

The applicant maintains that the forecasted number of transplants at APMC was selected from the more conservative of two need methodologies. APMC states that the “community need” approach is useful to see the potential underlying need and that OTSA 3 can support a PHT center without adversely affecting existing PHT programs in other parts of the state. Moreover, Orlando Health indicates that as previously shown it is clear that the pool for heart donor recoveries is not dependent on the state of residence for the purposes of transplantation. The applicant states that over the three-year period, however, the number of Florida heart recoveries exceeded the number of PHT transplants.

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

APMC provides the following table summarizing its provision of duplicated cardiac catheterizations and open heart surgeries on patients aged 0-14 and 0-17 in January – December 2016 performed at APMC. The reviewer notes that the applicant’s data does not match previously submitted data to the local health council. The reviewer further notes that updated data for CY 2016 provided to the local health council on February 6, 2018 was included based on a retrospective application of a definition amended which was finalized by the Agency on July 30, 2017. See

APMC Heart Program Volume: January - December 2016		
	0-14	0-17
Catheterizations	227	240
Open Heart Surgeries	138	141

Source: CON application #10518, page 104

The applicant indicates that a pending rule change to 59C-1.044, Florida Administrative Code, may expand the pediatric age cohort up to age 21 for Medicaid designated transplant centers which would then widen the eligible patient pool even further.

2. Agency Rule Criteria

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

- a. **Coordination of Services. Chapter 59C-1.044(3), Florida Administrative Code. Applicants for transplantation programs, regardless of the type of transplantation program, shall have:**

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

The applicant maintains that Orlando Health and APMC both have the staff and resources necessary to care for a PHT patient's chronic illness prior to transplantation, medical and surgical needs during transplantation and medical care in the post-operative period. APMC states that these services will include inpatient and outpatient care available on a 24-hour basis which are designed to provide individualized physical, emotional, spiritual and psychosocial care.

The applicant provides a list of notable heart specialists and support staff who will be a part of the program on pages 73 – 77 of CON application #10518, copies of curriculum vitae for these staff members are included in Attachment 6 of CON application #10518. APMC also describes its existing services and designations as a Level I and Pediatric Trauma Center with a nationally-ranked pediatric cardiology program. The applicant describes its capacity to recruit and retain highly skilled surgical and medical specialists and other key clinical personnel necessary to implement and maintain quality of care and a range of complex tertiary services.

Orlando Health states that staffing specific to the heart transplant program will include the following key positions:

- Medical Director
- Pediatric Transplant Surgeon
- Transplant Creditor
- Quality Accreditation Coordinator
- Transplant Psychologist
- Transplant Social Worker
- Transplant Nutritionist
- Transplant Financial Counselor

2. **If cadaveric transplantation will be part of the transplantation program, a written agreement with an organ acquisition center for organ procurement is required. A system by which 24-hour call can be maintained for assessment, management and retrieval of all referred donors, cadaver donors or organs shared by other transplant or organ procurement agencies is mandatory.**

The applicant identifies having an agreement for organ and tissue procurement services with TransLife since January 2017 which includes 24-hour call. A copy of the written agreement with TransLife is included in Attachment 7 of CON application #10518. A letter accompanied with the agreement identifies TransLife as a Centers for Medicare and Medicaid certified organ procurement organization servicing 10 counties in Central Florida. The applicant notes that the letter states that TransLife will provide deceased donor organs for the purposes of transplantation to the proposed PHT program at APMC. The letter is authored by the Executive Director of TransLife, Virginia McBride.

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

Orlando Health indicates that APMC has both a Pediatric ICU and a CVICU comprising of a 20-bed “state-of-the-art” unit dedicated exclusively to pediatric congenital heart care. The applicant states that the CVICU is staffed 24 hours, 7 days weekly, 365 days a year by an attending physician intensivist who is available in-house. The applicant maintains that APMC is also staffed with a “highly-specialized unit” with tenured nursing staff to better meet patient needs.

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

APMC states that a clinical review committee will be established for evaluation and decision-making regarding the suitability of PHT candidates upon CON approval. The clinical review committee will be organized under the leadership of the Program Director (William DeCampli, MD) and developed consistently with OPTN and CMS best-practices and regulatory requirements. Orlando Health

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identifies the following staff members as members of the APMC heart transplant clinical review committee:

- Transplant Program Director
- Transplant Attending Physician
- Transplant Coordinator
- Transplant Pharmacist
- Transplant Clinic and Inpatient Nursing
- Clinical Social Worker
- Child Life Specialist
- Spiritual Counselor (as needed)

The applicant states that the clinical review committee will discuss potential new candidates, patients approaching treatment initiation and patients currently in treatment. APMC indicates that the transplant coordinator will make sure that all necessary documents are in the chart pertaining to each patient being reviewed. During clinical review committee meetings the applicant indicates that all new patients will be presented in detail with the transplant attending physician summarizing the case to the committee. The applicant maintains that key elements are stated to include:

- Patients' eligibility and appropriateness for transplant will be assessed
- Preparative regimens will be discussed and selected
- Donors will be discussed and selected

Moreover, Orlando Health indicates that any additional care concerns or areas for support regarding new patients will be discussed. All members of the committee will also have the opportunity to comment on the case and raise any concerns, resolutions to potential programs are also expected to be identified at this point notes the applicant. APMC asserts that the coordinator will document comments in the patient chart for future reference. APMC indicates that the committee will present new protocols to the group and educate team members regarding new studies or protocols.

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.

APMC notes that it will include written protocols for the selection and management of heart transplant patients that

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will be used to guide care provided in the proposed program. The development of a complete set of protocols is expected to be developed upon CON approval under the guidance of William DeCampi, MD, PhD, Program Director. Orlando Health also states that a policy for developing standard operating procedures for the program will be created. In Attachment 13 of CON application #10518, the applicant provides a copy of CMS Organ Transplant Interpretive Guidelines that will be used to create written protocols for the proposal. APMC describes how quality patient care and process improvement are a hallmark of current cardiology services at its facility and discusses its voluntary reporting and performance record documented to the Society of Thoracic Surgeons National Database.

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.

Upon CON approval, APMC indicates that a set of protocols for PHT care will be developed. Protocols will include detailed therapeutic and evaluative procedures for both acute and long-term management of each transplant program patient, including the management of commonly encountered complications. The applicant includes a sample of a Pediatric Heart Transplant Guide in Attachment 9 of CON application #10518.

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.

APMC reiterates its existing agreement with TransLife, which was previously noted as an organ servicing organization that will fulfill this requirement.

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.

APMC identifies an existing contractual arrangement with OneBlood, Inc. for these services. In Attachment 8 of CON

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application #10518 a support letter from OneBlood is included, a sample of the agreement is not provided by the support letter authored by George School (President and CEO, OneBlood) states that : “[OneBlood] is committed to supply the increase of blood products needed for [the] added procedures [This] reference and histocompatibility laboratory will be able to support the additional testing required by your facility, including tissue typing for the heart transplant program” (CON application #10518, Attachment 8).

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

The applicant describes having board-certified pathologists and the full resources of the Orlando Health and APMC pathology and laboratory services available to provide pathology and laboratory support for the proposed PHT service. APMC indicates that the laboratory will have the appropriate capability for analyzing biopsy material as necessary. Orlando Health underscores the following key capabilities of its clinical laboratories below:

- Orlando Health Clinical Laboratories provide both clinical and anatomical pathology services for inpatients, outpatients and outreach customers. In addition, services are provided at the Point-of-Care (bedside testing) and alternative testing sites. Laboratory patient service centers are located in the community.
- Orlando Health Clinical Laboratories has seven laboratory testing site locations serving the system hospitals and community including: Orlando Regional Medical Center Laboratory and APMC Laboratory.
- Orlando Health Laboratories provide a comprehensive testing menu. Any testing not offered at Orlando Health Laboratories is sent to an approved referenced laboratory.
- The laboratories perform testing using standardized technical procedures, normal test ranges and laboratory practices. The laboratory quality management program uses the framework from the Clinical and Laboratory Standards Institute. There are quality system essentials which are the fundamental components used to establish the quality management system. Our Clinical Laboratories evaluate quality and the continuum of patient care through quality improvement indicator results and interaction with our customers to ensure

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positive patient outcomes. Process improvements are accomplished through multidisciplinary teams consisting of ancillary partners.

- The laboratory operates 24 hours a day, seven days a week. The main laboratory provides both general diagnostic testing including hematology, chemistry, coagulation, urinalysis, immunology and centralized services with highly complex specialized testing to include anatomical pathology, cytology, electron microscopy, microbiology, virology, molecular diagnostic, flow cytometry, toxicology and transfusion services

The applicant further describes how Orlando Health Laboratory provides laboratory services to APMC and on-site APMC has frozen section, point-of-care testing on the nursing units, and a pediatric outpatient draw site.

The applicant provides a description of its blood-banking services and provides copies of its laboratory credentials in Attachment 14 of CON application #10518.

10. Blood banking facilities.

APMC states that both Orlando Health and APMC have blood banking facilities and services necessary to support the proposed transplant service. The applicant also references the support of OneBlood. A description of the APMC blood bank, which is available 24 hours a day, seven days a week is provided below:

- The scope of products supplied includes red blood cells, platelets, fresh frozen plasma and cryoprecipitate. These products are acquired by contract with Florida Blood Centers. There is capacity to provide the needs of the proposed bone marrow service with washed, irradiated or leukocyte depleted products.³
- Services include: blood type and RH testing, cross matching, direct antiglobulin testing, antibody screens, irradiation and washing of blood products. The patient population is neonates, pediatrics and women with the only Level I pediatric trauma center in this area.

³ The reviewer notes that the proposal is for a pediatric heart transplantation program not for the approved but not implemented pediatric bone marrow transplant program.

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

APMC maintains that it has in place a large, vigorous and effective internal staff training and development department which will incorporate the requirements of the proposed PHT program into its existing training and education activities. The applicant provides a description of its corporate education structure which includes multiple areas, educators within corporate education are stated to use various teaching methods which include auditory, kinesthetic and visual methods to teach all team members. APMC notes that managers within corporate education have specific focus areas which contribute to integral parts of the system-wide plan. A summary of the corporate education structure is provided on page 86 of CON application #10518. Orlando Health describes how its corporate education department is responsible for the overall centralized education of team members at all levels to include direct-care nurses, managers, administrations and clinical technicians.

In order to specifically meet the needs of the Department of Nursing, the applicant indicates that a member of the Corporate Education Department is present on all nursing committees and is responsible for relaying educational needs to the CED. The applicant maintains that program development is based upon ongoing trends, quality data and data collected from performance evaluations and educational needs are assessed from input from leaders and direct-care nurses. APMC notes that compliance with regulatory and The Joint Commission requirements, performance improvements, root cause analysis action plans, issues identified through the Nurse Practice Council, trended data from regulatory and incident reporting procedures are among the ways education needs are determined. The applicant indicates that the top priority for identifying educational need is patient safety. Descriptions of corporate education physical resources, fiscal resources, educational and development courses and training for the heart transplantation program are included in CON application #10518, pages 87 – 88.

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

APMC states that successful PHTs depend on the effective coordination among medical, social and spiritual professionals as well as the family and friends who comprise the recipient's care-giving network. Orlando Health states that educational materials are under development for patients and their families regarding both pre-, during and post-transplantation care. The applicant states that the booklet "Pediatric Heart Transplant: A Guide for Patients and Families" (or similar) will be provided to each patient and family when they have been evaluated and determined to be a transplant candidate. APMC maintains that patient and family education is an ongoing process which begins with diagnosis and continues throughout the entire treatment and post-treatment. Families and patients receive an educational binder which includes information about diagnosis, treatment, medications, supportive care, available resources and physician and nurse contact information. The applicant notes that education for pediatric heart transplant families will be initiated by the transplant physician and heart transplant coordinator. APMC indicates that the education will include the patient's primary nurse, social worker, child life specialist, pharmacist, nutritionist and radiation oncologist.

b. Staffing Requirements.

Applicants for transplantation programs, regardless of the type of transplantation program, shall meet the following staffing requirements. Chapter 59C-1.044(4), Florida Administrative Code.

- 1. A staff of physicians with expertise in caring for patients with end-stage disease requiring transplantation. The staff shall have medical specialties or sub-specialties appropriate for the type of transplantation program to be established. The program shall employ a transplant physician, and a transplant surgeon, if applicable, as defined by the United Network for Organ Sharing (UNOS) June 1994. A physician with one year experience in the management of infectious diseases in the transplant patient shall be a member of the transplant team.**

The applicant indicates that Orlando Health and APMC have a staff of physicians with extensive expertise in caring for patients with the types of diseases that at times progress to a point of requiring

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transplantation. Orlando Health indicates that physicians have appropriate training and experience to serve as heart transplant physicians and heart failure physicians as well as related specialties. A list of physician staff with consolidated resumes is included on pages 89 – 91 of CON application #10518. Curriculum vitae for the following staff are included in Attachment 6 of the application:

- William Decampoli, MD, PhD (Cardiovascular Surgery)
- David G. Nykanen, MD (Cardiology)
- Carlos Javier Blanco, MD (Cardiology)
- Hamish M. Munro, MD (Anesthesiology)
- Kevin J. de la Rosa, MD (Anesthesiology)
- Donald A. Plumley, MD (General Surgery)
- Orlando R. Gonzalez, MD (Pathology)
- Alejandro Jordan-Villegas, MD (Infectious Disease)

APMC states that the recruitment of a transplant surgeon and a heart failure cardiologist and additional providers to augment resources are already in place. Orlando Health provides a three-pronged approach for recruitment which is noted below:

- Engage Orlando Health's existing, outside professional search firm to assist with this effort
- Engage a professional recruiter with extensive expertise in this field, and
- Use existing professional contacts, relationships and networking with affiliated societies/meetings

2. A program director who shall have a minimum one year formal training and one year of experience at a transplantation program for the same type of organ transplantation program proposed.

William DeCampoli, MD, is cited by the applicant as the program director for the transplant program. Dr. DeCampoli is identified by the applicant as the Chief of Pediatric Cardiac Surgery and Co-Director of The Heart Center at APMC. A summary of Dr. DeCampoli's experience and credentials is provided on page 92 of CON application #10518 and a curricula vita is provided in Attachment 6 of CON application #10518. Per Florida Department of Health's MQA Search Tool, William DeCampoli, MD, is a physician with staff privileges at APMC, Orlando Regional Medical Center-Orange and Miami Children's Hospital. Dr. DeCampoli is board certified in Thoracic Surgery by the American Board of Thoracic Surgery. Dr. DeCampoli is listed as a physician on staff at The Heart Center at APMC per Orlando Health's website.

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APMC reiterates its ongoing recruitment of a transplant surgeon, a heart failure cardiologist and additional providers and its three-pronged recruitment approach.

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

The applicant describes how 156 beds comprise APMC and these beds are exclusively dedicated to care for children and adolescents. Staff at APMC are noted for their experience in the special needs of children and delivering such care full-time. “Virtually all” of the care delivered in the various departments discussed in the application are described as ancillary or supportive to the proposed PHT program including the Heart Center. The Heart Center at APMC is cited by the applicant as a nationally recognized program, bringing together a specialized team to offer the most comprehensive heart care in central Florida for infants, children and teens. Since 1989, APMC maintains that the Heart Center has treated over a million kids and performs more than 200 cardiac operations annually. The Pediatric Cardiac Intensive Care Unit at APMC is noted as one of the only ICUs dedicated exclusively to pediatric congenital heart care, with an average of 375 admissions per year. Orlando Health also indicates that together, APMC and Winnie Palmer Hospital for Women and Babies constitute one of the largest facilities dedicated to children, babies and women in the United States.

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

Orlando Health states that in general, APMC has a wide and deep capability to care for related chronic conditions which may impact PHT patients during the course of their care, both prior to and post-transplantation. The applicant reiterates the services provided through the Heart Center and the CVICU at APMC.

APMC also indicates being magnet designated through the American Nurses Credential Center’s Magnet Recognition Program and provides summary of key areas of focus in nursing and healthcare on page 93 of CON application #10518 which are noted below:

- Visionary leadership transforming the organization to meet challenging needs
- Empowered staff properly prepared to face all challenges
- Competent, dedicated and skilled nurses
- Continued innovation within staff knowledge, clinical practice and systemic improvements

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- Outcomes measurement systems in place throughout the entire organization

Orlando Health also notes that Magnet designated organizations usually demonstrate:

- Higher patients satisfaction with nurse communication, availability of help and receipt of discharge information
- Lower risk of 30-day mortality and lower failure to rescue
- Lower rates of falls

The applicant notes that per Schedule 6A of the application Orlando Health currently employs nearly 3,000 registered nurses and has more than 700 medical assistants and advanced registered nurse practitioners on staff, including existing dedicated CVICU nursing staff.

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

The applicant reiterates its existing blood-banking resources in-house that are available 24 hours a day, seven days a week to meet the needs of transplant patients on a long-term basis, the description of its blood banking resources and services. APMC notes that Orlando Gonzalez, MD, is identified as the medical director of the APMC laboratory and blood bank. Dr. Gonzalez' curricula vita does not appear in Attachment 6 of CON application #10518. Per Florida Department of Health's MQA Search Tool, Orlando Gonzalez, MD, is a physician with staff privileges at Orlando Regional Healthcare System. Dr. Gonzalez is also board-certified by the American Board of Pathology in Anatomic and Clinical Pathology and Pediatric Pathology. APMC references its support letter from OneBlood in Attachment 8 of CON application #10518.

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

APMC states that both Orlando Health and APMC have nutritionists with appropriate knowledge, skill and expertise to address the nutritional needs of patients to be served in the proposed PHT program. The CV of Stephanie Holmes, MS, clinical nutrition manager of APMC is included in Attachment 6 of CON application #10518. Pediatric nutrition services and nutrition are described as vital components of every child's treatment, recovery process and daily life by the applicant. APMC indicates that it has registered dietitians who specialize in pediatrics in inpatient and

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outpatient settings. Dietitians provide a wide variety of nutrition support for patients with various conditions and illnesses and APMC indicates that dietitians are board-certified in nutrition support and pediatrics for patients that need to receive nutrition by feeding tube or intravenously. APMC notes its specialized programs like the Feeding Difficulties Center to work with patients who are learning or re-learning eating skills. The applicant indicates that critical care units at APMC have dietitians that participate with a multidisciplinary healthcare team to provide nutrition care to these patients. APMC states that dietitians participate in educating future pediatric dietitians through affiliations with FSU and UF.

The applicant indicates that clinical nutrition services provide timely nutritional assessments, counseling, nutrition education and diet instructions as ordered by the medical staff and/or as deemed appropriate according to the standards of care to meet the needs of patient's various backgrounds. A description of services provided, orientation, education and competencies is discussed on pages 96 – 97 of CON application #10518.

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

The applicant reiterates having all the necessary personnel and resources in place to provide appropriate respiratory care services to heart recipients in the proposed program. A description of services is included on pages 98 – 99 of the application. Philip McCabe, RRT, is identified as the department manager who with the advisement of the medical director is responsible for the overall function and delivery of respiratory care services at APMC on a twenty-hour basis. Mr. McCabe is noted to have extensive experience in PICU, CVICU and NICU.⁴ A CV for Philip McCabe is included in Attachment 6 of CON application #10518. The applicant notes that a supervisor will be responsible for the monitoring of all respiratory care delivery throughout the hospital, around the clock. Orlando Health notes that all critical care services are delivered by registered, certified or registry-eligible therapists who have completed the prescribed orientation and competency check.

APMC states that department management will collaborate with all departments to resolve patient and non-patient related problems. The applicant describes respiratory care practitioners as integral

⁴ Philip McCabe is also listed as a licensed Registered Respiratory Therapist on Florida Department of Health's MQA Search Portal, with an address of record listed at APMC

members of the health care team who, with guidance of a physician, assist with determining and delivering appropriate treatment for acute and chronic disorders of the pulmonary and cardiovascular systems. The applicant notes that the respiratory care departments at Orlando Health are accessible 24 hours a day, seven days a week. A list of respiratory care services based on policies, processes and guidelines on pages 98 – 99 of the application. A summary of respiratory staff orientation, education and competencies is included on page 99 of the application. Narrative descriptions of general respiratory staff orientation, education and competencies is included on page 99 of CON application #10518.

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

Orlando Health and APMC note that together it employs a number of patient services directed toward assessing patient needs, counseling patients and families in accessing needed financial support and community resources. Clinical social workers are identified by the applicant as key members of the healthcare team who work with patients and their families to help manage the difficulties of a hospital stay. The CV of Ana T. Rodriguez, LCSW, is referenced in Attachment 6 of the application. The applicant discusses the role of clinical social workers as experienced mental health professionals with master's degrees licensed by the State of Florida, who provide counseling and support to help families cope with the emotional stresses of illness and hospitalization, assist with discharge planning to ensure continuity of care and referrals to community services and resources. A summary of staff orientation, education and competencies is provided on pages 100–101 of the application. Orlando Health discusses its employment of full-time neuropsychologists like Lisa Cox Gibbons, a doctorate-trained psychologist who specializes in pediatric psychiatric and behavioral comprehensive assessments for both diagnosis of mental health conditions and behavioral indications for difficulties in patients' abilities for comprehension or compliance. Specially-trained psychologists are considered a vital part of all comprehensive psychosocial assessments according to the applicant, treatment programs and rehabilitation programs ranging from traumatic injury to organ transplantation.

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APMC maintains that chaplains and pastoral counselors are also available to patients. Attachment 10 of CON application #10518 includes a description of Spiritual Care available to patients which includes counseling services to assist in alleviating the burden of the financial aspects of health care. APMC states that financial services available to patients include consultation with a financial liaison to assist patients with billing and payment throughout the care process. The applicant maintains that financial liaisons also assist with bridging the gap between patients and insurance companies to ensure that patient care never suffers regardless of financial resources.

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

APMC expresses the intent to comply with this requirement.

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 following mileage chart indicates the driving distances from the proposed location in CON application #10518 to the four existing Florida PHT providers.

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Driving Distances in Miles - CON application #10518 Orlando Health, Inc. d/b/a Arnold Palmer Medical Center and Existing Florida Pediatric Heart Transplant Providers					
Facility	Arnold Palmer Medical Center	Johns Hopkins All Children's Hospital	UF Health Shands Hospital	Memorial Regional Hospital	Jackson Memorial Hospital
Arnold Palmer Medical Center		106 miles (114 min)	111 miles (108 min)	219 miles (208 min)	232 miles (218 min)
Johns Hopkins All Children's Hospital	106 miles (114 min)		153 miles (144 min)	248 miles (243 min)	261 miles (245 min)
UF Health Shands Hospital	111 miles (108 min)	153 miles (144 min)		320 miles (298 min)	333 miles (303 min)
Memorial Regional Hospital	219 miles (208 min)	248 miles (243 min)	320 miles (298 min)		18.6 miles (54 min)
Jackson Memorial Hospital	232 miles (218 min)	261 miles (245 min)	333 miles (303 min)	18.6 miles (54 min)	

Source: Mapquest

Orlando Health states that there are no PHT programs operating or approved in OTSA 3. The applicant describes how the program is warranted for “not normal circumstances” and discusses how APMC has the largest NICU under one roof in the country, which results in a disproportionate volume of newborns per year with complex forms of congenital heart disease. APMC attests to having extensive experience treating the most complex pediatric cardiology patients. Within the past four years, APMC documents having 33 NICU patients placed on ECMO and 11 CVICU patients placed on cardiac by-pass or other heart assist devices after surgery. Within this patient population, the applicant identifies a significant number of patients that are too sick to be transferred from APMC to another facility to receive a PHT. Orlando Health states that many of these patients do not get listed for a PHT since they likely would not survive the necessary transfer.

Orlando Health describes how patients on ECMO are chemically paralyzed, since slight movements can cause the cannula to shift and potentially cause death. Despite having experience in treating patients with ECMO, APMC states that transporting patients on ECMO carries significant risk of death. In many instances, APMC states that the risk of transporting a patient on ECMO listed for PHT is greater than the risk of waiting to see if the patient recovers on ECMO. APMC maintains that even with its nationally-recognized quality and extensive experience caring for these patients, the most fragile patients do not survive. The applicant additionally asserts that it is impossible to predict the exact number of patients who would have survived, or, for those who did survive would have had enhanced outcomes if APH had been able to offer PHT.

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Orlando Health posits that every child placed on ECMO or other heart assist device is a potential candidate for PHT as a life-saving procedure. APMC advances that even in the cases where transporting a patient on ECMO to a transplant facility may be an option, forcing a patient to accept the high and potentially fatal risks of this transport presents a major access issue.

Orlando Health additionally discusses the critical timing of post-transplant care which necessitates optimal medical management ideally within the patients' service area in addition to other specialized transplant urgent care at that center. While "distal" transplant centers may counter that they maintain 24/7 access for follow-up and for the aforementioned acute circumstances, travel times of two hours pose a barrier for compliance. APMC proposes that patients may "wait out" symptoms to see if they resolve to avoid a needless six to ten hour commitment on the road. The applicant asserts that patients in the eight to 17 age group (the most commonly transplanted age range) pose a particular behavioral challenge for compliance and are most apt to deny symptoms, fail an appointment or reschedule one. According to the applicant, the inevitable transport to the distant transplant center, with all its inefficiencies, is still a risk and this will ultimately reflect in excess complications, extended hospitalizations, decreased quality of life and death in this fragile pediatric population. APMC maintains that these reflect "not normal circumstances" and impediments to access that warrant approval of the application.

- 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.**

Orlando Health, Inc. currently operates Orlando Health, Arnold Palmer Medical Center, Dr. P. Phillips Hospital and South Seminole Hospital all in District 7, Subdistrict 2, Orange County. For the three-year period ending on January 16, 2018 the following table summarizes the substantiated complaint history of hospitals operated by Orlando Health, Inc.

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Orlando Health, Inc. 36-Month Substantiated Complaint History		
Complaint Category	Number Substantiated	Number Substantiated without Deficiency
Orlando Health		
Resident/Patient/Client Rights		1
Nursing Services	1	1
Quality of Care/Treatment	1	1
South Seminole Hospital		
State Licensure	2	
Nursing Services	2	
Admission, Transfer & Discharge Rights	1	
Resident/Patient/Client Assessment	1	
Resident/Patient/Client Rights	1	

Source: Florida Agency for Healthcare Administration Complaint Records. January 16, 2015 – January 16, 2018. Note one complaint can encompass multiple complaint categories

For the three-year period ending on January 16, 2018 hospitals operated by Orlando Health, Inc. received 12 substantiated complaints.

In response to this criteria, the applicant provides a list of historical distinctions and awards that are summarized below as evidence of AMPC capacity to provide quality care.

- For the eighth consecutive year, APMC has been ranked as a Best Children’s Hospital by *U.S. News and World Report*. Of approximately 220 children’s hospitals in the United States, APMC was ranked in the top 50 in diabetes and endocrinology, orthopedics, pulmonology, cardiology/heart surgery and urology.
- APMC has received the Get With the Guidelines – Resuscitation Gold Award for implementing specific quality improvement measures outlined by the American Heart Association for the treatment of patients who suffer cardiac arrests in the hospital. In order to qualify, hospitals must comply with the quality measure for two or more consecutive years.
- The Heart Center at APMC is a nationally recognized program, bringing together a specialized team to offer the most comprehensive heart care in Central Florida for infants, children and teens. Since 1989, the Heart Center at APMC has treated over a million kids and performs more than 200 cardiac operations annually. The CVICU at APMC is one of the only ICUs dedicated exclusively to pediatric congenital heart care, with an average of 375 admissions per year.
- APMC is magnet designated through the American Nurses Credential Center’s Magnet Recognition Program, the most prestigious distinction a health care organization can receive for nursing excellence.
- In 2016, the Leapfrog Group named APMC a recipient of its Top Children’s award.

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- Each year APMC sees thousands of children and families, many of whom have traveled from outside the City of Orlando. The Ronald McDonald House, located on the APMC downtown campus, is able to provide a home away from home for these families while their child is undergoing treatment.
- APMC has a Family Advisory Council, which includes a group of team members, parents and families whom have had an experience at the hospital with their child. The mission of the Family Advisory Council is to enhance the delivery of care at APMC through the collaboration of families and staff to provide state-of-the-art, family-centered healthcare, focused on restoring the joy of childhood in the environment of compassion, healing and hope.
- Together, APMC and Winnie Palmer Hospital for Women and Babies— is one of the largest facilities dedicated to children, babies, and women in the United States. The two hospitals are connected through a two-story connector bridge, allowing easy transport of patients to medical services and efficient sharing resources between the physicians and clinical staff providing services to women, babies and children. With the largest NICU in the country (142 beds and high risk OB services) along with the ability to deliver in the CVOR and the availability of the hybrid cath lab at APMC, the applicant is able to collaborate to deliver care to the most complex and emergent infants.

APMC provides a copy of its hospital license in Attachment 11 and a copy of its accreditation by The Joint Commission in Attachment 12 of CON application #10518.

- 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.

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

Orlando Health, Inc. & Controlled Affiliates		
	Sep-16	Sep-15
Current Assets	\$721,741,000	\$812,852,000
Total Assets	\$3,356,823,000	\$3,032,455,000
Current Liabilities	\$363,914,000	\$326,433,000
Total Liabilities	\$1,501,922,000	\$1,474,184,000
Net Assets	\$1,854,901,000	\$1,558,271,000
Total Revenues	\$2,507,482,000	\$2,311,582,000
Excess of Revenues Over Expenses	\$172,726,000	\$180,849,000
Cash Flow from Operations	\$601,207,000	\$290,514,000
Short-Term Analysis		
Current Ratio (CA/CL)	2.0	2.5
Cash Flow to Current Liabilities (CFO/CL)	165.21%	89.00%
Long-Term Analysis		
Long-Term Debt to Net Assets (TL-CL/NA)	61.4%	73.7%
Total Margin (ER/TR)	6.89%	7.82%
Measure of Available Funding		
Working Capital	\$357,827,000	\$486,419,000

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

Capital Requirements and Funding:

The applicant indicates on Schedule 2 capital projects totaling \$222,479,510, which includes this CON (\$556,000), other care centers, and routine capitalization. Funding for this project will be provided by cash on hand. The applicant provided a copy of its December 31, 2016 and 2015 audited financial statements. These statements were analyzed

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for the purpose of evaluating the applicant’s ability to provide the capital and operational funding necessary to implement the project. Based on our analysis above, the applicant has an adequate financial position.

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.

Analysis:

Our comparison is of the applicant’s estimates to its latest FHURs report.

Because the proposed pediatric heart transplant program cannot operate without the support of the hospital, we have evaluated the reasonableness of the projections of the entire hospital including the project. The applicant will be compared to its latest AHCA filing, which was September, 2016. Inflation adjustments were based on the new CMS Market Basket, 3rd Quarter, 2017.

	PROJECTIONS PER APPLICANT		Actual Data Inflated to
	Total	PPD	2021
Net Revenues	2,769,171,385	6,221	5,818
Total Expenses	2,600,427,093	5,842	5,247
Operating Income	168,744,292	379	681
Operating Margin	6.09%		
	Days	Percent	2021
Occupancy	445,162	59.20%	68.69%
Medicaid/MDCD HMO	119,854	26.92%	28.62%
Medicare/MCARE HMO	139,792	31.40%	31.14%

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

The projections for NRPD (106.9 percent), CPD (111.3 percent) are close to the actual data and considered reasonable. Operating income (55.7 percent) is under the inflated actual data and may be understated.

The pediatric heart transplant program represents .28 percent of the hospital’s total revenue and .38 percent of the hospital’s expenses. Projections indicate a \$2.6 million profit margin at the end of year two.

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Because the transplant program is such a minor part of the hospital's overall operations, the hospital could easily support the pediatric heart transplant program even if extended losses were projected.

Conclusion:

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

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

Analysis:

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

Conclusion:

Strictly from analysis of the financial schedules submitted by the applicant, this project is not likely to have a material impact on competition to promote quality and cost-effectiveness based strictly on the financial schedules submitted by the applicant.

- 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 applicant has submitted all information and documentation necessary to demonstrate compliance with the architectural review criteria. The cost estimate for the proposed project provided in Schedule

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9, Table A and the project completion forecast provided in Schedule 10 appear to be reasonable. A review of the architectural plans, narratives and other supporting documents did not reveal any deficiencies that are likely to have a significant impact on either construction costs or the proposed completion schedule.

The plans submitted with this application were schematic in detail with the expectation that they will be necessarily revised and refined prior to being submitted for full plan review. The architectural review of this application shall not be construed as an in-depth effort to determine complete compliance with all applicable codes and standards. The final responsibility for facility compliance ultimately rests with the applicant. Approval from the Agency for Health Care Administration’s Office of Plans and Construction is required before the commencement of any construction involving a hospital, nursing home, or intermediate care facility for the developmentally disabled.

- 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) 2016 provided by the Agency’s Florida Hospital Uniform Reporting System (FHURS).

District 7 Medicaid, Medicaid HMO, and Charity Care Average			
Applicant	Medicaid and Medicaid HMO Days	Charity Percentage Service	Combined Medicaid and Charity Care
Orlando Health	28.62%	3.83%	32.45%
District 7 Average	17.02%	3.83%	20.85%

Source: FY 2016 Agency for Health Care Administration Actual Hospital Budget Data

Hospitals operated by Orlando Health provided 32.45 percent of total patient days to Medicaid/Medicaid HMO and charity care.

This provision was the second largest provision of Medicaid/Medicaid HMO and charity care within District 7. Moreover, hospitals operated by Orlando Health, Inc. accounted for 33.2 percent of all Medicaid/Medicaid HMO and charity care across District 7.

As of January 19, 2018 9:28 am, Orlando Health had an annual Disproportionate Share Hospital allocation of \$3,432,365 and \$1,711,285 had been allocated.

In response to this criteria, APMC states that Orlando Health treats significant populations of indigent patients. Orlando Health also

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identifies as being among Central Florida’s only qualified participants in the Safety Net Hospital Alliance of Florida which includes 14 hospital systems comprised of state teaching hospitals, public hospitals and trauma centers. The applicant underscores that while these hospitals account for less than 10.0 percent of hospitals in Florida, they account for greater than 50.0 percent of the state’s charity care and nearly 50.0 percent of all Medicaid hospital care.

A table summarizing the community benefit provided by Orlando Health in FY 2016 is included below:

Orlando Health, Inc. Community Benefit	
Benefit Category	Dollar Benefit (\$)
Charity Care (total cost of services incurred)	69,382,950
Community Benefit Programs & Services	68,846,680
Medicaid/Other Means Tested Program Shortfall	114,774,672
Medicare Shortfall	18,192,849
Bad Debt	165,451,421
Community Building Activities	484,157
Total	437,132,729

Source: CON application #10518, Page 115

A copy of the 2016 Orlando Health Community Benefit Report is also included in Attachment 1 of CON application #10518. APMC maintains that Orlando Health will continue to extend services to all patients in need of care regardless of the ability to pay or source of payment. APMC notes that Medicaid-sponsored, Children’s Medical Services, self-pay and indigent patients are currently served in large proportions by its hospital system. The applicant indicates that the proposal will ensure continued accessibility to these patients and all others in need of care.

In Schedule 7A of CON application #10518, Orlando Health indicates that Medicaid/Medicaid HMO will account for 26.8 percent of annual total patient days in years one and two of the proposal. Self-pay is expected to account for 9.0 percent of annual total patient days in years one and two. While the applicant states that the financial forecast for the proposed program does not model self-pay and/or charity cases, Orlando Health expects for indigent and uninsured patients to receive transplant and transplant-related care. The Arnold Palmer Medical Center Foundation is anticipated to be a source of financial assistance for patients and families.

The application is not conditioned on the provision of a minimum level of Medicaid or charity care, pursuant to this proposal.

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The following table included in the application summarizes the write-offs of patient care revenues for the provision of charity care in FY 2015, 2016 and FY 2017 at Orlando Health:

Orlando Health, Inc. Charity Care Percentage			
Indicator	2017*	2016	2015
Medicaid Days	110,716	121,255	123,288
Total Days	426,950	429,673	435,380
Medicaid Percentage	25.93%	28.22%	28.32%
Charity Care Amount^	\$ 587,207,018	\$ 423,669,051	\$ 443,496,564
Hospital Net Revenue	\$2,249,162,160	\$2,054,849,156	\$ 1,938,566,938
Charity Care Percentage of Net Revenue	26.11%	20.62%	22.88%

Source: CON application #10518, Page 116 ^Charity Care does not include Bad Debt, *2017 consolidated financial statements are currently under audit

The reviewer notes that sixteen of 26 (61.54 percent) pediatric heart transplant recipients from July 2016 – June 2017, were insured by Medicaid/Medicaid HMO.

F. SUMMARY

Orlando Health, Inc. d/b/a Arnold Palmer Medical Center (CON application #10518) is an existing provider in District 7, Subdistrict 2, Orange County, seeking to establish a PHT program in OTSA 3. Orlando Health, Inc., currently operates APMC, Dr. P. Phillips Hospital, Orlando Health and South Seminole Hospital in Orange County, Florida. APMC is a provider of pediatric inpatient cardiac catheterization and pediatric open heart surgery.

The total project cost for the proposal is \$1,544,594. The total project cost includes land cost, building cost, equipment cost, project development costs and start-up costs. Schedule 9 of the application indicates that the project involves 1,100 GSF of renovation construction totaling to \$348,745.

Schedule 10 of the application forecasts the issuance of licensure in November 2018 and initiation of service in October 2019.

APMC is a statutory teaching hospital as are all other hospitals in Subdistrict 7-2 operated by Orlando Health, Inc. APMC is currently approved to operate a pediatric bone marrow transplantation program in Organ Transplant Service Area 3 (CON application #10208), the program is not yet operational since the final order for approval of the program was issued on March 12, 2014.

The applicant includes one condition of approval in Schedule C.

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

Orlando Health contends that the proposal will enhance access to a high quality cardiac program for PHT services for residents of District 7 and OTSA 3. APMC additionally maintains that the proposal satisfies the statutory and rule criteria for approval. Pursuant to 408.035(1), Florida Statutes and Rule 59C-1.044(6)(b), Florida Administrative Code the applicant attests to “not normal circumstances” for which approval of the proposal is merited. According to APMC patients residing within OTSA 3 who may be clinically eligible for PHT services must leave the service area to receive or be wait-listed for transplant services, which creates impediments to access, particularly for those patients for whom transport poses significant risk like those on ECMO.

APMC asserts that the proposal demonstrates that:

- There is no operational or approved PHT program in OTSA 3.
- Analyses of relevant data establish that APMC will perform a minimum of 12 PHTs per year within two years of CON approval.
- The application seeks approval for a PHT program only and does not seek approval of an adult heart transplant program so that the minimum volume criteria set forth in Rule 59C-1.044(6)(b)3, Florida Administrative Code, is not applicable.
- The annual duplicated cardiac catheterization patient caseload at APMC was at or exceeded 200 for the calendar year preceding the CON application deadline and the duplicated cardiac open heart surgery caseload was at or exceeded 125 for the calendar year preceding the CON application deadline.

In addition of the points discussed above, APMC states that approval of the project is merited for the following reasons:

- APMC has an extraordinary high birth volume. Annually, approximately 14,000 babies are born at Winnie Palmer Hospital, making it the busiest labor and delivery unit in the State of Florida and one of the busiest in the nation.
- APMC’s high birth volume results in a high-volume comprehensive NICU program. More than 1,600 babies are admitted into the Alexander Center for Neonatology each year and more than 40,000 neonates have been successfully treated since the unit opened in 1975.

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- APMC's 142-bed NICU is capable of the highest level of care for high-risk newborns and is one of the largest and most technology advanced NICUs in the U.S., and includes a 20-bed, state-of-the-art unit that is one of only a few in the U.S. dedicated exclusively to pediatric congenital heart care.
- APMC's CVICU, one of only a few in the United States-staffed 24/7 with an in-house cardiologist and other specialized doctors and providing a designated CV pediatric pharmacist, designated nursing staff, designated therapists and other dedicated resources to meet the specialized needs of pediatric patients, post-cardiac surgery. This results in the best outcomes for the patients.
- APMC offers the only pediatric echo lab in Central Florida accredited in transthoracic, transesophageal and fetal echocardiography.
- APMC provides weekly visits and 24/7 communication for the care and management of patients with single-ventricle heart defects between their first and second surgeries.
- The Fetal Cardiac Program works in tandem with Orlando Health's Adult Congenital Heart Program to offer care for a lifetime. With experience treating patients of all ages, APMC's pediatric cardiologists and pediatric cardiothoracic surgeons team with cardiologists and cardiac surgeons at the Orlando Health Heart Institute.

The reviewer notes that the applicant does not provide data illustrating:

- The morbidity or mortality outcomes associated with ECMO patients overall.
- Disparities in health outcomes between patients not transferred on ECMO in comparison to patients transferred while on ECMO.
- The differences in outcomes of potential or identified PHT patients on ECMO who reside within or outside of a OTSA with a PHT program.
- The volume of patients on ECMO who are refused PHT services as a result of transport risks.
- Demonstrated adverse effects of out-migration on PHT patients who reside in OTSA 3 in comparison to PHT patients who reside in a OTSA with a PHT program.

The reviewer contends that across all transplant service areas there are invariable and inevitable geographic constraints for pediatric heart transplant patients as residents within an OTSA do not reside at equidistances to providers within the OTSA. As there are no geographic access standards for the locations of transplant providers within Rule 59C-1.044, therefore the introduction of a provider in OTSA 3 will not necessarily result in increased access to PHT services.

The reviewer notes that the applicant's data submitted to the local health council for CY 2016 shows that APMC performed 225 cardiac catheterizations and 99 open heart surgeries. The reviewer also notes

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that on February 6, 2018, APMC informed Mr. Ken Peach, Executive Director of the Health Council of East Central Florida, Inc., that APMC “correctly and fully reported its pediatric open heart surgery case volume to the Society for Thoracic Surgeons national database for the relevant time period...[but] inadvertently under-reported its utilization to the local health council. APMC discovered the source of the error as APMC’s incorrect exclusion of pediatric OHS cases performed at APMC that do not involve cardio-pulmonary bypass but that meet the regulatory definition of “Pediatric Open Heart Surgery” as set forth in Rule 59C-1.032 (2)(f), Florida Administrative Code.” The reviewer notes that the Agency amended Rule 59F-1.032(2)(f), Florida Administrative Code on July 30, 2017.

The Agency notes that a public hearing was held regarding CON #10518. Opposition indicated that the lack of “robust” PHT program might limit programmatic access to all residents of Florida, including residents of OTSA 3. Other opposition indicated that NCH should have been awarded a PHT CON and that it is disingenuous for APMC to change their position on need for a program “just one year later”.

The Agency finds that the applicant did not demonstrate the applicable criteria specified in Section 408.035, Florida Statutes and Rule 59C-1.044, Florida Administrative Code, including the applicant’s failure to demonstrate need that would merit approval of the proposed service or to demonstrate special or “not normal” circumstances.

Quality of Care

For the three-year period ending on January 16, 2018, hospitals operated by Orlando Health, Inc. received 12 substantiated complaints.

APMC provides a list of historical distinctions and awards that are presented as evidence of APMC’s capacity to provide quality care on pages 109 – 110 of the application.

The applicant demonstrated its ability to provide quality of care.

Financial/Cost

Funding for this project and the entire capital budget should be available as needed. This project appears to be financially feasible and the projected NRPD, CPD and profitability appear to be attainable. Strictly from analysis of the financial schedules submitted by the applicant, this project is not likely to have a material impact on competition to promote quality and cost-effectiveness strictly based on the financial schedules submitted by the applicant.

Medicaid/Indigent Care

Hospitals operated by Orlando Health provided 32.45 percent of total patient days to Medicaid/Medicaid HMO and charity care in FY 2016. This provision was the second largest provision of Medicaid/Medicaid HMO and charity care within District 7. Moreover, hospitals operated by Orlando Health, Inc. accounted for 33.2 percent of all Medicaid/Medicaid HMO and charity care across District 7 in FY 2016.

As of January 19, 2018 9:28 am, Orlando Health had an annual Disproportionate Share Hospital allocation of \$3,432,365 and \$1,711,285 had been allocated.

In Schedule 7A of CON application #10518, Orlando Health indicates that Medicaid/Medicaid HMO will account for 26.8 percent of total patient days in years one and two of the proposal. Self-pay is expected to account for 9.0 percent of patient days in years one and two.

The reviewer notes that 16 of 26 (61.54 percent) PHT recipients from July 2016 – June 2017, were insured by Medicaid/Medicaid HMO.

The application is not conditioned on the provision of a minimum level of Medicaid or charity care.

Architectural:

The cost estimate for the proposed project provided in Schedule 9, Table A and the project completion forecast provided in Schedule 10 appear to be reasonable. A review of the architectural plans, narratives and other supporting documents did not reveal any deficiencies that are likely to have a significant impact on either construction costs or the proposed completion schedule.

G. RECOMMENDATION

Deny CON #10518.

AUTHORIZATION FOR AGENCY ACTION

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

DATE: _____

Marisol Fitch
Health Administration Services Manager
Certificate of Need