

STATE OF FLORIDA
DIVISION OF ADMINISTRATIVE HEARINGS

VARIETY CHILDREN'S HOSPITAL,
d/b/a NICKLAUS CHILDREN'S
HOSPITAL,

Petitioner,

vs.

Case No. 16-1695CON

AGENCY FOR HEALTH CARE
ADMINISTRATION,

Respondent,

and

THE PUBLIC HEALTH TRUST OF
MIAMI-DADE COUNTY, FLORIDA,
d/b/a JACKSON MEMORIAL HOSPITAL,

Intervenor.

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RECOMMENDED ORDER

Pursuant to notice, the Division of Administrative Hearings (DOAH), by its designated Administrative Law Judge, W. David Watkins, held a final hearing in the above-styled case on November 14 through 18, and 30; and December 1, 2, 5, 6, 12, and 13, 2016, in Tallahassee, Florida.

APPEARANCES

For The Public Health Trust of Miami-Dade County, Florida
d/b/a Jackson Memorial Hospital:

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STATEMENT OF THE ISSUES

Whether there is need for a new Pediatric Heart Transplant
program in Organ Transplant Service Area (OTSA), 4 and, if so,
whether Certificate of Need (CON) Application No. 10421, filed

by Variety Children's Hospital, d/b/a Nicklaus Children's Hospital (NCH,) to establish a Pediatric Heart Transplant program, satisfies the applicable statutory and rule review criteria for award of a CON to establish a Pediatric Heart Transplant program at NCH.

PRELIMINARY STATEMENT

NCH submitted CON No. 10421 in the second batching cycle of 2015, seeking to establish a new Pediatric Heart Transplant (PHT) program in OTSA 4. There were no competing applications.

The Agency for Health Care Administration (AHCA or Agency) issued its State Agency Action Report (SAAR) on February 19, 2016, stating its decision to deny CON Application No. 10421. On March 11, 2016, NCH timely filed its Petition for Formal Administrative Hearing to challenge the Agency's decision. NCH's petition was accepted and assigned DOAH Case No. 16-1695CON. On April 4, 2016, The Public Health Trust of Miami-Dade County, Florida, d/b/a Jackson Memorial Hospital (Jackson or JMH), moved to intervene in the proceeding, supporting the denial of NCH's CON Application. On April 18, 2016, the undersigned granted JMH's Motion to Intervene, subject to proof of standing. The final hearing was held on November 14 through 18, and 30; and December 1, 2, 5, 6, 12, and 13, 2016.

At the final hearing, NCH presented the testimony of:

Narendra Kini, CEO of Miami Children's Health System; Leonard G.

Feld, M.D., Ph.D, M.M.M, President, Physician Enterprise, Pediatric Specialists of America (PSA), Miami Children's Health System; Deise Granado-Villar, M.D., M.P.H, FAAP, Chief Medical Officer and Vice President of Medical & Academic Affairs, NCH; Michael Davis, Senior Vice President for Strategic Business Development and Innovation, Miami Children's Health System; Armando Llechu, Vice President Clinical Operations, NCH; Jacqueline Gonzalez, DNP, ARNP, MBA, NEA-BC, FAAN, Senior Vice President, Chief Nursing Officer, Patient Safety Officer, NCH; Erica Vila, DNP, MSN, RN, NE-BS, Heart Program Interim Service Line Administrator, NCH; Redmond Burke, M.D., FACS, Chief of Pediatric Cardiothoracic Surgery, NCH; John Rhodes, Jr., M.D., Director of Cardiology, NCH; Cecilio Lopez, M.D., Medical Director of Noninvasive Cardiac Imaging, NCH; Robert Hannan, M.D., Senior Medical Director for Quality and Analytics, PSA, Cardiovascular Surgeon, NCH; Kristine J. Guleserian, M.D., Senior Director, Heart Failure and Transplant Program, PSA; Anthony Rossi, M.D., Chief, Division of Cardiac Critical Care, NCH; Patricia Greenberg, Health Care Planner, National Healthcare Associates; Cassandra Smith-Fields, MSN, MBA, RN, Transplant Consultant; and Olga Ruiz, NCH patient family member. NCH offered the deposition transcripts of Michael Durr, Interim Chief Financial Officer, NCH; Nancy Dobrolet, M.D., FACC, Director of Inpatient Cardiology, NCH; Yadira Martinez-

Fernandez, M.D., NCH; Jamie Wiggins, RN, MS, CCRN-K, NEA-BC, FACHE, Administrative Director Inpatient Services, NCH; John Couris, President and CEO, Jupiter Medical Center; Donald Doddridge, President and CEO of One Blood; and the partial deposition of Eliot Rosenkranz, M.D, MBA, Chief Pediatric Cardiothoracic Surgery, University of Miami. NCH's Exhibits 1-9, 12-19, 21, 23, 24, 27-33, 37-41, 43, 46, 60, 62, 63, 66, 67, 70-90, 92-95, 97-99, 101-103, 107(a-c), 111-116, 128, 135, 140, 148, 149, 154, 155(2 pp. Depo Ex. 3), 156, 157, 171-5, 171-6, 171-8, 171-9, 176(p. 22, line 13; p. 25, line 21; and p. 65, line 16 to p. 66, line 4), 193, 194-201, 203-206 and 209 were admitted into evidence.

JMH presented the testimony of Pedro Alfaro, CFO of Holtz Children's Hospital; Gwenn McLaughlin, M.D., MSPH, CPE, Chief Quality and Safety Officer, Medical Informatics Officer, Holtz Children's Hospital; Judy Schaechter, M.D., MBA, Chair, Department of Pediatrics, University of Miami; Indra Battle-Triana, RN, MSN, MSM, NEA-BC, Chief Nursing Officer, Holtz Children's and the Women's Hospital at JMH; Eliot Rosenkranz, M.D, MBA, Chief Section of Pediatric Cardiothoracic Surgery, University of Miami; Paulo Rusconi, M.D., Interim Director Pediatric Cardiology, Medical Director Pediatric Heart Failure and Transplant, JMH; Rodrigo Vianna, M.D., Ph.D., Director of Transplant Services, Miami Transplant Institute, JMH; Satinder

Sandhu, M.D., Director, Pediatric Cardiac Cath Lab and Adult Congenital Heart Program, JMH; Matthias Loebe, M.D., Ph.D., Director of Thoracic Transplantation and Mechanical Support, Miami Transplant Institute and JMH; Michael Nares, M.D., Medical Director, Pediatric Critical Care Unit, JMH; Asumthia Jeyapalan, D.O., Pediatric Intensivist and Medical Director of Pediatric Transport Team, JMH; Marian O'Rourke, RN, BSN, CCTC, Associate Director of Quality, Compliance, and Outcomes Management, Miami Transplant Institute, JMH; Mary Cousins, ARNP, Nurse Practitioner in Pediatric Cardiothoracic Surgery, JMH; Barbara Davis-Sears, ARNP, Nurse Practitioner in Pediatric Cardiothoracic Surgery, JMH; Amy Beliveau, BSN, Nurse Manager, Pediatric Intensive Care Unit, JMH; Frank Scholl, M.D., Surgical Director of Pediatric Heart Transplant and Chief of Pediatric and Congenital Heart Surgery, Joe DiMaggio Children's Hospital; and Health Care Planner, Armand Balsano, Balsano Consulting, LLC.

JMH offered the deposition transcripts of Daniel Armstrong, Ph.D., Associate Chief of Staff, Holtz Children's Hospital; Barry Gelman, M.D., Chief Medical Officer, Holtz Children's Hospital; Gary Danton, M.D., Ph.D., Medical Director Radiology Services, JMH; Sethuraman Swaminathan, M.D., Fellowship Director, Pediatric Cardiology, JMH; Maryanne Chrisant, M.D., Medical Director Pediatric Heart Transplant, Heart Failure and

Cardiomyopathy Services, Joe DiMaggio Children's Hospital; and Patricia Forges, Jackson patient family member. Jackson Exhibits 4, 10-13, 15, 19, 20, 22, 24-36, 38(pp. 1-24), 41, 51, 72, 74, 76, 77, 80, 82-84, 87, 88, 97-103, 108, 110, 113-120, 127-135, 140, 195, 197, 200, 209, 211, 213, and 259c were admitted into evidence.

AHCA presented the testimony of Marisol Fitch, Health Services and Facilities Consultant Supervisor. AHCA's Exhibit 1 was admitted into evidence.

Evidence was submitted at final hearing related to the PHT Program at Memorial Regional Hospital, d/b/a Joe DiMaggio Children's Hospital (DiMaggio), located in Broward County, but also within OTSA 4. Objections to the evidence were preserved and taken under advisement pending consideration of post-hearing memoranda submitted by the parties. Having reviewed the post-hearing filings, the objections are overruled as to the admissibility of the testimony of Dr. Scholl and the deposition testimony of Dr. Chrisant, and to other testimony and evidence offered as it relates to the availability, quality of care, accessibility, and extent of utilization of the DiMaggio PHT program.

Final Hearing Transcript Volumes 1 through 23 were filed with the DOAH on January 5, 2016. All parties timely filed their Proposed Recommended Orders (PROs) on March 6, 2017, and

each has been carefully considered in the preparation of this Recommended Order.

All citations are to the 2016 Florida Statutes or Florida Administrative Code rules unless otherwise noted.

FINDINGS OF FACT

Based upon the demeanor and credibility of the witnesses and other evidence presented at the final hearing and on the entire record of this proceeding, the following Findings of Fact are made:

The Parties

The Applicant, NCH

1. NCH, formerly Miami Children's Hospital, was established in 1950 by Variety Club International. NCH is South Florida's only licensed specialty hospital exclusively for children, with more than 650 attending physicians and 130 pediatric subspecialists. NCH has 289 licensed beds, of which 218 are acute care, 20 are child psychiatric, 21 are Level II neonatal intensive care unit (NICU), and 30 are Level 3 NICU. NCH is part of the Miami Children's Health System, a not-for-profit corporation.

2. NCH does not deliver any babies. Thus, many children that have been treated at NCH have been referred to NCH based upon its excellent reputation in the community.

3. NCH is continually recruiting additional physicians in order to expand the pediatric subspecialty coverage it is able to offer. Dr. Leonard Feld, the President of Pediatric Specialists of America (NCH's employed physician group), came to NCH a little over a year ago, after a distinguished clinical and administrative career involving pediatric kidney transplant. He was drawn to NCH because of the depth and breadth of the existing medical staff and the administration's commitment to advance the field of pediatric medicine through innovation and subspecialization. Dr. Feld is responsible for ensuring NCH's quality of care from a medical perspective. He is confident NCH will implement a world-class PHT program if its CON is approved.

4. NCH has several nationally-recognized subspecialty programs, including eight programs listed by U.S. News and World Report as Top 50 Programs, and two Top 10 Programs. NCH's pediatric cardiac surgery program is currently ranked 40th by U.S. News and World Report, but this number is artificially suppressed because NCH does not provide heart transplants. NCH is the highest ranked cardiac program on the U.S. News and World Report ranking that does not have a PHT program.

5. NCH is a leader in clinical research, with its staff being published in over 800 medical journals in the last half dozen years, over 200 ongoing clinical trials, and 49 active cardiac studies.

6. NCH's Accreditation Council for Graduate Medical Education (ACGME) accredited pediatric residency and fellowship program is the largest in the southeastern United States, and has a 95-percent, first-time Board pass rate, which is a testament to its quality.

7. NCH is focused on providing pediatric patients in Miami-Dade County with the right care, in the right setting, at the right time. To this end, NCH has expanded its urgent and ambulatory care centers throughout Miami-Dade County to ensure that patients have convenient access to pediatric outpatient and subspecialty care.

8. NCH is a world-renowned, international heart center. NCH's cardiac team has cared for children from 39 countries and has performed 4,643 open-heart operations since 1995, more than any other program in Florida.

9. NCH has invested hundreds of millions of dollars in creating a telehealth program to allow access to pediatric subspecialists in areas where subspecialists are in short supply.

10. NCH's transport team, which consists of six ambulances and two helicopters owned by NCH and additional contracted transports, such as fixed wing aircraft, transports approximately 3,000 children per year. Recently, the transport team received the field's most prestigious honor when it was

named the Association of Air Medical Services' Neonatal Transport Team of the Year.

11. NCH has established relationships with Lee Memorial Health System, in Lee County, and Jupiter Medical Center, in Palm Beach County. These relationships will create access portals for transplant if NCH's CON application is approved.

12. NCH's excellent reputation and excellent outcomes have made it the largest pediatric cardiac surgery program in the state, performing 25 percent of all pediatric cardiac surgeries in Florida. In OTSA 4 and Miami-Dade County, NCH is the overwhelming provider of choice, performing 62.2 percent of the pediatric cardiac surgeries in OTSA 4 and 72.7 percent of those in Miami-Dade County. It is noteworthy that the pediatric cardiac surgery program at NCH has a higher surgical volume than any of the four existing Florida PHT centers.

13. NCH is on the forefront of technology and innovation. NCH physicians have pioneered surgical techniques and developed pediatric surgery tools and equipment used throughout the industry. NCH also has found innovative ways to use existing technology to improve care. For example, NCH uses social media to improve communication between families and caregivers, uses 3D printed hearts and virtual reality to better plan surgeries, posts real-time outcomes on the Internet for transparency, and photographs and digitally records every cardiac surgery to

eliminate guesswork in the event of future surgeries on the same patient.

14. NCH's cardiac programs operate on the most challenging cases, including, in some instances, when other providers have determined the patient was inoperable and terminal.

15. In 2016, NCH opened a six-story, state-of-the-art advanced pediatric intensive care tower. Technical advances located in the new tower include an intraoperative MRI, which allows the physicians to take an MRI without moving the patient from the operating room table, and one of the most advanced cardiac catheterization laboratories in the country, which allows NCH to perform pediatric heart catheterizations that cannot be performed in other hospitals.

16. NCH has a robust pediatric cardiology physician team, including 14 pediatric cardiologists, five pediatric cardiac intensivists, and three pediatric cardiac surgeons. Either during training or prior to coming to NCH most, if not all, of these physicians have had experience working in hospitals with pediatric transplant programs, and all of them are currently exposed to patients at NCH that are candidates for heart transplant.

17. NCH's Chief of Pediatric Medicine, Dr. Redmond Burke, is a Harvard-trained pediatric cardiac surgeon who has been instrumental in many advances in pediatric cardiac surgery. He

performed the first endoscopic cardiac surgery and the first casual ring division. He invented the venous pole circuit, a less invasive, less traumatic form of cardiopulmonary bypass, and he also invented the first portable extracorporeal membrane oxygenation (ECMO) machine to transport critically ill patients to NCH for care. Dr. Burke has been a pioneer in pediatric cardiac surgery technology.

18. Dr. Hannan, another one of NCH's pediatric cardiac surgeons, also trained at Harvard Medical School. He has performed approximately 2,000 open-heart operations at NCH. He was part of the team that created the Society of Thoracic Surgeons (STS) database reporting program, revolutionizing outcome monitoring in pediatric cardiac surgery.

19. Recently, NCH recruited a third pediatric cardiac surgeon, Dr. Kristine Guleserian, who is one of the highest volume pediatric heart transplant surgeons in the country. Dr. Guleserian trained at Harvard Medical School.

20. Dr. Guleserian is a world-renowned pediatric heart transplant and cardiac surgeon. In 2006, she performed the world's youngest surviving combined heart/liver transplant on a three-year-old girl. She has performed 133 pediatric cardiac transplants, including transplant on one of the smallest pediatric patients to ever receive an artificial heart. Dr. Guleserian serves on numerous boards and committees

dedicated to improving and advancing the field of pediatric cardiac surgery and heart transplant.

21. Beyond its pediatric cardiac surgeons, NCH has developed the infrastructure of a world-class pediatric cardiac program, including several physicians who are nationally recognized industry leaders in their subspecialties. For example, Dr. Cecilio Lopez is one of the foremost experts in the country in echocardiography. He is currently on the Board of Directors for the American Society of Echocardiography, International Society for the Nomenclature of Pediatric and Congenital Heart Disease, and the Intersocietal Accreditation Commission, and is also the immediate past President of the Society of Pediatric Echo. Dr. John Rhodes is the former director of the cardiac catheterization lab at the world-renowned PHT program at Duke Children's Hospital and Health Center. He is currently involved in cutting-edge clinical trials that involve the closing of large atrial septal defects and transcatheter valve replacement. Dr. Rhodes' involvement in all major pediatric cardiac trials allows him to provide his patients with treatment options that other hospitals cannot. Finally, Dr. Anthony Rossi was one the first and is one of the most experienced pediatric cardiac intensivists in the country, and was instrumental in developing the concept of using a dedicated pediatric cardiac intensive care unit (CICU).

22. In addition to the physicians already on staff, NCH has plans to recruit two additional pediatric cardiac intensivists and a pediatric cardiac heart failure specialist.

The Intervenor, Jackson

23. Jackson is the public safety net hospital system for Miami-Dade County and has been in existence since 1918. Its mission is centered on a mandate to treat all Miami-Dade County residents regardless of their ability to pay. Its main campus, Jackson Memorial Hospital, includes the Holtz Children's Hospital (Holtz) and the Women's Hospital. Pediatric cardiac services provided by Jackson, via Holtz, include PHT and pediatric heart failure, as well as cardiac surgery and cardiology services.

24. Holtz provides services for patients 21 years of age and under through its affiliation with the University of Miami, which provides physician services to JMH. Holtz cares for patients with all types of diseases, including, but not limited to, chronic illness; congenital heart disease; cardiology; cardiovascular, liver, kidney and intestinal disease; burn; trauma; neurology; and solid organ and bone marrow transplantation. Holtz has 373 beds, including 60 Level II NICU beds and 66 Level III NICU beds. The NICU at Holtz cares for the most complex infants, high-risk patients, and births.

25. In addition, Holtz has a 30-bed pediatric intensive care unit (PICU) consisting of individual, separate patient rooms, fully equipped and capable of treating critically ill children. The PICU cares for pediatric pre- and post-operative transplant, cardiac, burn, trauma, and surgical patients, among others. Patients in the PICU have highly acute conditions, frequently requiring ventilator support, ECMO support for cardiac patients, and access to subspecialty care. PICU nursing for the most critical patients is provided on a one-to-one ratio. Adjacent to the PICU on the same floor are two pediatric operating rooms, the pediatric cardiac catheterization laboratory, and the transplant unit. Patients are assigned to the transplant unit based on the type of organ transplanted and the patient's acuity.

26. Holtz has dedicated pediatric and neonatal pharmacies. Pharmacy, nursing, rehabilitation, and dietary services are provided by specialists in pediatrics and neonatology.

27. Holtz offers a wide variety of child life services, including diversionary techniques to alleviate pain and promote child development and therapies to provide a sense of normalcy in the lives of pediatric patients cared for at Holtz.

28. In addition, Holtz provides pediatric palliative care through its Pedi Pals program which provides care for pediatric patients who are critically ill and have frequent

hospitalizations or care needs at home. Services include pain management, bereavement services, and pastoral care as needed or indicated by families.

29. Holtz also provides a Prescribed Pediatric Extended Care program (PPEC) that offers day care type services for children with complex medical conditions, including cardiac patients. This allows the patients' parents and caregivers the ability to work while their children are cared for in a medically supervised setting.

30. JMH's transplant program has been in operation for over 45 years. Holtz and JMH provide a wide range of solid organ transplantation in conjunction with the Miami Transplant Institute (MTI) and the University of Miami (UM). MTI is a joint program between JMH and UM, employing nearly 300 people and 40 physicians dedicated to transplantation. It is the third largest transplant program, and the second largest pediatric transplant program, in the United States. In the past year, MTI performed over 420 adult and over 70 pediatric solid organ transplants, all at JMH. Pediatric transplant programs at JMH include heart, kidney, pancreas, kidney/pancreas, liver, lung, intestinal, and multi-visceral. JMH also performs bone marrow transplants. Due to the scope of both pediatric and adult solid organ transplant services offered at JMH, pediatric patients are easily transitioned into adult services for uninterrupted

treatment at JMH. PHT recipients will require lifelong care and follow up, frequently retransplantation, and adult services as they age.

31. The cardiothoracic surgery program at JMH has existed for over 50 years. It is multidisciplinary, caring for both children and adults with heart, lung, and mediastinal disease and includes a robust transplant and assistive device program. The program has a team of cardiothoracic surgeons, four of whom have PHT experience. Dr. Eliot Rosenkranz is JMH's primary pediatric heart transplant surgeon. He has been at JMH since 2000. The PHT team also includes Dr. Matthias Loebe and Dr. Nicolas Brozzi, who both have extensive experience in transplanting solid organ pediatric patients, teenagers, and young adults, and who provide support to Dr. Rosenkranz, whenever needed.

32. JMH has a heart failure program that includes a multidisciplinary team of physicians, nurses, therapists, and other providers who review the best modalities to treat and medically manage patients with heart failure. In addition to cardiology services, the heart failure program includes the cardiac transplant service. JMH's pediatric heart failure program, led by Dr. Paolo Rusconi, was only the eighth program in the U.S. to be accredited by the Health Care Colloquium, and the only program in Florida to receive such designation for

programs demonstrating quality in heart failure patient management.

33. Other cardiac-related services provided at JMH include interventional cardiology, under the direction of Dr. Satinder Sandhu; echocardiography and non-invasive imaging; electrophysiology, diagnostic pediatric and cardiothoracic radiology; and general cardiology.

Agency for Health Care Administration

34. AHCA is the state health planning agency that is charged with administration of the CON program as set forth in sections 408.031-408.0455, Florida Statutes.

Context of the PHT Application

35. Pursuant to Florida Administrative Code Rule 59C-1.044, AHCA requires applicants to obtain separate CONs for the establishment of each adult or pediatric organ transplantation program, including: heart, kidney, liver, bone marrow, lung, lung and heart, pancreas and islet cells, and intestine transplantations.

36. "Transplantation" is "the surgical grafting or implanting in its entirety or in part one or more tissues or organs taken from another person." Fla. Admin. Code R. 59A-3.065.

37. "Heart transplantation" is defined by rule 59C-1.002(41) as a "tertiary health service," meaning "a health

service which, due to its high level of intensity, complexity, specialized or limited applicability, and cost, should be limited to, and concentrated in, a limited number of hospitals to ensure the quality, availability, and cost effectiveness of such service."

38. AHCA rules define a "pediatric patient" as "a patient under the age of 15 years." Fla. Admin. Code R. 59C-1.044(2)(c). However, the United Network for Organ Sharing (UNOS), which regulates, monitors, and reports organ transplant and procurement data, defines pediatric patients as the age group 0-17. The STS, which reports risk-adjusted cardiac surgery data, also defines pediatric patients as the ages 0-17. As a practical matter, none of the clinicians that testified for either party limited their definition of pediatric patients to ages 0-15.

39. Heart transplantation is considered a last resort for patients with end-stage heart disease who may have no other medical or surgical therapies available. Typically, persons listed for heart transplantation have a life expectancy of less than one year. These patients often have significant limitations of their activity and lifestyle prior to transplantation.

40. At hearing, the cardiologists who testified agreed that whenever possible, PHT should be delayed as long as medically possible, since transplanted hearts typically have a limited, yet greatly variable period of viability, ranging from under a year

to possibly decades. However, in any event, retransplantation is frequently necessary.

41. The two most common causes of end-stage heart disease requiring a transplant in children are cardiomyopathy, which is a progressive deterioration of the function of the heart muscle, and congenital heart defects that are not amenable to further surgical correction.

42. The conditions that require heart transplantation in children are different across age cohorts (and from adults). Infants or neonates requiring transplantation typically have congenital heart defects that require surgical intervention relatively soon after birth. These conditions are typically dealt with anywhere from infancy to seven or eight years of age.

43. With the older pediatric age group (eight years of age to adolescence), the indications for transplant are different. Many children are perfectly healthy until then, and then contract a serious illness, such as viral cardiomyopathy. In this condition, the heart enlarges and children develop restrictive cardiomyopathy, leading to sudden heart failure or progressive decline of their function, ultimately requiring a transplant.

44. ECMO, also known as extracorporeal life support (ECLS), is an extracorporeal technique of providing both cardiac and respiratory support to persons whose heart and lungs are unable to provide an adequate amount of gas exchange to sustain

life. Generally it is only used in the later treatment of a person with heart or lung failure as it is solely a life-sustaining intervention.

45. Congress, through the National Organ Transplant Act, established the Organ Procurement Transplant Network (OPTN) to manage a national list of organ donors and available organs, along with the collection of data regarding organ transplant. OPTN administers these duties through a contract with UNOS.

46. Patients exhibiting symptoms of possible heart failure are referred to the heart failure team for initial evaluation. The evaluation includes assessment of the patient's medical history and anatomy, imaging, and review of alternative treatments to transplantation by various medical specialists. Because the goal recognized by most physicians is to delay or avoid PHT, in many cases, patients are not listed for PHT or may be removed from the waitlist when continued medical management or other palliative surgical intervention is proper.

47. If PHT is required, patients and their parents will meet with the PHT surgeon to discuss the procedure. All information from the assessment is reviewed by the multidisciplinary transplant review committee, which includes pertinent medical and surgical specialists, social workers, financial counselors, and other members necessary for decision-making. Upon approval by the transplant committee, and consent

from the patient's family, patients are listed with UNOS according to severity of disease, how soon the patient will require a new organ, and the expectation of their survival without a new organ.

48. Donor information, including donor location/region, blood type, age, donor size, and other factors that are used to identify potential organ matches, is provided by the donor hospital to the organ procurement agency. When a potential match is identified, the recipient hospital with the highest priority patient is provided the donor information or provided an "offer." At that time, the recipient hospital reviews the donor information to confirm whether the organ is appropriate for the matched recipient. In some infrequent circumstances, a donor is not appropriate due to both the condition of the donor and the condition of the recipient. If the donor is appropriate, the process for the transplant procedure begins.

49. AHCA rules divide Florida into four OTSAs, corresponding generally with the northern, western central, eastern central, and southern regions of the state. Fla. Admin. Code R. 59C-1.044(2)(f). The program at issue in this proceeding will be located in OTSA 4, which is comprised of Broward, Collier, Miami-Dade, Monroe, and Palm Beach Counties.

50. For purposes of CON review, Florida is divided into 11 health planning districts. § 408.032(5), Fla. Stat. The CON at issue in this proceeding will be in District 11.

51. Currently, there are two providers of PHT in OTSA 4: DiMaggio and Jackson. As discussed below, historically Jackson's PHT volumes have been extremely low.

52. Jackson is located in District 11. DiMaggio is located in District 10. In addition to these two programs, there are only two other PHT providers in Florida: UF Health Shands Hospital (Shands), located in Gainesville, OTSA 1, District 3; and Johns Hopkins All Children's Hospital (All Children's) located in St. Petersburg, OTSA 2, District 5.

53. The incidence of PHT in Florida, as compared to other types of solid organ transplants, is relatively small. The chart below sets forth the number of pediatric (ages 0-17) heart transplant discharges by year for the four Florida PHT programs during Calendar Years (CY) 2013 through 2015:

HOSPITAL	HEART TRANSPLANT		
	CY 2013	CY 2014	CY 2015
All Children's Hospital	7	14	9
UF Health Shands Hospital	6	8	9
Memorial Regional Hospital	5	5	5
Jackson Health System	2	2	1
Total	20	29	30

History and Utilization of Existing Providers of PHT in OTSA 4

The Jackson Program

54. At JMH, the surgical component of a PHT is a small piece of a very complex process. The critical components of the PHT process, managed by the cardiology and heart failure team at JMH, include timely referral for transplant, heart failure and transplant evaluation, pre- and post-operative transplant care (inpatient and outpatient), heart transplantation, and lifelong immunosuppression management.

55. JMH is approved by OPTN and UNOS to provide PHT. JMH's adult and PHT programs are certified by the Centers for Medicare and Medicaid Services (CMS) under a single certification. Certification with CMS requires OPTN membership and regulation compliance.

56. Jackson has a long history of running extremely low-volume pediatric and adult transplant programs, and has had a series of regulatory violations stemming from its failure to support and grow its adult and pediatric transplant programs, the consequence of which includes being under a federal Medicare/Medicaid System Improvement Agreement.

57. For several years, Jackson was unable to meet the Children's Medical Services' volume thresholds for a pediatric cardiac program, resulting in the program being placed on probation. The evidence demonstrated that currently and

historically, Jackson has not performed 90 "on-pump" (heart/lung bypass) pediatric heart surgeries on an annual basis.

58. Jackson's transplant volume for young children, infants, and neonates is nearly nonexistent. Jackson has not done a transplant on a patient under 30 days of age since 1998. Since 2007, Jackson has done no transplants on patients aged one to five. In the past six years, Jackson has only done five transplants on patients under 10 years of age.

59. Unlike NCH, Jackson is concentrated on providing cardiac surgery primarily to adults. In CY 2015, JMH had 37 pediatric (age 0-17) cardiac surgery cases, representing only 3.9 percent of its total cases. By contrast, during the same period NCH had 201 pediatric cardiac surgery cases, representing 21.2 percent of its total cases.

60. The difference in focus between JMH and NCH is even more pronounced when it comes to cardiac surgeries on neonates. In 2016, NCH did 200 on-pump pediatric cardiac surgeries, of which 52 were performed on neonates, meaning neonates accounted for 26 percent of NCH's on-pump cases. During the same period, Jackson only performed 42 on-pump cases, of which only seven were neonates, meaning neonates only accounted for 16 percent of Jackson's on-pump cases. Jackson is also performing about two times the national average in terms of the percentage of its cases that are performed on adult patients. Performing

pediatric cardiac surgery on neonates is typically more complex than performing congenital heart defect surgery on adult patients.

61. Jackson only has one pediatric cardiac surgeon. Jackson advised Children's Medical Services it intended to recruit a second pediatric surgeon in 2012, but this did not occur. Jackson's low cardiac surgery and transplant volumes make it difficult, if not impossible, for it to recruit a highly skilled pediatric cardiac and transplant surgeon. Dr. Rosenkranz testified that there is no need to recruit a second pediatric heart surgeon.

62. Jackson and NCH treat very different universes of patients. Jackson has not performed a PHT on a Miami-Dade County resident in the last three years; whereas, NCH performs 73 percent of the pediatric cardiac heart surgeries for Miami-Dade County residents and expects a significant percentage of its transplant cases to come from this patient population.

63. Jackson concentrates predominantly on pediatric cardiomyopathy cases. NCH is more focused on pediatric congenital heart defects and anticipates these patients will represent a significant portion of its transplant patients.

64. Jackson's patients tend to be older patients, whereas a significant percentage of NCH's patients are neonates and infants. In pediatric cardiac surgery, 25 percent of NCH

patients are neonates (under 30 days), and 30 percent are infants (31 days to one year).

65. Jackson has not done a transplant on a neonate since 1988. In fact, Jackson has only performed three transplants on infants and no transplants on any patients between one and five years old since 2008.

66. Jackson tends to be risk averse, whereas NCH treats the most complex patients. For example, Jackson has not had a single transplant patient on ECMO, whereas, based upon NCH's 20 years of historical data, it expects to have a pool of approximately 10 patients a year on ECMO that may benefit from transplant.

67. In August 2011, AHCA sent JMH a letter advising JMH that it had abandoned both its pediatric heart and pediatric lung transplant programs due to not performing a single pediatric heart or lung transplant for over twelve consecutive months in 2010. The letter, addressed to JMH's President and CEO, stated:

Re: Abandonment of Pediatric Heart
Transplant Program

Dear Mr. Migoya:

In the course of our regular data collection and analysis responsibilities, Agency staff has confirmed that your pediatric heart transplant program has been idle, i.e. no transplants have been performed, for a period in excess of 12 consecutive months,

from January 2010 through December 2010. Accordingly, pursuant to Certificate of Need rule sections 59C-1.002(41)(a), 59C-1.004(1), 59C-1.0085(5), and 59C-1.020 Florida Administrative Code, and section 408.036(1), Florida Statutes, the re-establishment of a pediatric heart transplant program in the future will require a new certificate of need. The program will be removed from the Agency's inventory of authorized transplant programs.

Within 14 days of receipt of this letter, please advise this Agency if the above findings are inaccurate. Should you have any questions regarding this request, please contact Steve Love of my office at (850)412-4345.

Sincerely,

/S/

Jeffrey N. Gregg, Chief
Bureau of Health Facility Regulation

(NCH Ex. 46).

68. Following receipt of the above letter, JMH drafted a response in which JMH did not take issue with the accuracy of the data cited in AHCA's letter. Rather, JMH's letter recited the reasons for its low PHT volume, including "low regional volumes, financial challenges in the system resulting in bad publicity, and intense competition from a new start-up program" It is unclear whether the draft response was ever sent to AHCA, however, no witness at hearing disputed the accuracy of the data contained in AHCA's letter.

69. AHCA's representative, Marisol Fitch, testified that the letter did not revoke or rescind JMH's CON, which is evidenced by the fact that AHCA did not notify JMH of its right to dispute a revocation or rescission pursuant to chapter 120, Florida Statutes. Ms. Fitch further advised that there was no final order revoking JMH's CON, nor had it ever been voluntarily surrendered by JMH. Either of these actions would have been required to delete services from the program inventory. According to AHCA, JMH has an active PHT program, is currently listed in AHCA's inventory of PHT programs, and at no time has AHCA taken further steps to terminate JMH's PHT license.

70. At hearing, and again in its PRO, JMH objected to the legal status of its PHT program being placed at issue in this proceeding. JMH is correct that this proceeding is not concerned with the validity of JMH's PHT license, however, consideration of the past volumes of PHT being provided at JMH and AHCA's documentation of periods of time when no PHTs were provided, is relevant to the statutory review criteria to be applied to the NCH application.

The DiMaggio Program

71. DiMaggio is also licensed to perform PHT services within OTSA 4. DiMaggio is part of the Memorial Healthcare System (Memorial) in Broward County, Florida. DiMaggio offers pediatric and adult congenital heart surgery and PHT. DiMaggio

also offers a heart failure program that includes both medical management and surgical services. Adult heart transplant is also offered by Memorial on the same campus.

72. DiMaggio received its CON for PHT services in 2009 and received UNOS approval in 2010, performing its first transplant in December 2010. DiMaggio has provided PHT related services and heart failure management since that time. DiMaggio's PHT surgeon is Dr. Frank Scholl and its pediatric heart failure program is led by Dr. Maryanne Chrisant. During CY 2013 through CY 2015, Memorial performed five PHTs each year.

The Proposed NCH Program

73. As noted, NCH proposes to establish a PHT program on its hospital campus in Miami, OTSA 4, District 11. Due to its robust pediatric cardiac program, NCH already has most of the infrastructure in place to support the transplant program. NCH has a staff of pediatric cardiac physicians with expertise in caring for patients with end-stage diseases requiring transplants, clinical staff and nurses with experience caring for chronically ill children and families, nutritionists, respiratory therapists, social workers, psychologists, and psychiatrists. The NCH staff and physicians are available on a 24-hour basis at NCH's dedicated cardiac intensive care unit. NCH also has educational and training opportunities available for staff, patients, and families.

74. NCH has a very well trained and experienced nursing staff, many with advanced certifications and specialized pediatric training. NCH has an excellent nurse training program in place to grow the skills of its nursing staff. NCH has been an American Nurses Credentialing Center (ANCC) Magnet Program institution for three consecutive years, a statistic only seven percent of hospitals across the country have been able to achieve.

75. NCH uses cardiac-dedicated nurses to care for its cardiac patients, and only uses dedicated cardiac advanced registered nurse practitioners to care for post-surgical cardiac patients in its dedicated CICU.

76. NCH's dedicated CICU has recently been relocated to the new advanced pediatric intensive care tower. There are distinct advantages to having a dedicated CICU when it comes to caring for complex cardiac patients, including transplant patients. It allows NCH to have extremely seasoned physician cardiac intensivists, cardiac nurse practitioners, cardiac nurses, and other support staff such as dietitians and social workers, who treat a high volume of pediatric cardiac surgery patients and understand their unique issues and complications. The constant exposure to complex cardiac patients allows NCH's team to recognize complications sooner and react quicker, resulting in better care and shorter lengths of stay.

77. In contrast to NCH's dedicated pediatric CICU, Jackson does not have a dedicated CICU. Heart transplant patients are placed in the same ICU as all other pediatric critical care patients.

78. The cardiac surgeons at NCH use innovative technology to improve their patients' outcomes and reduce patients' length of stay in the hospital.

79. One way NCH has earned its reputation for excellence is by operating on the toughest cases. NCH is the place where patients turn when other hospitals refuse to operate because the case is too complex. NCH is willing to take "hits" to its mortality/morbidity statistics to give the sickest patients a chance to live.

80. Despite having the highest volume of pediatric cardiac surgeries in Florida, NCH cannot perform PHT on its patients. These patients and their families must choose to continue alternative treatment at NCH, or be transferred away from their team who has been caring for them through the events that led up to the transplant, which often includes multiple prior heart surgeries. It is difficult on patients and families to lose continuity of care at this stage in their disease process.

81. While Jackson raised some criticisms of NCH not having an adult cardiac program for continuity of care after patients reach adulthood, the evidence shows the largest and best

pediatric heart programs in the United States are often located in pediatric-only programs, with no immediately available adult programs. Dr. Rhodes and Dr. Guleserian testified that even at places like Duke and Texas Children's that have adult programs, the two programs are completely separate. Moreover, NCH has a relationship with the Cleveland Clinic to transition patients when they need an adult program.

82. Dr. Rhodes also refuted JMH's claim that there needed to be a back-up adult interventional cardiologist on-site to run a quality interventional program. This is contrary to the Society of Cardiac Angiography and Intervention's recommendation. Further, Dr. Rhodes performs catheterizations on adults and has this training should it be necessary. There are also other adult interventional cardiologists on staff at NCH.

83. Jackson also argued NCH's program would be inferior because NCH does not offer other solid organ transplant services. However, as Dr. Guleserian explained, kidney and liver transplants are very different than heart transplants. Even in hospitals where both heart and other solid organ transplants are offered, the heart program is separated because it is unique. Heart transplant patients are much more similar to cardiac surgery patients than other solid organ transplant

patients. Dr. Guleserian does not endorse comingling heart transplant patients with other solid organ transplant patients.

84. After evaluating NCH's existing cardiac infrastructure, Cassandra Smith-Fields, accepted as an expert in transplant program development and operation, concluded that NCH had everything necessary to establish a PHT program, with the exception of recruiting a heart failure specialist. Ms. Smith-Field's expert opinion, which is credited, and is based on 32 years of professional experience working in transplant programs, is that NCH will be able to implement a high-quality PHT program.

AHCA's Preliminary Decision

85. Following AHCA's review of NCH's application, as well as Jackson's written Letter of Opposition, AHCA determined to preliminarily deny the application. The Agency's decision was memorialized in a SAAR, dated February 19, 2016.

86. The SAAR is mostly a restatement of the information presented in the NCH application. There is only one paragraph in the entire document that purports to explain why the Agency chose to preliminarily deny the application:

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

reduce already relatively low volumes at the existing pediatric heart transplantation provides in OTSA 4.

87. Marisol Fitch, supervisor of AHCA's CON and commercial-managed care unit, testified for the Agency. Ms. Fitch testified that AHCA does not publish a numeric need for transplant programs, as it does for other categories of services and facilities. Rather, the onus is on the applicant to demonstrate need for the program "based on whatever methodology that they present to the Agency for our analysis." In addition to the applicant's need methodology, "we (AHCA) look at availability and accessibility of service in the area to determine whether there is an access problem."

88. With respect to whether NCH had demonstrated need for its PHT program, Ms. Fitch testified:

The Agency did not feel that the applicant demonstrated need for the project in organ transplant area four. We did not find that there was an underserved population or that there were financial issues at stake or a quality issue, and so we did not feel that the applicant demonstrated that need for the project was produced within the four corners of the application.

Statutory Review Criteria

Section 408.035(1)(a): The need for the health care facilities and health services being proposed.

89. The statutory criteria for the evaluation of CON applications, including applications for organ transplantation

programs, are set forth at section 408.035, Florida Statutes, and rule 59C-1.044. However, neither the applicable statutes nor rules have a numeric need methodology that predicts future need for PHT programs. Thus, it is up to the applicant to demonstrate need in accordance with rule 59C-1.044.

90. To quantify the need for a new PHT program in District 11, NCH used the two need methodologies described in detail below.

Methodology 1: Ratio of Transplants to Cardiac Surgeries

91. NCH's first need methodology evaluates the ratio of PHT volume at the four existing Florida transplant centers to the volume of pediatric cardiac surgeries. It then applies this ratio to NCH's cardiac surgery volume to determine the internal demand for this service at NCH.

92. There is a positive correlation between the number of pediatric cardiac surgeries and the number of PHTs. The more pediatric cardiac surgeries a hospital performs, the more need there will be for PHTs. Conversely, low-volume pediatric cardiac surgery providers, such as Jackson, are also low-volume PHT providers.

93. Using data from STS and UNOS, NCH determined that during CY 2014:

- All Children's Hospital performed 146 cardiac surgeries and 14 transplants for a percentage of 9.6%;

- UF Health Shands Hospital performed 84 cardiac surgeries and 8 transplants for a percentage of 9.5%;
- Memorial Regional Hospital performed 61 cardiac surgeries and 5 transplants for a percentage of 6.0%; and
- Jackson performed 55 cardiac surgeries and 2 transplants for a percentage of 3.6%.

94. The above data strongly suggests there is a correlation between the number of pediatric cardiac surgeries performed and the number of transplants performed. This correlation is supported by AHCA's rule 59C-1.044(6)(b)4., which sets forth minimum volume thresholds for pediatric cardiac surgeries (125) and cardiac catheterizations (200), and with data reflecting that nationally, PHT programs are located in hospitals with the largest pediatric cardiac surgery programs.

95. To forecast pediatric cardiac surgical volume in OTSA 4, NCH used AHCA's CY 2014 discharge rates for OTSA 4 residents and applied those to the forecasted pediatric population for each of the planning years. This resulted in a forecast of 259 pediatric cardiac surgeries for the 12-month period ending June 30, 2018, increasing to 261 cases during the 12 months ending June 30, 2020.

96. Using CY 2014 AHCA data, NCH then determined that it had a 62.2 percent market share of all pediatric cardiac surgeries performed in OTSA 4 on OTSA 4 patients.

97. Applying this market share to the forecasted surgeries, NCH determined that it would perform 161 pediatric cardiac surgeries on OTSA 4 residents during the 12 months ending on June 30, 2018; 162 during the 12 months ending on June 30, 2019; and 163 during the 12 months ending on June 30, 2020, i.e., more than any other provider is currently performing.

98. NCH assumed a 25 percent in-migration percentage, and provided a conservative ramping-up ratio of three percent PHT to cardiac surgery for the 12-month period ending June 30, 2018; six percent for the 12-month period ending June 30, 2019; and seven percent for the 12-month period ending June 30, 2020. The assumption used is significantly lower than All Children's or Shands' ratios, despite the fact that NCH is forecasted to have significantly more pediatric cardiac surgeries than either of those two hospitals.

99. Applying these conservative assumptions, NCH could reasonably expect to perform six PHTs for the 12-month period ending June 30, 2018; 14 for the 12-month period ending June 30, 2019; and 15 for the 12-month period ending June 30, 2020.

100. Jackson criticized NCH's surgical ratio analysis, pointing out that AHCA defines pediatric as 0-14, not 0-17. However, as discussed above, STS and UNOS define pediatric as

0-17. Thus, the use of this age group is appropriate when considering the likely patients to be served. Moreover, the difference in the results using 0-14 data, versus 0-17 data, is de minimus. As a result of Jackson's criticisms, NCH's health care planner re-ran her analysis using 0-14 AHCA data. This resulted in almost the same outcome, with six PHTs projected for the 12-month period ending June 30, 2018; 13 for the 12-month period ending June 30, 2019; and 15 for the 12-month period ending June 30, 2020.

101. Jackson's argument that there is no positive correlation between the number of pediatric cardiac surgeries performed and the number of PHTs likely to accrue from that surgical volume is rejected. While there is not a specific ratio, or "magic" number which can be reliably applied to each institution, there is a range within which the ratio of cardiac surgery to PHTs will fall. According to Dr. Gulesarian, whose testimony is credited, for any particular institution, that ratio will likely vary from year to year depending upon a number of variables, most importantly, the complexity of the cardiac surgeries being performed. Specifically, the more complex and higher risk the surgeries, the more likely a heart transplant will be necessary.

Methodology 2: Ratio of Transplant Volume to Common Indicators

102. NCH's second need methodology evaluates the most common indications for PHTs and compares that to the cases by hospital and resident origin to determine the need for a PHT program at NCH. To do this, NCH's health care planner worked with NCH's physicians to compile a list of the 24 most common indicators for PHT, and to determine their corresponding International Classification of Disease, 9th Revision (ICD-9) codes.

103. Using AHCA data, NCH then determined that in 2014, there were 499 pediatric cases in Florida with the target ICD-9 codes. NCH had the most cases with 121, constituting 24.2 percent of all cases in Florida. The second greatest, All Children's, only had 66, constituting 13.2 percent.

104. In OTSA 4, for the years 2012-2014, NCH had a total of 296 patients with these common indicators, accounting for 55.6 percent of the volume for all OTSA 4 hospitals. Notably, the two existing PHT providers in OTSA 4, Jackson and DiMaggio, only had volumes of 51 and 125, respectively, during this same time period. Combined, these two hospitals still had a significantly lower volume of the targeted ICD-9 codes than did NCH.

105. Using AHCA data, NCH then determined that, from 2012 through 2014, an average of 11.2 percent of patients at the

four existing transplant hospitals that had a primary diagnosis of one of the identified ICD-9 codes received a transplant. Using just 2014 data, this average was 15.2 percent. This increase was due to DiMaggio, which opened in 2010, increasing from 3.4 percent in 2012 to over 11 percent in 2014.

106. Using NCH's market share in OTSA 4 and the population forecasts, NCH was able to determine its forecasted volume of patients with these common indicators. NCH then applied a very conservative ramping up ratio of ICD-9 volume to PHTs of five percent in 2018, eight percent in 2019, and 10 percent in 2020 to forecast the number of PHTs NCH could expect. When the above ratios are applied to the expected ICD-9 volumes, the result is six PHTs for the 12-month period ending June 30, 2018; 11 for the 12-month period ending June 30, 2019; and 13 for the 12-month period ending June 30, 2020.

107. At hearing, Jackson criticized NCH's common indicators methodology, pointing out variability where All Children's volume of common indicators only went from 64 to 66 between 2013 to 2014, yet the number of transplants doubled from seven to 14. However, as Ms. Greenberg explained, NCH looked at multiyear trends, not a single point in time. A single point in time may have large fluctuations due to things like what occurred at All Children's: the head pediatric cardiology surgeon left, which shifted patients from All Children's to

Shands. A change in surgery personnel was one of the factors identified by Dr. Gulesarian as potentially affecting PHT volumes.

108. Criticism was also raised regarding NCH's use of ICD-9, instead of the newer ICD-10, codes because the conversion resulted in the inclusion of certain indicators, e.g., Eisenmenger Syndrome, Coronary Artery Disease, and Ehlers-Danlos Syndrome, as being among the list of most common indicators for heart transplant. NCH's planner demonstrated that any differences due to the inclusion of these ICD-10 codes was de minimus or nonexistent. Thus, even had the newer codes been used, they would not have materially affected the volume projections for the proposed PHT program.

109. Jackson is correct that both need methodologies put forth by NCH are "institution specific," and are better characterized as an internal demand analysis than as a need methodology. Neither method identifies either an unserved population or an access issue. Rather, they project a volume of patients NCH anticipates would be available to receive a PHT at NCH if approved.

Section 408.035(1)(b): The availability, quality of care, accessibility, and extent of utilization of existing health care facilities and health services in the service district of the applicant.

Section 408.035(1)(e): The extent to which the proposed services will enhance access to health care for residents of the service district.

Disparity in Use Rates

110. OTSA 4 represents 32 percent of Florida's pediatric population. The five-county OTSA is home to more than 1.3 million residents age 17 and under. Yet, despite having approximately one-third of the pediatric population, OTSA 4 only provides one-tenth of the state's PHTs.

111. The chart below presents the PHT use rates in Florida by OTSA for CY 2013 through CY 2015:

Use Rates per 1,000,000, Age 0 to 17

OSTA	CY2013	CY2014	CY2015	3-Yr Avg
1	10.1	11.2	13.3	11.6
2	10.7	5.8	8.6	8.4
3	9.6	15.4	9.3	11.4
4	3.9	3.1	3.1	3.3
Statewide Average	8.2	8.1	8.0	8.1

(NCH Ex. 75).

112. As can be seen from the above, the three-year average use rate in OTSA 4 (CY 2013 through CY 2015) is 3.3 percent, compared to OTSA 1 at 11.6 percent, OTSA 2 at 8.4 percent, and OTSA 3 at 11.4 percent for the same time period.

113. There was no evidence that there was anything unique about the pediatric patients in Miami-Dade County to justify this disparity in PHT use rates. To the contrary, Dr. Rosenkranz conceded that he did not know of anything that would justify any disparity in the use rate in OTSA 4, and he would expect it to match the rest of Florida:

Q. . . . So for those counties in OTA 4, from a clinical perspective, are you aware of anything unique about those counties that would make the prevalence of pediatric heart disease or heart malfunctions that result in transplant any different than any other parts of Florida?

A. Nothing that I'm aware of.

Q. You would expect it to be similar to other parts of Florida, correct?

A. Yes, I would.

(NCH Ex. 176; pp. 25).

114. Dr. Rhodes similarly testified there was no clinical reason for the relatively low use rate in South Florida, other than the fact that the largest pediatric cardiac surgery provider in the state (NCH), which is doing 25 percent of the pediatric cardiac surgeries in the state, does not have a PHT program. Dr. Feld echoed these opinions and testified that if NCH's CON application is approved, with the addition of Dr. Guleserian, NCH will be able to rectify the disparate use rate.

115. Ms. Greenberg testified that the PHT use rate data shows a disparity that would indicate that residents of OTSA 4 have an access issue to PHT because many children are going without the service. On cross-examination, however, she conceded that patients who leave OTSA 4 in order to receive a PHT could also at least partially explain the disparity. But in either case, she concluded, whether it was lack of service or due to out migration, the low use rate indicated an access issue in OTSA 4.

116. The most convincing explanation for the disparate use rate came from Cassandra Smith-Fields who testified that the use rate disparity has resulted from the PHT programs being placed in the wrong hospitals. This opinion was echoed by Dr. Rhodes, who cited data showing that transplant programs across the nation were usually located at high-volume pediatric surgery providers.

117. NCH presented compelling data based upon its sheer volume of pediatric cardiac surgeries that approving NCH's PHT application will have a substantial impact in resolving the current disparity in PHT use rates. As noted previously, NCH performs 25 percent of all pediatric cardiac surgeries in Florida, 62.2 percent of those performed in OTSA 4, and 72.7 percent of those done in Miami-Dade County.

Inability to Transfer NCH Patients on ECMO

118. Several NCH cardiologists testified there are a significant number of their patients that are simply too sick to be transferred from NCH to another facility to receive a PHT. Many of these patients do not even get listed for a heart transplant since they likely would not survive the necessary transfer.

119. Dr. Burke provided 20 years of data showing 275 post-surgical pediatric heart patients that had been placed on ECMO after surgery. One hundred and forty-seven of those children died. While he could not opine as to exactly which of those patients' lives could have been saved if NCH had been able to offer them a PHT, he testified that each of those children were a potential candidate for a PHT in order to have a chance to save their lives.

120. Dr. Rossi explained the difficulties of moving patients on ECMO. Patients must be chemically paralyzed while on ECMO, because the slightest movement of the patient can cause the cannula to shift, potentially resulting in death. The risk of moving ECMO patients is so serious 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 even move the patient down the hall to the operating room.

121. Dr. Rossi explained that the only time one would ever transport a patient on ECMO is when not moving the patient would result in certain death. Despite NCH's award-winning transport team, its experience with patients transported on ECMO is that two-thirds of the patients die during the transport. Multiple NCH physicians discussed the inherent dangers of just moving a patient on ECMO down the hall for procedures.

122. While some patients are too sick to transport, they may yet be appropriate candidates for PHT. Approximately five percent of Dr. Guleserian's transplant patients have been patients transplanted while on ECMO. Ms. Smith-Fields testified that in her program, when there is a high-risk pediatric surgery taking place, the patient will often be pre-cleared as a PHT patient so that if the surgery is not a success, the patient can be supported on ECMO and immediately listed for transplant without any processing delays.

123. While NCH did pioneer a portable ECMO machine to transfer patients on ECMO, it has only been used to bring patients to NCH. Those patients were certain to die if they were not transported on ECMO, and one-third of them lived because of those transports.

124. However, when that risk is contrasted with the risk of transporting NCH patients on ECMO to be listed for PHT, the risk of transport is greater than the risk of waiting to see if

the patient recovers on ECMO. Approximately half of NCH's cardiac surgery patients who go on ECMO after a failed surgery survive. It would not be advisable to take the risk of transport on ECMO because the odds of the patient dying are increased.

125. Credible testimony established that there are significant risks to a patient being transported while on ECMO. Thus, even assuming that transporting a patient on ECMO from NCH to a transplant facility was an option, forcing a patient to accept the high, and potentially fatal, risks of this transport presents a major access issue.

Organ Out-migration from OTSA 4

126. The evidence did not establish that there is currently significant out-migration of PHT patients from OTSA 4 or Miami-Dade to other Florida or out-of-state PHT programs. Considering the risks inherent in transport discussed above, this is not surprising. However, there is a demonstrated out-migration of donor hearts from Florida.

127. During CY 2010 through August 2015, there were 205 pediatric hearts recovered throughout Florida. In 2014, specifically, there were 38 hearts recovered and 29 pediatric heart transplants performed the same year. Because there were more hearts recovered than transplanted in the state, Florida is a net exporter of donor pediatric hearts.

128. At hearing, Jackson asserted that its low volume of PHTs was caused by the lack of viable pediatric hearts to be transplanted in OTSA 4. However, this argument was inconsistent with the SRTR data showing approximately 25 percent of the adult and pediatric donor hearts harvested in Florida in 2015 (41 hearts) were being sent out of state, many to children's hospitals. The data also reflects that OTSA 4 is a net exporter of donor hearts.

129. To the extent there is any merit to Jackson's claim about the lack of viable pediatric hearts, however, the evidence also showed that adding PHT programs to an area increases the number of hearts procured in that region. This is known as the "push/pull phenomenon." As explained by Ms. Smith-Field, the push/pull phenomenon results when the presence of transplant centers within a given donor service area "pushes" the designated organ procurement organizations to a better job of procuring organs.

Quality of Jackson's PHT Program

130. Based upon persuasive evidence presented at hearing, there is a strong positive correlation between the number of pediatric cardiac surgeries a hospital performs and its PHT volumes. Not surprisingly, nationally PHT programs are almost universally located in the hospitals with the highest volume of pediatric cardiac surgery.

131. For procedures such as cardiac surgery, the number of procedures performed directly correlates to the quality of the outcomes. Generally speaking, surgeons and facilities with higher volumes experience higher quality. This volume-outcome relationship is expressly recognized by AHCA in several of its CON rules which require minimum projected volumes, including organ transplantation.

132. Jackson has struggled with low pediatric cardiac surgery volumes since at least 2012, when it was unable to meet the Children's Medical Services pediatric cardiac volume requirements and was placed on probationary status. The compelling evidence showed that in both its pediatric cardiac surgery program and its PHT program, Jackson has been a chronically low-volume provider. Indeed, it was undisputed that Jackson has the lowest PHT volume in the state.

133. Jackson's PHT waitlist activity indicates continued low volume. Ms. Smith-Fields compared Jackson's waitlist additions to her program's experiences and concluded Jackson's waitlist additions are not indicative of an active program:

And so the other thing I guess that really stood out for me when I looked at this was how many patients were put on the waitlist? So this says that they added two patients to the waitlist in 2014. That's telling me that's not a very active program. In my own program in 2015, where we did 15 transplants, we put 24 candidates on the list that year. Lucille Packard did

20 transplants last year, they put 32. So I just run the ratios, if I put two patients on the list, I am only expecting to do one or two transplants, that's going to keep you being a very small program.

134. Several NCH physicians discussed the correlation between volume and quality, and expressed concerns that Jackson's PHT program was just too low volume for them to feel comfortable recommending patients go there.

135. Ms. Smith-Fields examined Jackson's PHT scorecards and had several concerns about the quality of Jackson's PHT program, including: Jackson taking too long to waitlist patients; having patients on the waiting list too long; and putting patients on inactive status for unusually long periods of time. She agreed that risk aversion is a common phenomenon in small transplant programs.

136. Jackson unconvincingly attempted to explain its perennially low PHT volumes by suggesting that Dr. Rusconi was better at medically managing patients to avoid transplant. In response, Dr. Guleserian testified that all PHT programs do everything they can to medically manage their patients in an effort to avoid transplantation. According to Dr. Guleserian, to believe that Jackson has found some magic formula to avoid transplantation, but is somehow hiding this secretly away from the rest of the transplant world, is not plausible. She explained that she sits on various national committees and

boards dedicated to PHT, and if such an approach had been developed with those kinds of results, she would be aware of it. Moreover, there is no evidence of record to suggest that all four Florida PHT programs do not have heart failure programs at least as robust and successful as Jackson's program.

137. Jackson's contention that its low PHT volume is the product of a particularly successful heart failure program is not credible. While it is undisputed that PHT should be considered the intervention of last resort, the evidence also established that for some children, there is no alternative to PHT. This is reflected by the fact that in CY 2015 a total of 30 PHTs were performed in the four Florida PHT programs.

138. Whatever the reason(s) for its consistently low PHT volumes, the fact remains that during CY 2010 through CY 2015, Jackson performed a total of only seven PHTs, by far the lowest volume of any of the PHT providers in the state. During this same period of time, the other three Florida PHT programs performed a combined total of 121 PHTs. Given the well-documented relationship between volume and outcome of surgical procedures, Jackson's low PHT volume alone raises legitimate quality of care concerns.

Adverse Impact on Jackson and DiMaggio

139. The evidence demonstrated NCH only rarely refers PHT candidates to Jackson and DiMaggio. Jackson only presented

evidence of one potential transfer patient it claimed was referred by NCH in the last several years. However, no specific referring cardiologist was identified, no NCH witnesses corroborated the referral, and no records were produced to corroborate the referral was from NCH.

140. NCH presented evidence of two of its patients that sought transplant at Jackson. One of these patients died without being listed for transplant (despite at least one of the cardiologists at Jackson fighting to get the patient either listed or transferred to Shands), and the other patient ultimately received their transplant at Shands.

141. The consistent testimony from NCH physicians was that they are hesitant to refer PHT patients to Jackson because of its low volume and other perceived quality issues. This is particularly concerning since NCH's patients represent 60 percent of the pediatric cardiac surgeries performed in OTSA 4, and many of these patients have congenital heart defects that will eventually result in them requiring a PHT.

142. Jackson argued that NCH referring its patients to Shands and All Children's, rather than Jackson, was the reason why Jackson had been unable to grow its transplant program. Some Jackson witnesses intimated NCH was intentionally sabotaging Jackson's program by not referring its patients

because of prior fallings-out between the hospitals and their physicians.

143. While the evidence showed there had been several failed attempts for NCH and Jackson to work collaboratively with pediatric cardiac patients, it did not show that this was the reason why NCH physicians rarely refer patients to Jackson. Rather, the lack of referrals was based upon quality concerns. Indeed, credible testimony established that NCH physicians are advising their patients about the correlation between volume and quality as documented in the medical literature, resulting in those PHT candidates, who have the financial means and clinical ability to travel, choosing to pursue their PHTs at higher-volume programs. Given, NCH's dominant market position and quality concerns, these referral patterns do not appear likely to change.

144. The greater weight of the evidence established that approval of the NCH PHT program would have minimal, if any, impact on the volume of PHTs being performed at Jackson.

145. For the same reasons identified with respect to Jackson, approval of the NCH program will likely have minimal, if any, impact on the volume of PHTs performed at DiMaggio.

Section 408.035(1)(c): The ability of the applicant to provide quality of care and the applicant's record of providing quality of care.

146. NCH has a demonstrated record of providing quality cardiac services to its patients. NCH's cardiology and heart surgery program is ranked 40th in the United States by U.S. News and World Report. In addition, NCH has more pediatric programs ranked among "America's Best" by U.S. News and World Report than any other hospital in Florida.

147. NCH's dedicated CICU, staffed with a dedicated cardiac team, will be able to provide high quality care for PHT patients.

148. NCH's cardiac nursing staff has an average of 12 years' experience caring for heart patients. NCH's cardiac physicians are all highly qualified, with decades of experience.

149. Jackson alleged quality deficiencies related to NCH's staffing, clinical review committee, protocols and procedures, laboratory and pathology services, and staff and patient family educational programs. However, none of these alleged deficiencies persuasively shed doubt on NCH's ability to provide excellent quality of care to its PHT patients.

Section 408.035(1)(d): The availability of resources, including health personnel, management personnel, and funds for capital and operating expenditures, for project accomplishment and operation.

Short Term Financial Feasibility

150. The parties stipulated to NCH's ability to initially fund the project.

Availability of Health and Management Personnel

151. NCH's existing management personnel will oversee the proposed project. Given the relatively small size of the project, the existing management staff is more than capable of overseeing and managing this additional program.

152. Based upon its PHT volume projections, which are credible, NCH is expecting its average daily census (ADC) of cardiac patients to increase by only one to two patients a day as a result of the PHT program. NCH currently has a dedicated cardiac clinical staff of 16 to 20 registered nurses, nurse practitioners, and technicians who are more than capable of handling the projected increase in ADC.

153. In addition, NCH currently has eight registered nurses and four advanced nurse practitioners that have dedicated heart transplant experience. Upon approval of the program, NCH will ensure that all staff is properly trained and educated prior to the implementation of the PHT program. This includes

the training to prepare both a nutritionist and a transplant coordinator.

154. With the successful recruitment of Dr. Guleserian, who has performed 133 pediatric heart transplants, NCH's surgeons and other physicians are more than capable of staffing the PHT program.

155. NCH will not have any difficulty recruiting a high-quality heart failure specialist given NCH's reputation, cardiac surgery volumes and market shares, and reputable physician team already in place.

Section 408.035(1)(f): The immediate and long-term financial feasibility of the proposal.

156. As noted, the parties stipulated that NCH has the financial ability to fund the proposed program.

157. As to long-term financial feasibility, NCH has \$586 million in net assets with a net operating income of \$100 million per year. NCH is well-positioned to absorb any potential losses that the PHT program might incur, and is dedicated to maintaining the program, regardless of profit or loss, due to its commitment to meeting the needs of the community.

158. NCH has a history of funding financially unprofitable programs when there is a critical need for them in the community. An example is NCH's LifeFlight program, which

generates no profit for NCH and, in fact, operates at a \$3 million per year loss.

159. Jackson raised issues regarding errors in NCH's financial schedules attached to the CON application. Ms. Greenberg incorrectly included a full-time physician's salary in the financial schedule, at the wrong amount. Physicians are not employed directly by NCH and should not have been included. Ms. Greenberg's third-year financial projection, while correctly listing staffing costs as a line item, failed to include that cost in the final total. However, correcting for these minor errors shows that this program will still be profitable.

160. It is also worth noting that when AHCA is evaluating transplant programs, it looks at the financial health of the entire applicant, not just the program under CON review in a vacuum. As Ms. Fitch explained:

THE COURT: Okay. I have heard testimony today, and you may have heard it as well, from Mr. Balsano regarding an addition error that apparently existed on the NCH pro formas.

You have testified that the Agency found the project to be financially feasible in the long-term. At the time the Agency made that determination, had that addition error been revealed to the Agency?

THE WITNESS: Not that I know of. But I will say, in terms of the Agency, typically we don't see that transplant programs are necessarily profitable on their own. We do

look at the entire system to determine whether a facility can maintain a program.

We have seen a number of programs come in that, on their own, are not financially feasible but in an entire health system, it is a feasible feat for an application.

So I heard Mr. Balsano's testimony, and while I think that's a significant addition error, I don't know that that would have necessarily changed the review.

I don't want to speak for the financial analysis unit, but I have seen programs that on their own are not financially feasible but the Agency determines that the health system can support it, based on their total system.

161. Given the overall financial strength of NCH, and its commitment to continue to fund the PHT program regardless of its profitability, the long-term financial feasibility of the program is not in question.

Section 408.035(1)(g): The extent to which the proposal will foster competition that promotes quality and cost-effectiveness.

162. As detailed above, there is an unexplained use rate disparity between Miami-Dade County, OTSA 4, and the rest of the state with regard to PHT. This disparity is a strong indicator that there is an access issue for residents of District 11.

163. The evidence established that Jackson has not performed a PHT on any Miami-Dade County resident in the past three years.

164. The access issue is particularly pronounced for complex cases, both because Jackson appears to be reluctant to list and transplant complex cases, and because a significant population of critically ill children cannot be safely transferred from NCH to Jackson.

165. Approval of NCH's application will provide residents of District 11 and OTSA 4 access to a high-volume, high-quality cardiac program for PHT, something they do not have access to now.

166. There is no question that approval of the NCH program will foster competition. As Dr. Burke testified, in his experience approval of a new PHT provider serves as a stimulus to existing providers. There is also little question that once established, the NCH program will be high-volume, particularly relative to the volumes of PHT being done at Jackson and DiMaggio.

Section 408.035(1)(g): The costs and methods of the proposed construction, including the costs and methods of energy provision and the availability of alternative, less costly, or more effective methods of construction.

167. NCH did not propose construction for this project. This criterion is not in dispute.

Section 408.035(1)(g): The applicant's past and proposed provision of health care services to Medicaid patients and the medically indigent.

168. NCH has a long history of providing health services to Medicaid patients and the medically indigent. In CY 2013 and CY 2014 NCH provided \$2,327,848 and \$1,193,660 in charity care, respectively, representing 2.1 and 2.5 percent of its net patient revenue.

169. NCH provided \$106,941,948 in conventional Medicaid and \$134,616,815 to patients under Medicaid Managed Care in CY 2014.

170. NCH's projects that annually, over 60 percent of the PHT patient days will be Medicaid. This payor mix is based on NCH's complex cardiac patient payor mix, and is reasonable.

171. NCH has and will continue to provide health care services to Medicaid patients and the medically indigent.

172. Inasmuch as the majority of pediatric patients qualify for Medicaid, and NCH has a history of providing care to Medicaid patients and the medically indigent, both Jackson and AHCA concede the proposal's compliance with this criterion is not in dispute.

CONCLUSIONS OF LAW

Jurisdiction and Standing

173. The Division of Administrative Hearings has jurisdiction over the subject matter of and the parties to this proceeding. §§ 120.569, 120.57(1), and 408.039(5), Fla. Stat.

174. Whether NCH's proposed PHT CON application should be approved or denied must be based upon a balanced consideration

of applicable statutory and rule criteria. Dep't of HRS v. Johnson and Johnson Home Healthcare, Inc., 447 So. 2d 361 (Fla. 1st DCA 1984); Balsam v. Dep't of HRS, 486 So. 2d 1341 (Fla. 1st DCA 1986). "[T]he appropriate weight to be given to each individual criterion is not fixed, but rather must vary on a case-by-case basis, depending upon the facts of each case." Collier Med. Ctr., Inc. v. Dep't of HRS, 462 So. 2d 83, 84 (Fla. 1st DCA 1985).

175. NCH bears the burden, in this matter, to prove by a preponderance of the evidence that its CON application should be approved. See Boca Raton Artificial Kidney Ctr., Inc. v. Dep't of HRS, 475 So. 2d 260, 263 (Fla. 1st DCA 1985); § 120.57(1)(j), Fla. Stat.

176. An administrative hearing involving disputed issues of material fact is a de novo proceeding in which the administrative law judge independently evaluates the evidence presented. Fla. Dep't of Transp. v. J.W.C. Co., Inc., 396 So. 2d 778, 787 (Fla. 1st DCA 1981).

177. Furthermore, "while hearsay evidence is admissible in administrative hearings to supplement or explain other evidence, it is insufficient in itself to support a finding." Kaye v. Dep't of HRS, 654 So. 2d 298, 299 (Fla. 1st DCA 1995); Harris v. Game and Fresh Water Fish Comm'n, 495 So. 2d 806, 808 (Fla. 1st DCA 1986); § 120.57(1)(c), Fla. Stat.

178. Jackson, as the Intervenor, has the burden to demonstrate its standing to participate in this case. See Balino v. Dep't of HRS, 348 So. 2d 349 (Fla. 1st DCA 1977).

179. Section 408.039(5)(c) provides in relevant part:

Existing health care facilities may initiate or intervene in an administrative hearing upon a showing that an established program will be substantially affected by the issuance of any certificate of need, whether reviewed under s. 408.036(1) or (2), to a competing proposed facility or program within the same district.

180. Standing exists if a party can prove: (1) "injury in fact" of sufficient immediacy, and (2) that the injury is of a type the proceeding is designed to protect, commonly referred to as the "zone of interest" test. North Ridge Gen. Hosp., Inc. v. NME Hosps., Inc., 478 So. 2d 1138, 1339 (Fla. 1st DCA 1985); Agrico Chemical Co. v. Dep't of Env'tl. Reg., 406 So. 2d 478, 482 (Fla. 2d DCA 1981). "The first aspect of the test deals with the degree of injury. The second deals with the nature of the injury." Id.

181. The evidence established that Jackson has gone many months without performing a PHT, provides the fewest number, by far, of PHTs of any of the four Florida programs, and has very few patients listed on its PHT waiting list at any given time. Jackson's program is so nominal that any alleged impact to Jackson's patient census caused by NCH's approval is de minimus.

182. The evidence also established that historically NCH has referred few, if any, potential PHT candidates to Jackson. Accordingly, regardless of whether the NCH program is approved or not, Jackson's PHT program is likely to continue with its chronically low, and practically non-existent, volumes of PHTs.

183. Moreover, the Jackson PHT program will not be substantially adversely impacted by NCH's approval, since NCH proposes to serve a different universe of patients than Jackson serves. As noted, a significant portion of NCH's PHT volume will be infants and neonates with congenital birth defects, a population not served by Jackson.

184. Jackson failed to offer any quantification in terms of numbers or dollars for any potential staffing impacts, and has therefore failed to show such potential impacts would be material. Further, NCH only projects to hire minimal additional staff.

185. Because Jackson has failed to show that it will suffer injury in fact of sufficient significance or immediacy, Jackson has no standing to challenge NCH's CON Application. See e.g Kendall Healthcare Grp., Ltd., d/b/a Kendall Reg'l Med. Ctr. v. AHCA, Case No. 03-2822 (Fla. DOAH Mar. 12, 2004; Fla. AHCA May 19, 2004) (finding that Mount Sinai's impact was so minimal that it lacked standing to challenge Kendall's CON application).

186. In its PRO, NCH urged that should Jackson be found to lack standing, the evidence and argument presented by Jackson at hearing be excluded from consideration in the preparation of this Recommended Order. NCH cites no authority for this request, and independent research by the undersigned has revealed no precedent for granting the request. Indeed, the exclusion of Jackson's evidence and argument would be contrary to section 120.57(1)(f) which identifies the record in a case to include, among other things, the evidence admitted and the official transcript of the hearing. Accordingly, the evidence and argument presented by Jackson has not been excluded from consideration by the undersigned.

187. DiMaggio did not seek to intervene in this proceeding, and therefore, its standing is not at issue. However, Jackson was certainly within its rights to present the testimony of DiMaggio's physicians as part of its case in chief. See Baycare of S.W. Pasco, Inc. v. Ag. for Health Care Admin., Case No. 07-3482 (Fla. DOAH Oct. 28, 2008; Fla. AHCA Jan. 7, 2009) (A party opposing approval of an application may "present evidence that residents of a district did not 'need' a new facility in the district because the needs of the residents were met by a near-by facility outside the district.").

Impermissible Application Amendments?

188. Rule 59C-1.010(3)(b) states that “[s]ubsequent to an application being deemed complete or withdrawn by the Agency, no further application information or amendment will be accepted by the Agency.” However, “[a]pplicants may offer evidence that explains assertions, corrects errors, or updates information about an application if the evidence does not introduce a new element to the proceeding or change the nature and scope of the proposal.” Marion Cnty. Dev., LLC v. Ag. for Health Care Admin., Case No. 15-1966CON (Fla. DOAH June 23, 2016; Fla. AHCA Aug. 4, 2016) (citing Manor Care, Inc. v. Dep’t of HRS, 558 So. 2d 26, 29 (Fla. 1st DCA 1989)).

189. It is also well-settled “that as to matters within an applicant’s control, significant changes to a completed application are not permitted.” Manor Care, 558 So. 2d at 29; see All Eighth Fla. Living Options, LLC v. Ag. for Health Care Admin., Case No. 15-1897CON (Fla. DOAH Feb. 22, 2016; Fla. AHCA Apr. 13, 2016). A matter is within an applicant’s “control” if the applicant knew or reasonably should have known about the information. Charter Med.-Orange Co., Inc. v. Dep’t of HRS, Case No. 87-4748 (Fla. DOAH Nov. 28, 1988; Fla. DHRS Feb. 2, 1989).

190. “If the applicant reasonably should have known about the information and should have provided it to the Department with the information as a part of its original application, then

the new information cannot be considered during the formal administrative hearing." Id.

191. However, "[a]n applicant is not required to set forth in its application every piece of evidence, testimony, or argument upon which it intends to rely if a challenge is brought to its application, but must simply raise all issues which it contends support its application." Sarasota Cty. Pub. Hosp. Bd., d/b/a Mem'l Hosp., Sarasota, and Adventist Health System/Sunbelt, Inc., d/b/a Med. Ctr. Hosp. v. Dep't of HRS, Case No. 89-1412 (Fla. DOAH Sept. 28, 1989; Fla. DHRS Nov. 17, 1989). See also NME Hosp., Inc., d/b/a West Boca Med. Ctr. v. Dep't of HRS, Case No. 90-7037 (Fla. DOAH Feb. 25, 1992; Fla. DHRS April 8, 1992) (evidence is admissible that explains or elaborates on assertions made in a CON application, and does not change the nature and scope of the proposal); Columbia Hosp. Corp. of South Broward, d/b/a Westside Reg'l Med. Ctr. v. AHCA, Case No. 94-1020 (Fla. DOAH Jan. 31, 1996; Fla. AHCA Mar. 6, 1996) ("it was appropriate for Westside to provide [such] data . . . at hearing in an attempt to explain or elaborate on the information originally submitted. . . ."); Marriott Ret. Comm. v. Dep't of HRS, Case No. 91-2231 (Fla. DOAH Feb. 11, 1992; Fla. DHRS May 6, 1992) (details presented at hearing which supplied the basis for statements contained in the application did not constitute an impermissible amendment--an applicant is not

required to set forth in its application every piece of evidence upon which it may rely if it proceeds to hearing).

192. As explained more fully in NME Hospitals, supra, what is "[n]ot permitted are additional services, beds, construction, or other concepts not initially reviewed by the department."

Id. The Agency held in its Final Order that, the "evidence produced at hearing, though conflicting, does not constitute an improper amendment." Id.

193. Further "[i]f information in an application is incorrect, it must be corrected even if the correction is made after the application is deemed complete. The correction will be allowed so long as the information does not change the nature and scope of the application." Vitas Healthcare Corp. of Fla. v. Ag. for Health Care Admin. and Heartland Servs. of Fla., Inc., Case No. 04-3856CON (Fla. DOAH Oct. 18, 2006; Fla. AHCA Dec. 13, 2006).

194. At hearing, Jackson objected to virtually every piece of updated information that was not identical to what was presented in the CON application. This demonstrates a fundamental misconception about what is an impermissible amendment. Contrary to Jackson's assertions, it is routine in CON proceedings to update data and charts that may have changed since the CON was originally filed. It is also well within the acceptable parameters to look at new data or conduct different

analysis than what was presented in the CON application, so long as the new or updated information does not change the nature and scope of the project.

195. One argument raised by Jackson is that NCH's evidence on the disparity in use rate in OTSA 4 is an application amendment because it is not one of the two need methodologies NCH used to forecast its projected patient volumes. This argument is rejected. NCH included a discussion in its CON Application relating to the disparity in the OTSA 4 use rate. That section, on pages 37 through 47 of the CON application, includes references comparing Miami-Dade's and OTSA 4's use rate with the statewide use rate, and highlighting the historically low volumes of the existing PHT providers in OTSA 4.

196. At hearing, AHCA's representative conceded the concept of disparity in use rate was raised in the CON application, and that this argument was considered when AHCA reviewed the application before issuing the SAAR. Accordingly, there is no change in the nature or scope of NCH's application based upon this evidence presented at final hearing.

197. Jackson also argues that NCH amended its application at hearing by considering patients 0-15 as a group, instead of 0-17, as was presented in the application. In response, NCH counters that this is not an attempt at an amendment at all, but merely rebuttal to Jackson's argument. While AHCA's PHT rule

defines pediatric patients as ages 0-15, OPTN and UNOS both report pediatric patients as ages 0-17. OPTN data, which was used by both Jackson and NCH, groups pediatrics as 0-17. It was this data that was initially used to project need. However, the 0-15 age population is a subset of the 0-17 data set, therefore, the data was included in the application, albeit part of a slightly larger population subset. Notably, when the numbers are recalculated to only consider 0-15, as Ms. Greenberg did in a rebuttal exhibit, there is virtually no change in number of projected patients.

198. Whether considering patients age 0-15 or 0-17, the nature and scope of the application is a CON for pediatric heart transplant. Given the miniscule change in the projections (one case in year two) allowing NCH to present evidence on patients 0-15 does not constitute an application amendment. There was no change in the nature and scope of the application by this subsequent analysis.

199. Finally, Jackson argues that while NCH attempted to correct some of the financial errors contained within its application during the final hearing, these attempts amount to improper amendments to the application and cannot be considered.

200. It is well-established precedent in Florida that financial errors contained within a CON application can be corrected by an applicant if they do not alter the purpose,

nature, or scope of the application. HCA Health Servs. of Fla., Inc., d/b/a Oak Hill Hosp. v. Hernando HMA Inc., d/b/a Brooksville Reg'l Hosp., Case No. 02-0454 (Fla. DOAH Feb. 19, 2003; Fla. AHCA Feb. 19, 2003).

201. Specifically, Jackson argues that NCH committed significant errors when projecting its proposed program's expenses and revenues in the first three years of operation, and that to permit correction of those errors at hearing would constitute an impermissible amendment to the application. Those alleged errors were: (1) a mathematical computation error caused when a line item was excluded from the calculation in an excel formula; (2) using the wrong Medicaid reimbursement rate; and (3) excluding costs for certain necessary staff and equipment.

202. As to the mathematical error, the Vitas case is directly on point with regards to corrections in financial pro formas. There, the ALJ held: "[c]orrection of the information in its pro formas did not introduce a new element into the proceeding and therefore does not constitute an impermissible amendment to the application." Id. In Vitas, the health planner made a mathematical error on the pro formas in using patient hours instead of patient days in a calculation. In response to criticism, evidence at hearing was presented regarding the corrected amounts, but still showing that, with

the corrected amounts, Vitas would be profitable by year two. The ALJ held that this was not an impermissible CON amendment, but merely a correction. Id.

203. Here, the missing line item was related to costs that were identified in the application and part of the analysis. Correcting the mathematical error where a line item was inadvertently excluded from the calculation in a financial pro forma does not introduce any new element into the proceeding and does not constitute an impermissible CON amendment.

204. The second alleged error related to the Medicaid reimbursement rate used by NCH in its financial projections. There was conflicting testimony as to whether the rate used by NCH was in fact erroneous, but in any case the issue is the same as the correction discussed above: it does not change the nature and scope of the project and therefore is not an application amendment.

205. The third alleged error was the failure to include certain staffing costs in the financial pro formas. NCH included physician costs for a pediatric heart surgeon in its pro formas, but did not include costs for a heart failure specialist, a position NCH has admitted it will need to fill. NCH's position is that it erred when it included the surgeon cost at all, since the physician is employed by a separate company and therefore not required to be included on the pro

forma. Moreover, according to NCH, if the surgeon cost was required to be shown on the pro forma, the proper presentation would also have included the surgeon revenues, which was not done.

206. If the full complement of necessary physician cost and revenues are either both added in or both taken out of the pro formas, NCH still shows a profit, even after correcting for the first identified mathematical error and even accepting Jackson's disputed Medicaid rate. If, however, only the physician costs are added in and the revenues are not added in, the program does not demonstrate a profit within the time period shown in the pro formas. In any event, correcting the alleged errors on the financial schedules does not change the nature or scope of the proposed project.

207. Here, NCH submitted, and AHCA reviewed, a CON application for NCH to provide PHT at its existing hospital, with no construction necessary. This is the same project that was furthered at final hearing. NCH's revisions do not alter the purpose, nature, or scope of its application and therefore do not constitute prohibited substantial amendments to NCH's application under rule 59C-1.010(3)(b).

Statutory and Rule Review Criteria

Threshold Volume Criteria in Rule 59C-1.044(6)(b).

208. Rule 59C-1.044(6) regulates "Heart Transplant Programs." However, the parties disagree over which portions of rule 59C-1.044(6)(b) apply to PHT programs. The disputed subsection provides in full:

(b) Need Determination. An application for a Certificate of Need to establish a heart transplantation program shall not normally be approved in a service area unless:

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;

2. The application contains documentation that a minimum of 12 heart transplants per year will be performed within 2 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;

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

the Certificate of Need application deadline; and,

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

209. NCH argues that only section 4. applies to PHT proposals, while Jackson and AHCA argue that all four sections apply. Under AHCA's and Jackson's interpretation, applicants would not normally be approved unless they documented they would provide at least 12 transplants by the end of year two, and all existing providers in OTSA 4 were performing 24 transplants a year. NCH argues these provisions are only applicable to adult programs, not pediatric programs, since other requirements in the rule identify specific pediatric criteria.

210. The undersigned has found that NCH has reasonably projected that it will perform at least 12 pediatric (whether defined as age 0-14 or 0-17) heart transplants per year by the end of the second year of operation. Accordingly, it is only rule 59C-1.044(6)(b)1., relating to the volumes of existing heart transplant providers, that remains at issue.

211. No party has cited a prior DOAH decision regarding a PHT CON application, and the undersigned has discovered no precedent which might shed light on the issue.

212. At hearing, AHCA's representative testified that with respect to two other heart transplant applications with which she was familiar (DiMaggio and Delray Medical Center), AHCA interpreted rule 59C-1.044 to require an applicant for a heart transplant CON to meet the requirements outlined in subsection (6)(b), whether the application was for a pediatric or adult program. Conversely, NCH's transplant program expert, Ms. Smith-Fields, testified that the requirement for an annual minimum of 24 PHTs to be performed by all existing providers would not be an appropriate pediatric standard, since it would result in all but one or two of the very largest programs in the country not meeting the standard in any given year. The undersigned notes that the 24 PHT threshold requirement does not appear to have been a strict prerequisite to approval of new PHT programs, since at the time of DiMaggio's approval, Jackson was performing few, if any, PHTs.

213. Florida courts have determined that an agency is given broad discretion and is entitled to great deference when interpreting its governing statutes and promulgated rules. Bd. of Podiatric Med. v. Fla. Med. Ass'n, 779 So. 2d 658, 660 (Fla. 1st DCA 2001); Miles v. Fla. A & M Univ., 813 So. 2d 242, 245

(Fla. 1st DCA 2002); Verizon Fla., Inc. v. Jacobs, 810 So. 2d 906, 908 (Fla. 2002). Furthermore, “[i]f an agency’s interpretation of a rule is one of several permissible interpretations, the agency’s interpretation must be upheld despite the existence of other reasonable alternatives.” Suddath Van Lines, Inc. v. Dep’t of Env’tl Prot., 668 So. 2d 209, 213 (Fla. 1st DCA 1996); Pershing Indus., Inc. v. Dep’t of Banking and Finance, 591 So. 2d 991, 993 (Fla. 1st DCA 1991).

214. From a common sense perspective, it would not appear that the 24 transplant requirement should apply to PHT programs, since no PHT program in Florida, and most in the country, have not achieved this volume of PHTs. Moreover, given Jackson’s persistently low PHT volumes, it is unlikely any new PHT program could be approved in OTSA 4 in the foreseeable future should the 24-case threshold requirement be imposed on PHT applicants.

215. However, even if this provision applied, NCH has demonstrated sufficient, not normal, circumstances to justify its approval based upon all of the findings herein, regardless of whether the 24 transplants threshold has been achieved by Jackson and DiMaggio.

216. Rule 59C-1.044(3), (4), and (5) sets forth requirements related to coordination of services, staffing requirements, and data reporting requirements. At hearing, Jackson raised a number of criticisms related to NCH’s documented

ability to comply with these requirements. Specifically, Jackson faulted NCH for failing to provide program policies, procedures, training guidelines, educational programs, and staffing plans and projections for physicians, nurses, and other healthcare professionals with sufficient specificity to assure the provision of quality care.

217. No party disputed NCH's past ability to provide quality of care to its patients in its cardiac program and hospital-wide. Given NCH's history of providing excellent care to some of the sickest and most complex patients, and the administrative and medical staff commitment to the proposed PHT program, there is no reason to believe that NCH will not implement those procedures and programs necessary to ensure the highest possible quality of care in its new PHT program.

218. Rule 59C-1.044(6)(b)4. provides that "[a]n application for a pediatric heart transplantation program shall include documentation that the annual duplicated cardiac catheterization patient caseload was at or exceeded 200 for the calendar year preceding the Certificate of Need application deadline; and that the duplicated cardiac open heart surgery caseload was at or exceeded 125 for the calendar year preceding the Certificate of Need application deadline." NCH performed 321 pediatric cardiac catheterizations and 214 pediatric open

heart surgeries in 2015, and therefore complies with this rule requirement.

219. Rule 59C-1.044(6)(b) does not establish a numeric need methodology for PHT programs. NCH proved need for its project based upon the demonstrated access and quality issues discussed above. The compelling data showed that Miami-Dade County, one of the most populous counties in the state, is underserved with regards to PHTs, despite no record evidence that there is a clinical reason for this disparity. While Jackson argued that its chronically low volume of PHTs reflect an absence of need in the OTSA, a more reasonable explanation is the access and perceived quality issues raised by NCH.

220. While there is no static value which establishes the ratio of pediatric cardiac surgeries to PHT, there is a positive correlation between a program's volume of pediatric cardiac surgeries and the anticipated PHT volume. NCH is the highest volume pediatric cardiac surgery provider in the state, and it is reasonable to expect that this will result in NCH becoming a large-volume PHT program. Based upon the ECMO patients alone that cannot be transferred because they are too critically ill, there is a significant need for this service at NCH. The reality is that this universe of patients currently does not have meaningful access to PHT.

221. Without question, there is direct relationship between surgical volume and quality of care. Due to its anticipated PHT volumes, NCH's program will enhance access to a high-quality PHT program for residents of District 11 and OTSA 4.

222. The availability of a high-quality PHT program at NCH will likely be an impetus for Jackson to improve its PHT program to compete for patients. Alternatively, NCH's approval may cause Jackson to reassess whether it wishes to continue to operate a low-volume PHT program, and instead focus on adult transplant patients. In either event, approval of the NCH program will promote quality and cost-effectiveness.

223. NCH's cardiac team has an extensive history of providing high-quality, innovative care, and there is no reason to expect that NCH and its team will not continue to provide that in the future.

224. NCH has the resources, funds, and staff necessary to carry out this project. NCH's reputation and the reputation of its cardiac team will ensure that any additional staff can easily be recruited.

225. As discussed above, NCH is financially feasible in the short- and long-term.

226. NCH has an extensive history of providing services to Medicaid and medically indigent patients and proposes to continue that with its PHT program.

227. NCH persuasively established need for its PHT program and its ability to implement the program in a manner that will ensure high-quality patient care. The NCH program will improve access and availability of PHT to patients currently unable to access that service without significantly adversely affecting the PHT programs at Jackson and DiMaggio. On balance, NCH has demonstrated entitlement to its requested CON.

RECOMMENDATION

Based on the foregoing Findings of Fact and Conclusions of Law, it is RECOMMENDED that a final order be entered approving CON Application No. 10421 filed by Variety Children's Hospital, d/b/a Nicklaus Children's Hospital, subject to the conditions contained in the applications.

DONE AND ENTERED this 15th day of May, 2017, in Tallahassee, Leon County, Florida.



W. DAVID WATKINS
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NOTICE OF RIGHT TO SUBMIT EXCEPTIONS

All parties have the right to submit written exceptions within 15 days from the date of this Recommended Order. Any exceptions to this Recommended Order should be filed with the agency that will issue the Final Order in this case.