

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

A. PROJECT IDENTIFICATION

1. Applicant/CON Action Number

**South Broward Hospital District
d/b/a Memorial Regional Hospital/CON #10386**
3501 Johnson Street
Hollywood, Florida 33021

Authorized Representative: Ilene Sultan
(954) 265-3550

**North Broward Hospital District
d/b/a Broward Health Medical Center/CON #10387**
1600 South Andrews Avenue
Fort Lauderdale, Florida 33316

Authorized Representative: Charlotte Mather Taylor
(954) 473-7180

2. Service District/Subdistrict

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

B. PUBLIC HEARING

A public hearing was not held or requested regarding either of the two co-batched proposals.

Letters of Support

South Broward Hospital District d/b/a Memorial Regional Hospital (CON application #10386): The applicant submitted a large number of letters of support and the Agency received a few independently. These letters were of TSA 4/local area origin and generally were of a form letter variety, though some were individually composed. Of these letters,

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physicians, many of whom indicate affiliation with Memorial Healthcare System, offering support and expressing need for the proposed project in the area, usually based on their medical practice experience. Major themes expressed to support the proposed project include:

- High population density, high demand and a large number of patients on kidney transplant waiting lists
- Memorial Regional Hospital's distinguished history of providing outstanding health care which contributes to their high quality care
- Enhancing patient and family access to fill a community void in an essential health care option
- To complement existing transplantation programs at Memorial Regional Hospital

Some support letters are noted from the following:

- Jeremy Ring, 29th District and Eleanor Sobel, 33rd District, State Senators, The Florida Senate
- Evan Jenne, District 99, Shevrin D. Jones, District 101 and Richard Stark, District 104, State Representatives, The Florida House of Representatives
- Mayor of:
 - City of Cooper City
 - City of Hollywood
 - City of Pembroke Pines
 - City of West Park
- City Commission of the City of West Park-Resolution No. 2015-46 (voted yes by three listed commissioners, vice-mayor and mayor)
- President/CEO of
 - Bethesda Health
 - Boca Raton Regional Hospital
 - Cleveland Clinic Hospital-Florida
 - OneBlood, Inc.
 - ChildNet
 - Children's Services Council of Broward County
 - Hispanic Unity of Florida
 - Live United-United Way of Broward County
 - Aventura Marketing Council
 - Chamber of Commerce
 - Coral Springs
 - Dania Beach
 - Greater Fort Lauderdale
 - Greater Hollywood
 - Greater Plantation
 - Miramar/Pembroke Pines

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- YMCA of South Florida
- Chief Medical Officer
 - Boca Raton Regional Hospital
 - Life Alliance Organ Recovery Agency University of Miami
 - Pediatric Associates
- Executive Director
 - American Diabetes Association-South Florida
 - EASE Foundation, Inc.
 - JDRF-Improving Lives Curing Type I Diabetes
- Chief Operating Officer
 - Jewish Federation of Broward County
- Director of Programs/Operations
 - National Kidney Foundation of Florida
 - Russian American Chamber of South Florida
- Nova Southeastern University
 - Associate Professor/Coordinator of Clinical Services-College of Nursing

North Broward Hospital District d/b/a Broward Health Medical Center (CON application #10387): The applicant submitted a very large number of letters of support and the Agency received one independently. The majority of these letters were of a TSA 4/local area origin and were generally of a form letter variety, though some were individually composed. Of these letters, physicians, many of whom indicate affiliation with Broward Health Medical Center, offered support, expressing need in the area for the proposed project, usually based on their medical practice experience. Major themes expressed to support the proposed project include:

- Enhancing and expanding access to patients who would not otherwise have access to a kidney transplantation program in the area
- Broward Health Medical Center being well known and highly regarded for its efforts to provide quality health care, regardless of ability to pay
- Broward Health Medical Center having 10 years of experienced in successful liver transplantation
- The proposed project would add to the applicant's existing transplantation services

Some support letters are noted from the following:

- Alcee L. Hastings, Member of Congress, 20th Congressional District Florida, U. S. House of Representatives
- Jeremy Ring, 29th District, Christopher L. Smith, 31st District, Eleanor Sobel, 33rd District and Oscar Braynon II, 36th District, State Senators, The Florida Senate

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- Gwendolyn “Gwyn” Clarke-Reed, District 92, George R. Moraitis, District 93, Bobby B. DuBose, District 94, Hazelle P. Rogers, District 95, Jared Moskowitz, District 97, Katie Edwards, District 98, Evan Jenne, District 99 and Richard Stark, District 104, State Representatives, The Florida House of Representatives
- Broward County Commissioner for each of the following districts:
 - District 3, District 4, District 5 and District 7
- Mayor of:
 - City of Coral Springs
 - City of Tamarac
- City Commissioner of:
 - City of Lauderhill
- President/CEO of
 - Cleveland Clinic Hospital-Florida
 - Broward County Medical Association
 - Broward Community & Family Health Centers, Inc.
 - North Broward Radiologists, PA
 - National Kidney Foundation of Florida
 - FirstPath, LLC
 - Broward Health Coral Springs
 - Broward Health Imperial Point
 - Broward Health North
 - Alternative Home Health Care
 - Responsive Home Health
 - Elder Services Resource Network
 - ARC Broward
 - Mad 4 Marketing, Inc.
 - Chamber of Commerce
 - Greater Fort Lauderdale
 - Greater Plantation
- Director
 - Broward County Health Department, Florida Department of Health
 - Senior Services, City of Deerfield Beach
 - Pediatric Residency, Broward Health Medical Center-Chris Evert Children’s Hospital
- Chief Medical Officer
 - Life Alliance Organ Recovery Agency University of Miami
- Board Chair and Board Vice Chair
 - Children’s Diagnostic and Treatment Center

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- Executive Director
 - Children’s Diagnostic and Treatment Center
 - Aging and Disabilities Resource Center of Broward County
 - American Diabetes Association-South Florida
- Florida International University
 - Executive Associate Dean for Clinical Affairs and Assistant Vice President Strategic Planning
 - Dean and Professor, Nicole Wertheim College of Nursing & Health Sciences
- Nova Southeastern University
 - Dean, Center for Psychological Studies
 - Director, Institute for Child Health Policy and Professor, Pediatrics COM
- University of Miami
 - Professor of Surgery and Pathology and Director, Transplant Laboratories and Immunopathology

One support letter includes 13 physician signatures from Broward Health Medical Center-Chris Evert Children’s Hospital. These physicians include the chief of staff, vice chief of staff and various hospital department chairs.

Several support letters are from patients (or former patients) who received liver transplantation at Broward Health Medical Center. Overall, these support letters state that the hospital has already demonstrated the ability to provide a first-rate liver transplant program. These support letters also indicate that many patients had to travel back and forth to Miami on multiple occasions, for examinations, tests, surgery and aftercare. Additionally, these letters state that the proposed program increases access to residents in the northern portion of the transplant service area.

Several support letters are included from staff or board members of the following: Broward Health, Broward Health Foundation and Broward Health Medical Center. Overall, these support letters comment on Broward Health’s commitment to serve all patients, regardless of ability to pay. The letters note that currently there are over 4,000 people in Florida on the waiting list for organ transplantation and of this number over 3,400 are awaiting kidney transplants. These letters also indicate that Broward Health Medical Center is a statutory teaching hospital which offers graduate medical education to over 100 residents and medical students.

C. PROJECT SUMMARY

South Broward Hospital District d/b/a Memorial Regional Hospital (CON application #10386), proposes to establish a pediatric kidney transplantation program within Memorial Regional Hospital (MRH or the applicant) at Joe DiMaggio Children's Hospital (JDCH), in Hollywood, Broward County, Florida, District 10, TSA 4. South Broward Hospital District, also known as Memorial Health System or the South District, operates Memorial Regional Hospital, Memorial Regional Hospital South, Memorial Hospital West, Memorial Hospital Miramar and Memorial Hospital Pembroke--all Class 1 acute care hospitals.

MRH is a 757-bed general hospital, licensed for 621 acute care, 22 Level II neonatal intensive care unit (NICU), 42 Level III NICU, 45 adult psychiatric, 10 child/adolescent psychiatric, 11 adult substance abuse and six comprehensive medical rehabilitation (CMR) beds. MRH offers pediatric cardiac catheterization, pediatric open heart surgery and pediatric and adult heart transplantation programs, as well as Level II adult cardiovascular services and is a Comprehensive Stroke Center. In addition, MRH is a Level I Trauma Center¹. MRH is approved to add 20 Level III NICU beds (NF130002), is approved to add 11 adult inpatient psychiatric beds through termination of its 11-bed adult substance abuse program (NF130024) and is approved to delicense 23 acute care beds (NF150016). In this batching cycle, MRH is also seeking approval to establish an adult kidney transplantation program (CON application #10388).

Project costs total \$217,060. These costs include equipment, project development and start-up costs. There is no reported construction or renovation associated with the project. The proposed pediatric kidney transplant program is expected to be licensed in October 2016 with initiation of service in November 2016.

In addition to the project location at 3501 Johnson Street, Hollywood, Florida 33021, Schedule C includes the following conditions:

- (1) The MRH pediatric kidney transplant program will comply at all times with Medicare conditions of participation and meeting Medicare specified transplant patient survival standards.

¹ This is confirmed, per the Florida Department of Health, Office of Trauma website at http://www.floridahealth.gov/licensing-and-regulation/trauma-system/_documents/traumacenterlisting20151.pdf.

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- (2) Although kidney transplantation programs can continue to operate following the loss of Medicare certification MRH agrees that, in the event it loses Medicare certification, it will not continue to operate the program.
- (3) South Broward Hospital District d/b/a Memorial Regional Hospital stipulates that consistent with its mission and vision, it is committed to accept and provide care TO ANY AND ALL pediatric kidney transplant patients (ages 0-14) from Organ Transplant Service Area 4 (Monroe Miami-Dade, Broward, Palm Beach, and Collier Counties) regardless of their ability to pay.

North Broward Hospital District d/b/a Broward Health Medical Center (CON application #10387), also referenced as BHMC or the applicant, proposes to establish a pediatric kidney transplantation program at BHMC, in Fort Lauderdale, Broward County, Florida, District 10, TSA 4. North Broward Hospital District, also known as Broward Health® or the North District, operates BHMC, Broward Health Coral Springs, Broward Health Imperial Point and Broward Health North, all Class 1 acute care hospitals.

BHMC is a 716-bed general hospital, licensed for 570 acute care, 36 Level II NICU, 27 Level III NICU and 83 adult psychiatric beds. BHMC is also a designated statutory teaching hospital. BHMC offers Level II adult cardiovascular services, is a Comprehensive Stroke Center, a Level I Trauma Center² and provides adult liver transplantations.

In this batching cycle, BHMC is also seeking approval to establish an adult kidney transplantation program (CON application #10389). BHMC states that it will focus on serving residents of TSA 4, but will be available to anyone in need.

Project costs total \$527,650. These costs include equipment, project development and start-up costs. There is no reported construction or renovation associated with the project.

The applicant's pediatric kidney transplant program, if approved, is expected to be licensed in March 2016 with initiation of service in April 2016.

² This is confirmed, per the Florida Department of Health, Office of Trauma website at http://www.floridahealth.gov/licensing-and-regulation/trauma-system/_documents/traumacenterlisting20151.pdf.

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The applicant includes the following conditions in its Schedule C:

- (1) BHMC conditions this application such that if the companion adult kidney transplant program is not ultimately approved, this pediatric program will not be developed as a stand-alone pediatric kidney transplant program.
- (2) BHMC conditions this application such that an outpatient pediatric dialysis service will be established by BHMC's dialysis partner – DaVita (DVA Healthcare Renal Care) – in an existing DaVita dialysis center located proximate to BHMC. The outpatient pediatric dialysis service will provide a centralized, pediatric focused dialysis service in support of the outpatient needs of BHMC's pediatric kidney transplant patients. Compliance with this condition will be documented by an annual report to AHCA presenting documentation regarding the operation of the outpatient pediatric dialysis service.

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

D. REVIEW PROCEDURE

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

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

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

As part of the fact-finding, the consultant Steve Love, analyzed the applications in their entirety with consultation from the financial analyst Eric West of the Bureau of Central Services, who evaluated the financial data. There is no reported construction or renovation associated with either of the proposed co-batched projects.

E. CONFORMITY OF PROJECT WITH REVIEW CRITERIA

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

1. Fixed Need Pool

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

There is no fixed need pool publication for pediatric kidney transplant programs. Therefore, it is the applicant's responsibility to demonstrate the need for the project, including a projection of the expected number of pediatric kidney transplants that will be performed in the first years of operation.

TSA 4 includes Districts 10 and 11, Collier County in District 8 and Palm Beach County in District 9. TSA 4 has one operational pediatric kidney transplant program, located at Jackson Memorial Hospital (Miami-Dade County, District 11). During calendar year (CY) 2014, TSAs 1, 2 and 3 also each had one pediatric kidney transplantation program.

Rule 59C-1.004(2)(c), Florida Administrative Code, defines a pediatric patient as being under the age of 15 years. Data reported to the Agency by the local health councils for CY 2014 show the following pediatric kidney transplant utilization, by facility, service area and district:

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Florida Pediatric Kidney Transplantation Program Utilization January 2014 – December 2014			
Hospital	Service Area	District	Total Procedures
UF Health Shands Hospital	1	3	5
Tampa General Hospital	2	6	8
Florida Hospital	3	7	5
Jackson Memorial Hospital	4	11	13
TOTAL			31

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

As shown in the table above, in CY 2014, Service Area 4’s sole pediatric kidney transplant provider, Jackson Memorial Hospital (Miami-Dade County) provided 13 pediatric kidney transplantation procedures. Additionally, as shown above, Jackson Memorial Hospital provided the most such procedures of any single provider (41.94 percent). After Jackson Memorial Hospital, the next most procedures were performed at Tampa General Hospital followed by UF Health Shands Hospital and Florida Hospital. Below is a five year chart to account for pediatric kidney transplantation utilization, by service area, county and facility, CY 2010 through CY 2014.

Florida Pediatric Kidney Transplantation Utilization CY 2010—2014								
Service Area	County	Facility	2010	2011	2012	2013	2014	Total
1	Alachua	UF Health Shands Hospital	10	1	3	5	5	24
2	Hillsborough	Tampa General Hospital	2	4	7	8	8	29
3	Orange	Florida Hospital	1	4	1	1	5	12
4	Miami-Dade	Jackson Memorial Hospital	7	13	20	26	13	79
		Total	20	22	31	40	31	144

Source: Florida Need Utilization Data for Adult and Pediatric Transplant Programs issued April 2011—April 2015

During the five-year period shown above, Jackson Memorial Hospital, in Miami-Dade County performed the most pediatric kidney transplants in Florida (54.86 percent).

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

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The reviewer notes that the Organ Procurement Transplantation Network (OPTN), the national database of patients waiting lists for organ transplantation in the United States, shows 58 pediatric patients (age 0-17) in Florida currently registered on the kidney transplantation waiting list³. See the organ by waiting time table below.

**Organ Procurement and Transplantation Network (OPTN)
Current Florida Wait List of Registrants (0 – 17 Years of Age)
Based on OPTN Data as of May 15, 2015**

	Pediatric* Kidney
Total	58
< 30 Days	2
30 to < 90 Days	14
90 Days to < 6 Months	9
6 Months to < 1 Year	7
1 Year to < 2 Years	16
2 Years to < 3 Years	3
3 Years to < 5 Years	3
5 or More Years	4

Source: <http://optn.transplant.hrsa.gov/latestData/rptData.asp>, as of June 3, 2015

* Age 0-17 years is according to the OPTN online database

Donor/patient matches are also a factor in transplant services. The chart below contains the most recent five-year volume of pediatric kidney donations (0-17 years of age) by Florida residents.

**Florida Kidney Donors 0 – 17 Years of Age Recovered
January 1, 2009 - December 31, 2014
Based on OPTN Data as of June 3, 2015**

	2009	2010	2011	2012	2013	2014
All Donor Types	67	53	60	62	67	55
Deceased Donor	67	53	60	62	67	55
Living Donor	0	0	0	0	0	0

Source: <http://optn.transplant.hrsa.gov/latestData/rptData.asp>, as of June 3, 2015

As shown above, there were 55 pediatric (0-17 years of age) Florida kidney donors in 2014. Florida Center for Health Information and Policy Analysis data indicates there were a total of 24 pediatric (under age 15) kidney transplants performed at Florida hospitals in CY 2014. The total procedures (24 pediatric kidney transplants) were fewer than the donor recovery total of 55 (a difference of 31).

Agency data indicates that all 24 (100 percent) of the pediatric patients (under 15 years of age) receiving kidney transplants performed in Florida in CY 2014 were Florida residents⁴. TSA 4 residents accounted for nine

³ As of June 3, 2015 per the OPTN website @ <http://optn.transplant.hrsa.gov>.

⁴ There were 31 total pediatric kidney transplant procedures reported to the local health councils for CY 2014. Some variation in the patient data is to be expected.

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of the 24 procedures (37.50 percent). TSA 4 residents did not migrate outside their home service area for pediatric kidney transplantation. This is verified for CY 2014. Below is a chart to account for these procedures.

**Service Area 4 Resident Facility Selection
Pediatric Kidney Transplantation Procedures
CY 2014**

Facility/Organ Transplant Service Area	Patient Total	Patient Percent
Jackson Memorial Hospital (TSA 4)	9	100.0%
Service Area 4 Total	9	100.0%

Source: Florida Center for Health Information and Policy Analysis CY 2014 database, MS-DRG 652

For the five-year period ending December 31, 2014, given somewhat rising demand for pediatric kidney transplantation at TSA 4's existing pediatric kidney transplantation provider (from seven procedures in CY 2010 to 13 procedures in CY 2014), and no outmigration to a non-TSA 4 facility to have this procedure, it is reasonable to conclude that the approval of either of the proposed projects should have no impact on outmigration.

The sole TSA 4 provider of pediatric kidney transplantation (Jackson Memorial Hospital) averaged 15.8 of these procedures and a median of 13 of these procedures, over the five-year period ending December 31, 2014.

South Broward Hospital District d/b/a Memorial Regional Hospital (CON application #10386) contends that from a planning and service delivery perspective, it makes sense that tertiary services, such as kidney transplantation, be co-located in hospitals with existing services and patient populations that complement them, and allow patients with chronic and complex conditions to be treated within the same setting. The applicant further contends this is especially true in today's health care environment, which encourages coordination of services and management of the health conditions of patients in a coordinated approach. MRH explains that the proposed project will complement its existing pediatric and adult heart transplant programs.

MRH expects to perform two pediatric kidney transplantations in the 12 months ending October 31, 2017 (year one) and five pediatric kidney transplantations in the 12 months ending October 31, 2018 (year two).

North Broward Hospital District d/b/a Broward Health Medical Center (CON application #10387) contends that unlike where an existing transplant program would have minimal commonality to the proposed kidney transplantation program, such as a heart transplant program expanding into kidney transplantation, the existing BHMC liver transplant program resources will provide a strong baseline for the develop of the proposed kidney transplant program.

BHRC expects to perform two pediatric kidney transplantations in in the 12 months ending March 31, 2017, five procedures in year two, three procedures in year three and six procedures in year four.

b. Determination of Need.

Applications for the establishment of new pediatric kidney transplantation programs shall not normally be approved in a service planning area unless the following criteria are met:

- 1. Each existing pediatric kidney transplantation provider in the applicable service area performed a minimum of 10 transplants in the most recent calendar year preceding the application deadline, and no additional program has been approved for the same service planning area.**

Jackson Memorial Hospital is the sole existing pediatric kidney transplantation provider in TSA 4. Jackson Memorial Hospital performed 13 pediatric kidney transplants during the 12-month period ending December 31, 2014. There are no additional pediatric kidney transplant programs approved for TSA 4.

- 2. The application shall include documentation that a minimum of 5 pediatric kidney transplants per year will be performed within two years of program approval. Such documentation shall include, at a minimum, the number of kidneys procured in the state during the most recent calendar year, and an estimate of the number of patients who would meet commonly-accepted criteria identifying potential kidney transplant recipients. This estimate shall be based on the number of patients on dialysis within the same service planning area.**

South Broward Hospital District d/b/a Memorial Regional Hospital (CON application #10386) indicates plans for five pediatric kidney transplantations in 2018 (ending October 31,

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2018), the second year of planned operations. According to the applicant, this estimate is based on the following factors:

- There is a growing waiting list for pediatric kidney transplants at Florida Centers. The waiting list from TSA 4 transplant centers is growing at a faster rate than other service areas.

Using Scientific Registry of Transplant Recipients (SRTR) program-specific reports data, the applicant indicates a 64 percent increase (from 2012 to 2014) and a 28 percent annual rate of growth for pediatric kidney waiting list candidates in TSA 4 and that this is greater than any other TSA for the same period. See the figure below.

Number of Persons on Pediatric (Ages 0-17) Kidney Transplant Waiting List At Florida Transplant Centers June 30, 2014 versus June 30, 2012

Center	As of 6/30/2012	As of 6/30/2014	Change 2012-2014	Percent Change 2012-2014	Annual Rate of Growth
UF Health Shands Hospital (TSA 1)	23	32	9	38%	17%
Tampa General Hospital (TSA 2)	13	18	5	41%	19%
Florida Hospital-Orlando (TSA 3)	1	1	0	2%	1%
Jackson Memorial Hospital (TSA 4)	17	27	10	64%	28%
Total	54	79	25	46%	21%

Source: CON application 10386, page 41, Figure 6

- The number of donor kidneys procured in Florida is significantly greater than the number of pediatric kidney transplants performed in Florida.

Using Agency inpatient hospital discharge data and SRTR OPO-specific reports, the applicant indicates that pediatric kidney recovery cases rose from 117 (in 2012) to 124 (in 2014) and that these totals are greater than total pediatric kidneys transplants in Florida (from 17 in 2012 to 21 in 2014) and also greater than the total organs procured but not transplanted (from 100 in 2012 to 103 in 2014). MRH also notes that pediatric kidney recovery cases in TSA 4 went from 23 in 2012 to 44 in 2014. MRH points out that for this same period, Life Alliance Organ Recovery Agency was the only OPO where the number of pediatric kidneys procured increased. MRH further points out that approximately 100 more pediatric kidneys were recovered than were transplanted in Florida. See the figure below.

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Number of Pediatric Kidneys Recovered by Organ Procurement Organizations in Florida, 12 Months Ending June 30, 2012-2014

OPO	Number of Pediatric Kidneys		
	2012	2013	2014
Life Quest Organ Recovery Services (TSA 1)	32	28	28
LifeLink of Florida (TSA 2)	29	43	26
TransLife Organ & Tissue Donation Services (TSA 3)	33	30	26
Life Alliance Organ Recovery Agency (TSA 4)	23	28	44
Total Organs Procured	117	129	124
Total Pediatric Kidneys Transplanted in Florida (1)	17	25	21
Total Organs Procured, but Not Transplanted	100	104	103

(1) Source data is obtained from the Agency for Health Care Administration (AHCA) inpatient database through June 30, 2014. Although data through September 30, 2014 from AHCA is available, data through June 30, 2014 was utilized in this figure for consistency with the organ procurement data provided by SRTR, whose most up to date data is June 30, 2014. In all other sections of this application, the most recent data available from AHCA (as of September 30, 14) was utilized. Source data obtained from Scientific Registry of Transplant Recipients (SRTR)-OPO Specific Reports, Pediatric –specific data is estimated based on the percentage of pediatric donors to total donors as outlined by SRTR.

Source: CON application #10386, page 42, Figure 7

- There is a growing number of end stage renal disease (ESRD) patients on dialysis in Florida.

Using Florida Medical Quality Assurance, Inc., ESRD Network 7 and Agency data, the applicant indicates as of March 2015, 9,658 ESRD cases (all ages) in TSA 4, with 1,546 ESRD cases per million in TSA 4 for the same period, noting that TSA 4 has the highest prevalence of ESRD cases in the state. See the figure below.

Number of ESRD Cases (All Ages) and ESRD Rates by TSA as of March 2015

Patient Residence Location	ESRD Cases	Estimated 2015 Population	ESRD Cases per Million
TSA 1	6,309	4,355,613	1,448
TSA 2	7,008	5,187,046	1,351
TSA 3	5,750	4,027,337	1,428
TSA 4	9,658	6,246,180	1,546
Florida	28,725	19,816,176	1,450

Source: CON application #10386, page 43, Figure 8

The applicant maintains that statewide ESRD cases per million rose from 1,326 (2012) to 1,469 (March 2015), a percent change of 11 percent and an annual growth rate of five percent. MRH proceeds by stating that according to Florida Medical Quality Assurance, Inc. – ESRD Network 7 data, as of March 2015, there was an estimated 85 ESRD patients age 0-14 in Florida and that TSA 4 has more pediatric ESRD patients than any other service areas – 29 accounting for 34 percent of all pediatric dialysis patients in the State. See the figure below.

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ESRD Patients on Dialysis by TSA, as of March 2015

County	All Ages Cases	Ages 0-14 Cases	Ages 15+ Cases	Percent of 0-14 ESRD Cases of Total 0-14 Cases
TSA 1	6,309	19	6,290	22%
TSA 2	7,008	21	6,987	25%
TSA 3	5,750	17	5,733	20%
TSA 4	9,658	29	9,629	34%
Florida Total	28,725	85	28,640	100%

Note: Network 7 data is not broken down by patient resident county but by dialysis center location. It can be reasonable to estimate that the county where residents receive dialysis treatment is a lot the county where they reside in. The age breakout was estimated based on a 0.3% ESRD prevalence for children ages 0-14, determined from ESRD incidence and prevalence data from the United States Renal Data System. This 0.3% prevalence rate was applied to total ESRD cases per service area to estimate the number of ages 0-14 and ages 15+ ESRD cases.

Source: CON application #10386, page 44, Figure 10

MRH contends that expanding JDCH’s program to include kidney transplantation services will enhance access for residents of Broward and Palm Beach Counties, who will be able to receive all their care – pre-transplant, transplant surgery, post-transplant – in a familiar, convenient location, much closer and easier to access than Jackson Memorial Hospital. The applicant proceeds by stating that this is confirmed by parents describing the hardships involved in trying to obtain needed kidney transplantation services outside the TSA. According to the applicant, these letters are in CON application #10386, Volume 2, Attachment Q. However, the reviewer notes that letters were not found. The applicant’s summary of these letters (CON application #10386, pages 50 – 53) indicates the access challenges and travel hardships for patients and families in seeking these services outside their local area.

- The pediatric population (ages 0-14) in TSA 4 is projected to grow approximately three percent by 2020 – from 1.0 million to 1.1 million pediatric residents.

Using Agency population estimates, MRH estimates 1,073,253 pediatric (age 0-14) residents in TSA 4, in 2014, to 1,109,397 by 2020, an increase of 36,144 pediatric residents, with a growth rate of 3.4 percent. The reviewer presents the total TSA 4 age-specific resident totals only, without the individual county totals. See the figure below.

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**TSA 4 Pediatric (Ages 0-14) Current and Projected Population
2014-2020**

	2014	2015	2016	2017	2018	2019	2020	Change 2014- 2020	Percent Change 2014- 2020
Total	1,073,253	1,078,727	1,085,167	1,091,198	1,097,024	1,103,106	1,109,397	36,144	3.4%

Source: CON application #10386, page 54, Figure 16

- The demand for kidney transplantation in TSA 4 will continue to increase through 2020 given the projected population growth in the region and the expectation that the prevalence of ESRD will continue on an upward trend.

Using Agency estimates and ESRD and ESRD conversion rate assumptions developed by Health Strategies and Solutions, Inc., MRH provides estimated pediatric kidney transplants for residents of TSA 4. In making its estimate, MRH indicates use of the following:

- The population growth projections shown in Figure 16
- A 10 percent per year increase in the ESRD rate
- No change in the ESRD to transplant conversion rate between now and 2020

MRH estimates TSA 4 resident pediatric kidney transplants ranging from six (in 2015) to 10 (in 2020). See the figure below.

**Projected Number of Pediatric (Ages 0-14) Kidney Transplants
Provided to Residents of TSA 4**

	2015	2016	2017	2018	2019	2020
Pediatric Population	1,078,727	1,085,167	1,091,198	1,097,024	1,103,106	1,109,397
Annual % Change in Pediatric Population		0.6%	0.6%	0.5%	0.6%	0.6%
Annual % Change in ESRD Rates		10.0%	10.0%	10.0%	10.0%	10.0%
Ts Pediatric ESRD Cases per Million	26.0	28.6	31.5	34.6	38.1	41.9
Pediatric ESRD Cases	28	31	34	38	42	46
Annual % Change in Conversion Rate		0.0%	0.0%	0.0%	0.0%	0.0%
Conversion Rate	21.4%	21.4%	21.4%	21.4%	21.4%	21.4%
Transplants Performed	6	7	7	8	9	10
Pediatric Kidney Transplants per Million	5.6	6.5	6.4	7.3	8.2	9.0

Source: CON application #10386, page 55, Figure 17

According to MRH, given the comprehensive range of specialized services offered by JDCH's Pediatric Nephrology and Hypertension Program, its pediatric-only dialysis center, its Chronic Kidney Disease Clinic devoted to caring for children with chronic kidney disease, the program's 10 years' experience treating pre- and post-kidney transplant patients, and the fact that five of the 15 patients currently being seen in the Chronic Kidney Disease Clinic have

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stage 4 or stage 5 chronic kidney disease, it is reasonable to expect that the proposed project will meet minimum volume requirements.

MRH contends that regarding impact on the transplant programs at Jackson Memorial Hospital and Cleveland Clinic Florida, the South District is committed, as in all other instances, to collaborate with the pediatric transplant program at Jackson Memorial Hospital in identifying patients to assure that every patient is cared for in the most appropriate setting and location.

North Broward Hospital District d/b/a Broward Health Medical Center (CON application #10387) indicates plans for five pediatric kidney transplantations by March 31, 2018, the second year of planned operations. Below is the BHMC's need justification.

Using Agency transplant utilization data, the applicant indicates that from 2012 to 2014, Jackson Memorial Hospital realized 20, 26 and 13 pediatric transplants, respectively, while Florida realized 31, 40 and 31 such procedures, for the respective years. See below.

**Pediatric Kidney Transplant Volume
2012-2014**

	2012	2013	2014
Jackson Memorial	20	26	13
Total FL	31	40	31

Source: CON application #10387, page 20

BHMC discusses the number of pediatric kidney transplants by facility in CY 2014--noting that in CY 2014, Jackson Memorial Hospital performed more pediatric kidney transplants (13 procedures) than any other single provider, statewide.

BHMC states that based on a review of Jackson Memorial Hospital's 2012-2014 average annual pediatric transplant case volume of 19.7 cases per year, Jackson Memorial Hospital would remain above the 10 case minimum for existing programs if the TSA 4 market remained stable and five cases were shifted to the BHMC.

Using Agency population estimates, BHMC indicates that in 2015, the 0-14 age cohort in Broward County is 30 percent of TSA 4's pediatric population and Palm Beach County is 21 percent of this

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population. BHMC indicates that combined, Broward and Palm Beach Counties account for 51 percent of the pediatric population in TSA 4. See below.

2015 TSA 4 Population

	2015 Population Age 0-14	Percent of Total TSA 4 Population Age 0-14
Miami-Dade	467,853	43%
Broward	320,163	30%
Palm Beach	226,796	21%
Collier	54,918	5%
Monroe	8,997	1%
TOTAL TSA 4	1,078,727	

Source: CON application #10387, page 21

Using 2013 Florida Vital Statistics data, BHMC indicates that in 2013, Broward County accounted for 30 percent of live births in TSA 4, Palm Beach County accounted for 20 percent of such births and that together, Broward and Palm Beach County realized 50 percent of the live births in TSA 4 in 2013.

Using Agency hospital discharge data for 2013, BHMC indicates that in 2013, Broward County realized 30 percent of TSA 4 total age 0-14 discharges, Palm Beach realized 24 percent of such discharges and that together, these two counties realized 54 percent TSA 4's age 0-14 hospital discharges. See table below.

2013 TSA 4 Pediatric Inpatient Discharges

	2013 Facility Discharges Patients Age 0-14	Percent of Total TSA 4 Facility Discharges Patients Age 0-14
Miami-Dade	45,682	41%
Broward	33,371	30%
Palm Beach	26,836	24%
Collier	4,076	5%
Monroe	635	1%
TOTAL SPA 4	110,600	

Source: CON application #10387, page 21

The reviewer notes that CY 2014 Agency inpatient hospital discharge data and Florida Office of Vital Statistics live birth data is available and the applicant does not offer an explanation for why older data was utilized to reach its conclusions.

BHMC contends that Broward County alone could support a pediatric kidney transplant case volume of six cases, and Broward and Palm Beach County together could support a case volume of nine to 10 pediatric kidney transplants.

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BHMC asserts that its forecast estimates are realistic and achievable, and that the proposed project would significantly reduce travel time and costs in traveling to Miami from Broward or Palm Beach County for care.

BHMC points out that its small pediatric case volume alone would prove problematic to operate an efficient program but that the companion application (CON application #10389) will have adequate volume to operate an efficient and effective kidney transplant program. CON application #10387, pages 23 – 29, includes excerpts of BHMC's letters of support.

2. Agency Rule Criteria

Does the project respond to preferences stated in agency rules? Please indicate how each applicable preference for the type of service proposed is met. Chapter 59C-1.031-044, Florida Administrative Code.

Chapter 59C-1.044, Florida Administrative Code, contains criteria and standards by which the department is to review the establishment of organ transplantation services under the certificate of need program regardless of the type of organ. These criteria and standards also specifically address additional requirements for kidney transplant programs. The appropriate areas addressed by the rule and the applicant's responses to these criteria are as follows:

- a. Coordination of Services. Chapter 59C-1.044(3), Florida Administrative Code. Applicants for transplantation programs, regardless of the type of transplantation program, shall have:**
- 1. Staff and other resources necessary to care for the patient's chronic illness prior to transplantation, during transplantation, and in the post-operative period. Services and facilities for inpatient and outpatient care shall be available on a 24-hour basis.**

South Broward Hospital District d/b/a Memorial Regional Hospital (CON application #10386) states that JDCH is a pediatric hospital within MRH and that JDCH has the requisite staff and resources currently in place to provide expert care to pediatric patients with chronic and end-stage

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renal failure. The applicant also points out that staff on the general nursing units and in pediatric critical care have extensive experience in the care of patients with chronic kidney disease. MRH asserts a full range of appropriate inpatient and outpatient services for this patient population on a 24-hours basis including but not limited to CRRT, hemodialysis and cyclic peritoneal dialysis. MRH maintains having developed a program to educate staff regarding specific issues related to transplant care as a pre-requisite for its cardiac transplant program and that much of this education is relevant to the kidney transplant population. Further, the applicant assures that education will be made available related to specifics of pediatric kidney transplantation during the lead up to program establishment and inception.

MRH states plans to utilize a multidisciplinary approach involving the medical director (Alex Constantinescu, MD, board-certified in pediatric nephrology), pediatric kidney transplant surgeons, pediatric kidney nephrologists, pediatric transplant coordinators, pediatric social workers, a pediatric living donor advocate, financial counselors, pediatric nutritionists, child/adolescent psychologists, pediatric dialysis unit nurse manager, pediatric staff nursing to provide 1:1 ratio patient care of the pediatric dialysis patient and age-appropriate education services.

Dr. Ivy Boysdstun and Dr. Xamayta Negroni-Balasquide are mentioned as board-certified pediatric nephrologists who are also involved in the care of these patients—noting that the team provides a complete coverage 24 hours per day, seven days a week for the pediatric nephrology service. MRH further indicates that JDCH will recruit additional providers (including an experienced transplant surgical director, transplants surgeons, surgical team and all necessary staff as required) and will expand services including overseeing plasmapheresis. MRH provides detailed descriptions of these and other staff, as well as transplant services (CON application #10386, pages 59 – 71).

North Broward Hospital District d/b/a Broward Health Medical Center (CON application #10387) states it will have the necessary staff and other resources needed to care for kidney transplant patients' chronic illness prior to,

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during and after the transplant procedure. BHMC indicates that it has 24-hour availability of all required inpatient and outpatient services and facilities necessary to support kidney transplant patients.

BHMC maintains having pediatric nephrologists on staff. The applicant contends that while a pediatric transplant nephrologist is not yet at BHMC—one is currently being recruited and commits that this resource will be in place prior to program initiation. BHMC asserts having an experienced team of transplant nurses and support staff already in place to support the existing liver transplant program that will also be used to support the proposed kidney transplant program. The applicant states that CVs of the existing transplant team members and other BHMC professionals who will support the proposed program are provided (CON application #10387, Volume 2, Appendix 10). The reviewer notes that no physician CVs are included in this appendix.

BHMC indicates that diagnostic and treatment services, including services available at the Chris Evert Children's Hospital, are available to evaluate patients regarding appropriateness for transplantation and to meet the medical, social and behavioral needs of the patient while waiting for transplantation. According to BHMC, specialty services, such as immunological testing, that are not available, will be provided via contract with existing programs.

The applicant notes that it has two kidney transplant surgeons currently committed to support the proposed projects (CON application #10389 and CON application #10387), and a third surgeon is currently being recruited with all other necessary transplant medical resources currently available at BHMC. The applicant maintains that the transplantation portion of the patient's care will be provided.

The reviewer notes CON application #10387, Volume 2, Appendix 14, includes a CV for Galal Hussein El-Gazzaz, MD and a CV for Roysuke Misawa, BS, MD, PhD. The reviewer also notes that according to Dr. El-Gazzaz's CV, his current position is Clinical Fellow as ASTS multi-organ transplant in

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transplant center, Cleveland Clinic Foundation, Cleveland, Ohio and among other professional society memberships is a member of the American Society of Transplant Surgeons (ASTS). The reviewer further notes that according to Dr. Misawa's CV, his professional background is solid organ transplant, islet transplant with sub-specialty in gastroenterological and hepato-pancreato-biliary surgery and also having ASTS membership.

BHMC maintains that post-transplant care will be coordinated by the transplant surgeon and the transplant nephrologist, along with the patient's community nephrologist and the support staff currently in place in support of the existing liver transplant program.

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

South Broward Hospital District d/b/a Memorial Regional Hospital (CON application #10386) includes a June 2009, written agreement between South Broward Hospital District and Life Alliance Organ Recovery Agency in CON application #10386, Volume II, Attachment D. According to MRH, this agreement is to coordinate procurement of suitable donor kidneys to JDCH in accordance with organ allocation policies and procedures established by the United Network of Organ Sharing (UNOS).

MRH indicates that experienced kidney transplant surgeons will be recruited for the proposed adult kidney transplant program. The reviewer notes that CON application #10386 is a pediatric proposal, while CON application #10388 is the applicant's corresponding and accompanying adult proposal, in the current batching cycle.

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MRH provides a narrative description of coordinating functions between the Pediatric Kidney Transplant Team, the Transplant Donor Coordinator, the surgeon and related pediatric team members (CON application #10386, pages 71 - 72).

The applicant maintains that it has a well-established 24/7 and 365 day per year call schedule that has provided services to the adult renal population for several years and that the call schedule covers the following pediatric services: nephrology, hospitalist, vascular surgeon, CV urology and OR team, perfusion, cardiac anesthesia, cardiologist and sonographer. MRH notes that the call schedule already has an on-call pediatric team (transplant coordinator/donor coordinator service, heart transplant surgeon and transplant cardiologist) with a 24/7 ECMO (heart-lung bypass) call schedule if a patient needs support at that level either pre-operative or post-transplant.

North Broward Hospital District d/b/a Broward Health Medical Center (CON application #10387) states that cadaveric transplantation will be part of the proposed program. BHMC provides a support letter (CON application #10387, Volume 2, Appendix 12) documenting the local OPO's (Life Alliance Organ Recovery Agency's) willingness to support the applicant's proposed kidney transplant program. The reviewer notes that no written agreement is included in this appendix.

BHMC maintains that a system of 24-hour call support will be provided for the assessment, management and retrieval of all referred donors, cadaver donors or organs shared by other transplant or organ procurement agencies as is stated to be currently the case with the existing liver transplant program.

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

South Broward Hospital District d/b/a Memorial Regional Hospital (CON application #10386) indicates that JDCH provides a 22-bed pediatric intensive care unit (PICU), on the fourth floor of MRH. Further, the applicant states

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that designated critical care beds are outfitted and available as required to provide reverse isolation when indicated. MRH's PICU intensivists and other related staff and services are discussed (CON application #10386, pages 73 – 75).

North Broward Hospital District d/b/a Broward Health Medical Center/CON application #10387 states that the existing 12-bed PICU will be used in support of the proposed project. BHMC also states that this PICU includes facilities for prolonged reverse isolation within the Chris Evert Children's Hospital.

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

South Broward Hospital District d/b/a Memorial Regional Hospital (CON application #10386) states that the JDCH Pediatric Transplant Selection Committee (committee) is the clinical review committee and currently functions for evaluation and decision-making regarding the suitability of a transplant candidate. Per MRH, the proposed project will be incorporated into this existing committee structure and it will continue to determine suitability. The committee is stated to be under the leadership of Dr. Alex Constantinescu. The committee is stated to meet weekly or as needed.

The applicant maintains that its existing pediatric heart transplant information will be developed for the proposed pediatric kidney transplantation program. MRH states that there are three possible outcomes resulting from a committee evaluation: accepted, not suitable for transplant or tabled.

According to MRH, once committee-approved, a candidate will be placed on the waiting list as maintained by UNOS. MRH indicates that appropriate correspondence will be made to the referring physicians, patients and families. The applicant indicates emergency evaluations may be conducted bedside in the case of severely ill patients.

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North Broward Hospital District d/b/a Broward Health Medical Center (CON application #10387) states that a clinical review committee and a defined process for the suitability of kidney transplant candidates will be established. BHMC also states that information regarding transplant candidate evaluation utilized in the prior kidney transplant program is provided (CON application #10387, Volume 2, Appendix 8). The reviewer notes that this appendix, the BHMC Kidney Transplant Services Policy and Procedures Manual 2013, names and includes 24 policies under the title “Adult Kidney Transplant Department”. The reviewer indicates that while BHMC was awarded CON application #10152 to establish an adult kidney transplantation program on August 17, 2012 but the CON was not implemented prior to the termination date of March 24, 2014. It is unclear to the reviewer what prior kidney transplant program the applicant is referring to since according to Agency records, BHMC did not have an operational kidney program in 2013.

The reviewer also notes that “pediatric” does not appear in any of the named policy titles found in the table of contents, in this referenced appendix. The reviewer notes that CON application #10387 is a pediatric proposal, while CON application #10389 is the applicant’s corresponding and accompanying adult proposal, in the current batching cycle.

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

South Broward Hospital District d/b/a Memorial Regional Hospital (CON application #10386) states that JDCH will establish written protocols for selection and management of adult kidney transplant patients. As stated previously, CON application #10386 is a pediatric proposal, while CON application #10388 is the applicant’s corresponding and accompanying adult proposal, in the current batching cycle. According to MRH, these protocols will be modeled after similar protocols developed and successfully utilized for the existing JDCH pediatric heart transplant and those of other existing nationally renowned

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adult kidney transplant facilities. MRH maintains that these protocols include identification of patient selection criteria, patient inclusion and exclusion criteria, guidelines for patient management and evaluation during pre-hospital, in-hospital and immediate post-hospital phase as well as long-term management. The applicant offers its existing pediatric heart transplant information (CON application #10386, Volume II, Attachment H).

North Broward Hospital District d/b/a Broward Health Medical Center (CON application #10387) indicates that written protocols for patient care for the proposed program, including patient selection criteria for patient management and evaluation during the pre-hospital, in-hospital and immediate post-discharge phase of the program will be established in conjunction with the transplant surgeons and transplant nephrologists. The applicant provides information regarding patient care protocols utilized in the current liver transplant program (CON application #10387, Volume 1, Appendix 7). The reviewer notes that this appendix includes: Marketing Communications Plan-Transplant Services, Organ Transplant Education Course Adult Liver Transplant Patient, Liver Transplant Handbook (10 item agenda), 2014/2015 Adult Liver Transplant Continuing Education Review and associated/related documents.

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

South Broward Hospital District d/b/a Memorial Regional Hospital (CON application #10386) states it will model protocols after similar protocols developed and successfully utilized by MRH's existing pediatric heart transplantation protocols and those of other existing nationally renowned adult heart transplant facilities. The applicant offers its existing pediatric heart transplant information (CON application #10386, Volume II, Attachment H). MRH maintains that protocols will be developed and based on the experience of staff physicians - Frank Scholl, MD and Maryanne Chrisant, MD.

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North Broward Hospital District d/b/a Broward Health Medical Center (CON application #10387) asserts that detailed therapeutic and evaluative procedures for the acute and long-term management of pediatric kidney transplant patients, including the management of commonly encountered complications, will be established.

- 7. Equipment for cooling, flushing, and transporting organs. If cadaveric transplants are performed, equipment for organ preservation through mechanical perfusion is necessary. This requirement may be met through an agreement with an organ procurement agency.**

South Broward Hospital District d/b/a Memorial Regional Hospital (CON application #10386) states it will work in coordination with Life Alliance Organ Recovery Agency in the procurement and appropriate preservation of the kidney--the cooler and organ preservation solution as well as all necessary special equipment will be provided. The applicant states that it will purchase a perfusion pump for kidneys. MRH states that as a Level I Trauma Center, it is in the network for procurement of cadaveric transplant grafts. According to MRH, it was the donor hospital for 244 successful procurements from 83 patients from February 2011 to February 2015 – the most organs procured from any hospital in Florida.

North Broward Hospital District d/b/a Broward Health Medical Center (CON application #10387) contends that all required equipment for preserving, cooling, flushing and transporting organs will be provided.

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

South Broward Hospital District d/b/a Memorial Regional Hospital (CON application #10386) provides a signed May 2013 letter of agreement in the provision of

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laboratory and blood product support (CON application #10386, Volume II, Attachment J) from LifeLink®. MRH states that the applicable laboratory meets the requirements of the American Society of Histocompatibility.

North Broward Hospital District d/b/a Broward Health Medical Center (CON application #10387) states that BHMC current has a contract in place with the University of Miami School of Medicine's Transplant Laboratories and Immunopathology program to provide all required tissue typing support services for BHMC's existing liver transplant program. According to BHMC, this existing relationship will be expanded to include support for the proposed project. The reviewer notes that the applicant does not provide a copy of the stated contract.

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

South Broward Hospital District d/b/a Memorial Regional Hospital (CON application #10386) indicates that MRH's laboratory and staff will provide the expertise and resources required for pathology and laboratory support for the proposed project. MRH maintains that services available will include the capability of studying and promptly reporting a patient's response to kidney transplantation surgery and the analysis of appropriate kidney biopsy material.

The applicant states that its MRH/JDCH state-licensed and Joint Commission accredited laboratory operates 24 hours a day, seven days a week, has high-level pathology/laboratory capabilities and maintains responsibility for the Level I pediatric and adult trauma center, NICU, open heart surgery unit, pediatric specialty center, breast cancer center, adult and pediatric heart transplant and MRH's oncology center. MRH reports that the main laboratory as well as the blood bank and transfusion medicine service, is under the direction of Ujvala Bhuta, MBA, BSMT (ASCP), Director of Clinical Laboratories. The applicant indicates the laboratory performs nearly six million tests annually.

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MRH reports that seven pathologists have specific clinical and scientific experience that is directly relevant to transplant service: Paul Malek, MD; Mohammed Ali Ansari-Lari, MD, PhD; Lisa N. Tyler, MD; Lawrence M. Wong, MD; Frederick Kiechle, MD, PhD; Neil Abrahams, MD and Mandolin S. Ziadie, MD, PhD. The applicant includes extensive resumes of these physicians (CON application #10386, Volume II, Attachment P).

North Broward Hospital District d/b/a Broward Health Medical Center (CON application #10387) maintains that all required pathology services are currently available within BHMC laboratories. The applicant offers a profile of BHMC's Laboratory Services (CON application #10387, Volume 2, Appendix 13). The reviewer notes that this appendix includes a three-page BHMC's Policy and Procedures Manual/Laboratory Scope of Service.

10. Blood banking facilities.

South Broward Hospital District d/b/a Memorial Regional Hospital (CON application #10386) states that it has blood banking facilities and services necessary to support the proposed project. MRH provides an eight-page amendment, signed March 2015, between the applicant and Comprehensive Care Services, Inc., (CCS). However, the reviewer notes that the signature page is blank regarding the nine-page agreement between the applicant and CCS. According to the CCS support letter, CCS provides perfusion, autotransfusion and therapeutic apheresis services to adult and pediatric clients (CON application #10386, Volume II, Attachment K).

MRH indicates that the blood bank/transfusion medicine service is licensed by the Agency and is accredited by The Joint Commission. The applicant also provides a four-page laboratory transfusion service/scope of service description (CON application #10386, pages 82 – 86).

North Broward Hospital District d/b/a Broward Health Medical Center (CON application #10387) states that all required blood banking services and facilities are currently available within BHMC's blood banking resources. The reviewer notes that according to BHMC's Policy and

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Procedures Manual/Laboratory Scope of Service (CON application #10387, Volume 2, Appendix 13), blood component inventory and reference lab services specific to blood bank are supplied by “OneBlood”.

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

South Broward Hospital District d/b/a Memorial Regional Hospital (CON application #10386) states that it will recruit for a surgical director for the proposed project as well as an experienced pediatric kidney transplant coordinator. Alex Constantinescu, MD, is the stated medical director and program director for the proposed project. MRH maintains that Dr. Constantinescu is currently the medical director of the pediatric nephrology and hypertension program at JDCH.

MRH indicates that the physician medical director along with the transplant administrator will be responsible for overseeing the training of staff regarding the special care the transplant population requires and will initiate the education process until the new positions are filled. According to MRH, Teresa Bueno, DNP, CCTC, Clinical Director of Adult Cardiac Transplant, will be the individual who will work directly with the adult educator to develop a comprehensive plan. The reviewer notes that the stated application is for a pediatric program.

The applicant indicates that comprehensive training will be provided to the staff on all aspects of pediatric kidney transplant including: transplant evaluation, diagnosis suitable for transplant, psychosocial evaluation and support for the transplant patient/family, pre-transplant management strategies, anticipated wait list times by listing status and blood type, management of elevated panel reactive antibody (PRA), surgical transplant procedure, organ procurement, post-op care of the transplant recipient, transplant medications (all aspects), immunology, infectious disease as it relates to the transplant patient, rejection (signs, symptoms, treatment, monitoring), long-term management and potential long-term complications.

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MRH states that the education will be done collectively by the very experienced pediatric transplant team members as well as experienced adult heart transplant team members currently on staff which include Alex Constantinescu, MD. MRH assures that competencies, based on the current pediatric heart transplant competencies and knowledge of other team members who practiced at other transplant facilities, will be developed to ensure the knowledge base of those caring for the transplant population meets standards. The applicant indicates that applicable topics are to be covered weekly within one month of obtaining project approval. The applicant indicates education will occur on an ongoing basis as well as built into the orientation curriculum for staff in the units previously mentioned. Selected staff from the PICU will attend national conferences on kidney transplants and transplants in general to gain further information regarding the field of transplant.

MRH maintains that mock transplants, something the applicant states is a very successful and invaluable exercise utilized by the pediatric heart transplant program, will be organized and utilized by the pediatric kidney transplant program.

North Broward Hospital District d/b/a Broward Health Medical Center (CON application #10387) maintains that a program for the education and training of staff regarding the special care of pediatric kidney transplant patients will be established. BHMC states that similar staff training programs are currently in place for the liver transplant program. The applicant references CON application #10387, Volume 1, Appendix 7 and Appendix 8 (discussed previously in this section).

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

South Broward Hospital District d/b/a Memorial Regional Hospital (CON application #10386) states that it will develop a “patient handbook” for the proposed program, upon project approval. MRH offers the patient education manual (CON application #10386, Volume II, Attachment M).

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The reviewer notes that this attachment appears to be printed slides from PowerPoint or related software.

MRH assures that it will be a priority of JDCH transplant physicians and team to establish and maintain close working relationships with the community to promote an understanding of the criteria for referral, as well as to be available and accessible to address their patient issues. The applicant states that once the proposed project is approved, the addition of pediatric kidney transplant to the hospital's scope of service will be formally announced to the community, primary care physicians, nephrologists and staff physicians.

Referring physicians will be advised on all patient evaluations, tests required to maintain the patient on active waiting lists and early signs of rejection post-transplant. Feedback with and between JDCH, physician and related staff, patients and families is discussed. MRH provides a booklet to address patient education, rehabilitation and follow-up materials, some materials are in Spanish (CON application #10386, Volume II, Attachment N).

North Broward Hospital District d/b/a Broward Health Medical Center (CON application #10387) indicates that educational programs for patients, their families and the patient's primary care physician regarding after-care for transplantation patients will be established. BHMC maintains that similar education programs are currently in place for the liver transplant program. The applicant references CON application #10387, Volume 1, Appendix 7 and Appendix 8 (discussed previously in this section).

b. Staffing Requirements.

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

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

South Broward Hospital District d/b/a Memorial Regional Hospital (CON application #10386) states that JDCH has a comprehensive group of physicians on staff who are board-certified and actively practice at the hospital in the full array of specialties and sub-specialties that support and complement the existing pediatric heart transplant program. MRH states that there are three board-certified pediatric nephrologists with active medical staff privileges at Memorial Healthcare System's sister hospitals.

MRH asserts that upon project approval, recruitment of an additional pediatric transplant nephrologist to support the medical director for the program will occur. The applicant also discusses the recruitment of an experienced pediatric transplant surgical director, transplant surgeons, transplant nephrologists and surgical team along with all necessary staff as required, upon proposed project approval. The application further discusses the transplant surgeon, pediatric infectious disease physicians and other physicians (CON application #10386, pages 89 – 90).

North Broward Hospital District d/b/a Broward Health Medical Center (CON application #10387) contends that all required physicians necessary to support the ESRD medical needs of kidney transplant patients, including pediatric kidney transplant patients, are currently in place and active at BHMC. The applicant states 30+ nephrologists, including pediatric nephrology support, multiple infectious disease specialists, urologists, endocrinologists, cardiologists (both adult and pediatric) and every other specialist or subspecialist (adult and pediatric) that may be required to

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support kidney transplant patients are on staff at BHMC. The applicant maintains that adequate patient support will be provided.

BHMC states that the required pediatric transplant nephrologist is currently being recruited with this resource to be in place by program initiation. The applicant references attention to CON application #10387, Volume 2, Appendix 14, for the CVs of the two transplant surgeons.

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

South Broward Hospital District d/b/a Memorial Regional Hospital (CON application #10386) states it will recruit a pediatric transplant kidney surgeon who will serve as medical director of the program. The applicant indicates being prepared to implement the project within 12 to 18 months with plans to seek UNOS certification for pediatric kidney transplant within this period. MRH maintains having been able to commence both the pediatric and adult heart transplantation programs and receive UNOS approval in a timely manner.

North Broward Hospital District d/b/a Broward Health Medical Center (CON application #10387) states that a program director with all required training and experience in pediatric kidney transplantation is currently being recruited and that the position will be filled by the proposed program's initiation.

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

South Broward Hospital District d/b/a Memorial Regional Hospital (CON application #10386) mentions Rebecca Kordsmeier, MSN, RN, Director of Nursing and Administrative Leader, JDCH, PICU. According to the applicant, Ms. Kordsmeier has a 19-year history in the Memorial Healthcare System. Ms. Kordsmeier's CV is located in CON application #10386, Volume II, Attachment O. According to MRH, the PICU allows for the acute recovery of a large volume of postoperative pediatric kidney transplant surgery patients. The applicant maintains that

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JDCH is a member of the National Association of Children's Hospitals, whereby patient care standards are benchmarked with other children's hospitals for best practices.

North Broward Hospital District d/b/a Broward Health Medical Center (CON application #10387) indicates that BHMC and Chris Evert Children's Hospital's current staff of nurses and nurse practitioners have extensive experience in the care and support of chronically ill patients (adult and pediatric) and their families, specifically chronically ill renal disease patients (adult and pediatric) and their families. BHMC maintains that in addition, the current nurse and support staff, BHMC's existing transplant clinic has strong experience in working with the needs of chronically ill transplant patients and their families, support systems and support groups. BHMC asserts that all of these resources will be used in support of the future kidney transplant patients.

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

South Broward Hospital District d/b/a Memorial Regional Hospital (CON application #10386) previously stated that MRH has in place blood banking facilities and services necessary to support the proposed project.

North Broward Hospital District d/b/a Broward Health Medical Center (CON application #10387) contends that existing resources within BHMC's blood bank systems are capable and available to meet the unique needs of the applicant's proposed kidney transplant patients. See Item E.2.a.10 of this report.

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

South Broward Hospital District d/b/a Memorial Regional Hospital (CON application #10386) states having clinical dietitians with experience and expertise in the nutritional needs of patients with chronic illness, ESRD and transplant patients. MRH notes having a clinical nutritionist with experience in pediatric nutrition including diabetes, who also provides renal education to patients and families – Briekeda Lambert, MS, RD, LDN. According to the applicant, Ms. Lambert provides nutritional oversight and

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education of the patients at JDCH with chronic kidney disease or who are in ESRD. Ms. Lambert's CV is located in CON application #10386, Volume II, Attachment O.

North Broward Hospital District d/b/a Broward Health Medical Center (CON application #10387) states that nutritionists are available at BHMC and at the Chris Evert Children's Hospital with expertise in the nutritional needs of adult and pediatric kidney transplant patients and will be available to support the proposed patient group. The applicant provides the BHMC Nutritional Services Department Scope of Service and the CV of Lisa Fernandez Ashley, RD, LD/N, CDE (CON application #10387, Volume 2, Appendix 15). According to the applicant, Ms. Fernandez Ashley is one of the clinical dietitians who supports the current transplant program. The reviewer notes that according to the appendix, the scope of service indicates the ages of patients served are from neonate/infant to geriatric.

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

South Broward Hospital District d/b/a Memorial Regional Hospital (CON application #10386) states that "JDCH currently employs ____ Respiratory Therapists, two thirds of which have experience and training in caring for clinically ill patients". The applicant also indicates that "The patient population of the PICU's includes Level I trauma patients, Cardiac, Infectious Disease, and multi-system organ failure and many more sub-specialties".

MRH states that Sandra Santoro is the manager of respiratory therapy for JDCH, with over 37 years of respiratory therapy experience, specializing in neonatal and pediatric respiratory care. Ms. Santoro's CV is located in CON application #10386, Volume II, Attachment O. The reviewer notes that this CV does not expressly state having respiratory therapy licensure, though it states years of experience in this area.

North Broward Hospital District d/b/a Broward Health Medical Center (CON application #10387) contends that respiratory therapists with expertise and experience in the needs of kidney transplant patients, both adult and pediatric, are available at BHMC and the Chris Evert Children's Hospital to support this patient population. The applicant states that an overview of BHMC's Respiratory Services Program is provided. The reviewer

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notes that the BHMC Individual Department Plan Respiratory Care Services and the CV of Gary J. Richmond, MD, FACP, FCCP is provided (CON application #10387, Volume 2, Appendix 16).

The reviewer notes that the applicant does not reference Dr. Richmond in the application narrative. However, a review of his CV indicates that among other certifications and experience, Dr. Richmond is Medical Director, Division of Pulmonary Medicine, Broward General Medical Center (2003 to present) and is a Diplomate, Subspecialty Board of Pulmonary Diseases. The reviewer also notes that according to the appendix, the BHMC Individual Department Plan Respiratory Care Services indicates the ages of patients served are from neonate/infant to geriatric.

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

South Broward Hospital District d/b/a Memorial Regional Hospital (CON application #10386) states that JDCH has a support team to meet all of the requirements of this criterion. MRH asserts that all patients will be interviewed by a social worker during the pre-, inpatient and post-transplant phase. The applicant maintains that it will provide the arrangements of all discharges, including home health, medications and follow-up care coordination, clinical assessment and referral as needed, arrangement for educational and support groups for patients and their families as well as work with patients, families, community resources and insurance companies to ensure that client needs are met in a complete and timely manner. MRH notes that the social worker for the transplant team will assist with timely financial referrals for Medicaid and coordination of services through patients' insurance.

Memorial Regional Hospital assures that when a formal psychiatric/psychological evaluation is necessary as part of the pre-transplant evaluation or if psychiatric/psychology services are needed for the patient or family at any time during the transplant process, they will be referred to a psychiatrist or psychologist on staff at MRH/JDCH.

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North Broward Hospital District d/b/a Broward Health Medical Center (CON application #10387) contends that practitioners referenced in this rule staffing requirement are currently available at BHMC or at the Chris Evert Children’s Hospital and will be used in support of the proposed adult and pediatric transplant programs.

BHMC asserts that a transplant social worker is part of the current transplant team and will remain an integral component of the expanded transplant service once kidney transplant services are brought online. The reviewer notes that the applicant does not list any of these practitioners by name in the narrative portion of the application. However, CVs are provided (CON application #10387, Volume 2, Appendix 10).

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

South Broward Hospital District d/b/a Memorial Regional Hospital (CON application #10386) states that it has experience in reporting a wide variety of data regarding patient care in its facilities to the Agency or designees. According to MRH, reporting requirements will be integrated into existing data management and reporting capabilities without difficulty. The applicant indicates it will report registry data to UNOS and the OPTN. MRH also reports it currently has licensing and is utilizing the organ transplant service platform EPIC™. According to the applicant, this platform is a “full-featured, robust transplant and reporting system”. Per the applicant, the heart transplant, VAD and heart failure modules of this system have been purchased.

North Broward Hospital District d/b/a Broward Health Medical Center (CON application #10387) states that it will provide all required data to the Agency or to other appropriate entities within the required timeframes.

- 9. Kidney Transplantation Programs. In addition to meeting the requirements specified in subsections (3) – (5), a certificate of need for a new kidney transplantation program shall not normally be approved unless the following additional criteria are met:**

(a) Coordination of Services.

- 1. Inpatient services shall be available which shall include renal dialysis and pre- and post-operative care. There shall be 24-hour availability of on-site dialysis under the supervision of a board-certified or board-eligible nephrologist. If pediatric patients are served, a separate pediatric dialysis unit shall be established.**

South Broward Hospital District d/b/a Memorial Regional Hospital (CON application #10386) states it currently provides onsite pediatric dialysis 24 hours per day and pre- and post-operative care under the direction of Alex Constantinescu, MD. The applicant also states that Dr. Ivy Boydston and Dr. Xamaya Negroni-Balasquide are both board-certified nephrologists and are also involved in the care of these patients and the team provides a complete coverage 24 hours per day, seven days per week for the pediatric nephrology service. Also, see Item E.2.a.1 of this report.

North Broward Hospital District d/b/a Broward Health Medical Center (CON application #10387) indicates that a full array of pre- and post-operative inpatient services are currently available 24 hours per day at BHMC in support of the proposed pediatric kidney transplant program. BHMC maintains that inpatient renal dialysis for pediatric patients is provided at the patient's bedside 24 hours per day and is under appropriate nephrologist supervision. Also, see Item E.2.a.1 of this report.

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- 2. Outpatient services shall be available which shall include renal dialysis services and ambulatory renal clinic services.**

South Broward Hospital District d/b/a Memorial Regional Hospital (CON application #10386) states that it established the pediatric outpatient dialysis unit in 2004--complementing the inpatient dialysis services. MRH contends having the only outpatient unit in Broward County. The applicant maintains that Dr. Constantinescu and his team of physicians and nurses provide pediatric nephrology expertise across the South District's hospitals, and follow their patients in the offices throughout Broward and Palm Beach Counties.

North Broward Hospital District d/b/a Broward Health Medical Center (CON application #10387) states that all required outpatient services in support of the proposed project are available at BHMC or at the Chris Evert Children's Hospital. The applicant notes that this includes outpatient pediatric renal clinic services. BHMC contends that pediatric outpatient dialysis care is typically provided at outpatient dialysis centers but can be provided within BHMC's dialysis capabilities when needed.

BHMC reiterates its proposed condition regarding a contract with DaVita (DVA Healthcare Renal Care)—bringing a focused pediatric dialysis approach to this required care and providing a dialysis support system uniquely developed to serve the pediatric population.

- 3. Ancillary services shall include pre-dialysis, dialysis and post transplantation nutritional services; bacteriologic, biochemical and pathological services; radiologic services; and nursing services with the capability of monitoring and support during dialysis and assisting in home care including vascular access and home dialysis management, when applicable.**

South Broward Hospital District d/b/a Memorial Regional Hospital (CON application #10386) states

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that it has a broad array of ancillary services to meet all the needs of pediatric kidney transplant candidates and patients throughout the entire continuum of care, beginning with evaluation, transplantation and the post-transplantation phases of the process. MRH reiterates portions of its application regarding dietary/nutritional services (see Item E.2.b.5 of this report) and its clinical laboratory and its pathologists (see Item E.2.a.9 of this report).

MRH discusses its Division of Pediatric Radiology, described as providing comprehensive imaging and expert services to pediatric patients. According to the applicant, all pediatric imaging is supervised and interpreted by board-certified pediatric radiologists. MRH notes that the comprehensive range of radiology services include: X-rays, fluoroscopy, CT and MRI scans, ultrasound, nuclear medicine and PET imaging and interventional radiology.

North Broward Hospital District d/b/a Broward Health Medical Center (CON application #10387) maintains that each of the listed ancillary services is currently available at BHMC. The applicant contends that nursing services in support of monitoring and support during dialysis is currently available as is nursing support used in assisting vascular access and home dialysis management.

(b) Staffing Requirements for Pediatric Kidney Transplantation Programs. Applicants for a kidney transplantation program which will serve pediatric patients shall have the following staffing:

- 1. A medical director who is sub-board-certified or sub-board-eligible in pediatric nephrology.**

South Broward Hospital District d/b/a Memorial Regional Hospital (CON application #10386) states that Alex Constantinescu, MD, is the medical director and program director for the proposed project. MRH maintains that Dr. Constantinescu is now the medical director of the pediatric nephrology and hypertension

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program at JDCH. This physician is stated to be a board-certified pediatric nephrologist. He is also stated to be the medical director of the dialysis unit at JDCH.

North Broward Hospital District d/b/a Broward Health Medical Center (CON application #10387)

indicates that a medical director with the appropriate skills and qualifications is currently being recruited and will be in place prior to implementation of the proposed program to assist with development and staff training.

2. A dialysis unit head nurse with special training and expertise in pediatric dialysis.

South Broward Hospital District d/b/a Memorial Regional Hospital (CON application #10386)

indicates that Lisa Doyle, RN, MSN, is the current nurse unit manager for its Pediatric Dialysis Unit. The reviewer notes that neither the applicant, nor Ms. Doyle's CV (CON application #10386, Volume II, Attachment O) affirmatively state special training in pediatric dialysis.

North Broward Hospital District d/b/a Broward Health Medical Center (CON application #10387)

notes that pediatric dialysis services within BHMC are managed by a nurse with special training/expertise in pediatric dialysis and the care of pediatric patients obtaining dialysis support. The applicant indicates that the proposed pediatric outpatient service will likewise be managed by a nurse with specific training and expertise in pediatric dialysis.

3. Nurse staffing at a nurse to patient ratio of 1 to 1 in a pediatric dialysis unit.

South Broward Hospital District d/b/a Memorial Regional Hospital (CON application #10386)

states that it has additional nursing staff in the pediatric dialysis unit to support the current patient population

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on dialysis. The applicant maintains having the only pediatric dialysis unit in Broward County and that the nursing ratio at the unit is one-to-one.

North Broward Hospital District d/b/a Broward Health Medical Center (CON application #10387)

states nurse staffing in support of pediatric dialysis, both at BHMC and at the outpatient center is based upon each individual patient's needs, with up to a one-to-one staffing ratio provided when required.

4. A registered dietician with expertise in nutritional needs of children with chronic renal disease.

South Broward Hospital District d/b/a Memorial Regional Hospital (CON application #10386)

states that it has clinical dieticians with experience and expertise in the nutritional needs of pediatric patients with chronic and end stage kidney disease and transplant patients. MRH contends that experienced registered dieticians who have training in the dietary needs of acute and chronic renal patients are available for kidney transplant candidates.

North Broward Hospital District d/b/a Broward Health Medical Center (CON application #10387)

states that it has registered dieticians with the expertise in the nutritional needs of children with chronic renal disease available at BHMC and at the Chris Evert Children's Hospital to support this patient group.

5. A surgeon with experience in pediatric renal transplantation.

South Broward Hospital District d/b/a Memorial Regional Hospital (CON application #10386)

indicates that JDCH will recruit an experienced pediatric transplant surgical director, transplant surgeons, surgical team and all necessary staff as required, upon project approval. The reviewer notes that the applicant does not affirmatively state that the surgeon will have experience in renal transplantation.

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North Broward Hospital District d/b/a Broward Health Medical Center (CON application #10387)

reiterates that there are two kidney transplant surgeons (adult and pediatric) that have accepted letters of intent to join BHMC in support of the proposed project, plus one additional surgeon currently being recruited.

6. A radiology service with specialized equipment for obtaining x-rays on pediatric patients.

South Broward Hospital District d/b/a Memorial Regional Hospital (CON application #10386)

discusses its Division of Pediatric Radiology, described at providing comprehensive imaging and expert services to pediatric patients. According to MRH, all pediatric imaging is supervised and interpreted by board-certified pediatric radiologists. The applicant contends that the comprehensive range of radiology services includes: X-rays, fluoroscopy, CT and MRI scans, ultrasound, nuclear medicine and PET imaging and interventional radiology.

North Broward Hospital District d/b/a Broward Health Medical Center (CON application #10387)

contends that BHMC's and Chris Evert Children's Hospital's existing radiology staff and services have extensive experience in providing imaging services for pediatric patients and have all the required technology and equipment to provide this pediatric imaging service. The applicant offers the BHMC Individual Department Plan RADIOLOGY (CON application #10387, Volume 2, Appendix 21).

7. Education services to include home and hospital programs to ensure minimal interruption in school education.

South Broward Hospital District d/b/a Memorial Regional Hospital (CON application #10386)

states that JDCH has an existing contract with Broward County Schools to provide the necessary education for pediatric patients. According to MRH, a Broward

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County homebound teacher is on site during regular school hours to help hospitalized children (K-12) keep up with their schoolwork.

North Broward Hospital District d/b/a Broward Health Medical Center (CON application #10387) states that Chris Evert Children’s Hospital’s Child Life Program brings educational services to children who require them as a result of their medical conditions/care. The applicant also states coordination with each patient’s residential school resources to ensure that educational advancement is maintained, regardless of the setting. BHMC provides a narrative of the Child Life Department and the Nursing Outcomes Report 2013 (CON application #10387, Volume 2, Appendix 17).

3. Statutory Review Criteria

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

The mileage chart below indicates the driving distances to the nearest seven Florida pediatric kidney transplant providers, within 321 miles or less, from the proposed locations for **co-batched proposals CON application #10386 and CON application #10387**.

Driving Distances in Miles – CON application #10386 (Memorial Regional Hospital), CON application #10387 (Broward Health Medical Center) and Florida Pediatric Kidney Transplantation Providers						
Facility	Memorial Regional Hospital	Broward Health Medical Center	Jackson Memorial Hospital	Florida Hospital -Orlando	Tampa General Hospital	UF Health Shands Hospital
Memorial Regional Hospital		8.85	19.15	221.66	266.55	320.81
Broward Health Medical Center	8.85		26.03	215.95	264.05	315.11
Jackson Memorial Hospital	19.15	26.03		235.74	279.06	334.48
Florida Hospital-Orlando	221.66	215.95	235.74		88.29	115.03
Tampa General Hospital	266.55	264.05	279.06	88.29		131.14
UF Health Shands Hospital	320.81	315.11	334.48	115.03	131.14	

Source: www.Mapquest.com

The reviewers notes that both co-batched applicants are within 26.03 miles distant or less to the nearest existing pediatric kidney transplant provider. As previously shown, Jackson Memorial Hospital has been the largest volume pediatric kidney transplant provider for the five-year

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period ending December 31, 2014. Agency data has also previously shown that TSA 4 pediatric kidney transplant recipients, in CY 2014, did not travel outside of their home service area for this procedure.

South Broward Hospital District d/b/a Memorial Regional Hospital (CON application #10386) states that the proposed project will have a positive effect on the overall availability of pediatric kidney transplant services in the service area. MRH reiterates the need justifications it offered previously (see Item E.1.b.2 of this report). The applicant expects that the proposed project will ameliorate the current geographic access problem faced by many residents of TSA 4, especially those who live in Palm Beach and Broward Counties, where ESRD to transplant conversion rates are stated to be much lower than the conversion rate in Miami-Dade County. The applicant also asserts that travel distances and travel times will be greatly reduced. The applicant maintains that access to the proposed program at JDCH will substantially reduce the financial burden and inconvenience to patients, caregivers and family members throughout the many months entailed in the most active phases of the kidney transplant and post-transplant process.

Using Agency hospital inpatient discharge data (through September 30, 2014) and Broward Regional Health Council, Inc., hospital emergency department (ED) discharge data (CY 2014), MRH provides the following table and contends that JDCH has approximately 40 percent more pediatric medical/surgical discharges and nearly two and a half times the number of ED visits as Chris Evert Children’s Hospital.

Pediatric (Ages 0-17) Utilization, JDCH and Chris Evert Children’s Hospital, 2014

	Inpatient Medical/Surgical Utilization				ED Utilization	
	Discharges	Patient Days	ALOS	Average CMI	Pediatric Visits	Pediatric Admits
Joe DiMaggio Children’s Hospital	3,973	21,107	5.31	1.75	67,284	3,146
Chris Evert Children’s Hospital	2,852	11,155	3.91	1.58	26,744	2,712

Source: CON application #10386, page 115, Table 1

MRH also contends that based on the above table, JDCH has a higher average case mix index, indicating that JDCH typically cares for a more complex patient population than Chris Evert Children’s Hospital and that this higher case mix accounts for JDCH’s higher ALOS. MRH asserts that these several factors - more robust children’s services, more complex patients and a much larger patient base – all demonstrate that JDCH is the preferred location for the proposed project.

North Broward Hospital District d/b/a Broward Health Medical Center (CON application #10387) states its intent to enhance geographic and financial access to kidney transplantation care, indicating that the proposed project will provide a local alternative for pediatric kidney transplant care. According to BHMC, the proposed project will reduce travel time and associated travel costs and also enhance the continuum of care that will be collaboratively provided by the physicians and staff of BHMC.

BHMC contends being the superior choice for delivering and operating the proposed project to ensure long-term access by all area residents regardless of ability to pay.

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

South Broward Hospital District d/b/a Memorial Regional Hospital (CON application #10386) states that it is a leader in providing comprehensive, high quality health care to patients of all ages. The applicant contends that the vast majority of physicians who practice at the South District's facilities are board-certified or board-qualified in their specialties. MRH includes recognitions and awards at its South District hospitals (CON application #10386, pages 108 - 110). Specific to JDCH and MRH, below are the applicant's stated awards for these two hospitals.

At JDCH:

- Best Children's Hospital rankings – *US News & World Report* top 50 in Pediatrics, Orthopedics, Pediatric Urology and Pediatric Cardiology and Heart Surgery (2015-2016)
- Guardian of Excellence Award, Patient Satisfaction, Inpatient Pediatrics and Outpatient Services, Press Ganey (2013)
- Favorite Pediatric Hospital, Broward Family Life's BFF, 2014, 2013
- Best Hospital for Pediatrics in Broward County, South Broward Parenting, 2013, 2012, 2006-1996
- Hall of Fame: Best of the Best Pediatric Hospitals, *South Florida Parenting*, 2011, 2010, 2009, 2008, 2007
- Excellence in Patient Care "Special Category Award" – Physician Satisfaction, Studer Group®, 2011
- Excellence in Patient Care "Special Category Award" – Children's Hospitals and Clinics, Studer Group®, 2010
- Best Hospital for Families with Special Needs, *South Florida Parenting*, 2009, 2003

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- Best of the Best: Readers' Choice, Florida's Top Hospitals for Quality of Care, Organizational Culture, Communication, Professional Development and Retention Efforts, *Advance for Nurses*, 2009, 2008

At MRH:

- Family Favorite Fitness Center, Broward Family Life's BFF, 2014
- Best Hospital in Southern Florida, *US News & World Report*, 2013
- Leapfrog's Hospital Safety Score, "A" Ranking for Patient Safety, Leapfrog Group, 2015-2012
- Premier Quest Award, High-Value Healthcare (Citation of Merit) 2013
- Luminaire Hospital Achievement Award, The Life Alliance, 2012
- Quest for Quality Prize®, American Hospital Association – McKesson, 2011
- Hall of Fame: Best of Best Places to Give Birth, *South Florida Parenting*, 2011, 2010, 2009, 2008, 2007
- Gold Plus Achievement Award (Stroke), American Heart Association/American Stroke Association, 2015, 2014, 2013, 2012, 2011, 2010, 2009
- Best of the Best: Readers' Choice, Florida's Top Hospitals for Quality of Care, Organizational Culture, Communication, Professional Development and Retention Efforts, *Advance for Nurses*, 2009
- Premier Award for Quality, Premier, Inc., 2009

Memorial Healthcare System notes inclusion in *Modern Healthcare* magazine's Best Places to Work in Healthcare, *Florida Trend* magazine's Best Companies to Work for in Florida, 100 Top Hospitals, Consumer Choice Award, Best Practice Leader Award, Best Nursing Staff, Best Pediatric Hospital and Best Maternity Hospital. The applicant indicates that most recently, Memorial Healthcare System was recognized as one of the National Leaders in Emergency Stroke Care by the American Heart/Stroke Association and was also honored by the American Hospital Association with the Living the Vision Award and the Foster G. McGraw Award and was selected from more than 5,000 hospitals as the national model for improving the health of the community.

The applicant indicates that in 2006, the South District launched a community program known as Health Interventions with Targeted Services (HITS). MRH indicates that HITS is designed to improve health care in the District's poorest neighborhoods based on the highest concentration of uninsured/underinsured residents. Additionally, the applicant states that the National Committee for Quality Assurance (NCQA) awarded the

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district the “Patient Centered Medical Home Recognition Level III” and that this is the highest level awarded. MRH also includes its Mission and Vision (CON application #10386, page 112).

MRH contends that JDCH is the only hospital in the area to offer comprehensive programs in the following highly specialized pediatric areas: pediatric heart transplantation, open heart surgery and cardiac catheterization, endocrinology, gastroenterology, hematology/oncology, kidney failure, neurosurgery, orthopedic surgery and psychiatry. According to MRH, its Cardiac, Craniofacial, Oncology, Regional Perinatal Intensive Care and Pediatric Dialysis Programs have been designated pediatric centers by the Florida Department of Health, Children’s Medical Services.

MRH discusses being committed to quality and safety, the Memorial Health Network (Clinically Integrated Network), Memorial Physician Group and Organ Donor Kiosk (CON application #10386, pages 115 - 120).

Agency complaint records indicate, for the three-year period ending June 1, 2015, Memorial Regional Hospital had no substantiated complaints and for the same period, South Broward Hospital District had no substantiated complaints. South Broward Hospital District operates five Broward County hospitals with 1,900 beds.

North Broward Hospital District d/b/a Broward Health Medical Center (CON application #10387) maintains that it has a long and proven history of providing high quality of care to all segments of patients served. BHMC notes service strengths among numerous clinical service lines that provide proven high quality care to many sectors of the community. Below is a list of BHMC’s stated quality features (CON application #10387, pages 41 – 42):

- Recognized by *US News & World Report* as a Best/Top Performing Regional Hospitals in two adult specialties – Cardiology/Cardiac Surgery and Nephrology
- The Joint Commission Disease Specific Certification in CABG, Stroke, Palliative Care and Joint Replacements
- 2014 Rings Award by IntelliCentries, Inc., a leader in operational security and compliance management, which recognizes hospitals for creating a culture of vigilance to safeguard their facilities, their employees and their patients, winning hospitals selected from more than 6,500 health care facilities

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- 2015 American Heart Association/American Stroke Association’s “Get with the Guidelines” Gold Plus Award for excellence in treatment of stroke for the fifth consecutive year and qualifying for recognition on the Target-Stroke Honor Roll
- Broward County’s only hospital to receive no Medicare readmission penalty for all publicly reported measures
- 2015 Nova Southeastern University Quality of Life (QOL) Outstanding Community Partner of the Year for partnership and commitment to QOL community-based applied research
- Three Patient Experience Awards from Avatar Solutions, a leading provider of patient, employee, Consumer Assessment of Healthcare Providers and Systems and physician surveys. These surveys are stated to cover topics that are important to consumers and focus on aspects of quality that consumers are best qualified to assess, such as the communication skills of providers and ease of access to health care services
- South Florida Parenting Kids Crown Award in three different categories – Best Maternity Hospital, Best Urgent Care and Best ER Hospital in Broward County
- Press Ganey “Guardian of Excellence Award” and following last year’s award, which recognizes organizations that reached the 95th percentile for each reporting period during the award year for core measures
- American Heart Association’s Gold Fit-Friendly Worksite Award
- Live Strong Music Therapy Grant (awarded to BHMC’s Comprehensive Cancer Center)
- Identified by the National Accreditation Program for Breast Centers as having three best practices in Research: Clinical trial accrual; Leadership: utilization of grant funds to care for indigent population and Community Outreach: screening process using Mammopaloza
- Recognized by Truven Analytics (formerly Solucient/Thompson-Reuters) as a Top 50 Cardiovascular Hospitals in the nation
- Accreditation (at BHMC’s Lillian S. Wells Women’s Center) by the National Accreditation Program for Breast Cancer, with several areas being recognized as national best practice
- CAP and AABB accredited (for BHMC’s lab)
- First place for *Ambulatory Care for Healthcare Design* magazine’s 5th Annual Remodel and Renovation Competition (for BHMC’s Adult Infusion Center)
- Over seven residency/fellowship programs and over 100 residents as a Florida statutory teaching hospital
- Full American College of Radiology three-year accreditation for Nuclear Medicine, PET/CT and Ultrasound Services

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BHMC asserts that these awards and recognitions document the organizational approach that BHMC will take when establishing the proposed kidney transplant program.

Agency complaint records indicate, for the three-year period ending June 1, 2015, Broward Health Medical Center had one substantiated complaint. A single complaint can encompass multiple complaint categories. The substantiated complaint category was quality of care/treatment.

North Broward Hospital District operates four Broward County hospitals with 1,529 beds. Agency complaint records indicate, for the three-year period ending June 1, 2015, North Broward Hospital District had five substantiated complaints in the following complaint categories:

North Broward Hospital District Substantiated Complaint Categories for the 36 Months Ending June 1, 2015	
Quality of Care/Treatment	3
Dietary Services	1
Infection Control	1
Physical Environment	1
Resident/Patient/Client Assessment	1

Source: Agency Complaint Records

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

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

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Historically we have compared all applicant financial ratios regardless of type to benchmarks established from financial ratios collected from Florida acute care hospitals. While not always a perfect match to a particular CON project it is a reasonable proxy for health care related entities.

South Broward Hospital District d/b/a Memorial Regional Hospital (CON application #10386): Below is an analysis of the audited financial statements of South Broward Hospital District where the short-term and long-term measures fall on the scale (highlighted in gray) for the most recent year. All numbers are in thousands.

South Broward Hospital District (in thousands)		
	Apr-14	Apr-13
Current Assets	\$1,589,413	\$1,474,059
Total Assets	\$2,487,529	\$2,414,524
Current Liabilities	\$234,444	\$261,147
Total Liabilities	\$866,854	\$895,309
Net Assets	\$1,620,675	\$1,519,215
Total Revenues	\$1,574,044	\$1,480,931
Excess of Revenues Over Expenses	\$99,591	\$101,148
Cash Flow from Operations	\$174,394	\$271,449
Short-Term Analysis		
Current Ratio (CA/CL)	6.8	5.6
Cash Flow to Current Liabilities (CFO/CL)	74.39%	103.94%
Long-Term Analysis		
Long-Term Debt to Net Assets (TL-CL/NA)	39.0%	41.7%
Total Margin (ER/TR)	6.33%	6.83%
Measure of Available Funding		
Working Capital	\$1,354,969	\$1,212,912

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

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Capital Requirements and Funding:

The applicant lists \$335,456,407 for capital projects which include expansions, renovations, routine and reserves, infrastructure, equipment, information technology, energy plants, other, maturities of long-term debt through FY 2016, CON application #10388, and the CON currently under review.

The applicant currently has two CON applications in this batch under review (CON application #10386 and CON application #10388) for total project costs of \$446,300. Both of these projects will be funded by cash on hand.

Staffing:

The table below shows the MRH’s projected staffing for years one and two, ending October 31, 2017 and December 31, 2018, respectively. By the end of year two, MRH estimates increases in FTEs regarding two of the FTE categories shown in the table below, with these being the categories of physicians-other and social services-other. All other FTEs are to remain constant for both years. The table accounts for FTEs to be added as a result of the proposed project, if approved.

South Broward Hospital District d/b/a Memorial Regional Hospital CON application #10386 Pediatric Kidney Transplantation Program Staffing Patterns		
	Year One Ending 10/31/17	Year Two Ending 10/31/18
ADMINISTRATION		
Other: All Other	2.5	2.5
PHYSICIANS		
Unit Program Director	0.8	0.8
Other: All Other	0.5	1.0
ANCILLARY		
Other: All Other	0.5	0.5
Dietary		
Dietary Supervisor	0.5	0.5
SOCIAL SERVICES		
Other: All Other	2.0	3.0
GRAND TOTAL	6.8	8.3

Source: CON application #10386, Schedule 6A

Conclusion:

Funding for this project should be available as needed.

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North Broward Hospital District d/b/a Broward Health Medical Center (CON application #10387): Below is an analysis of the audited financial statements of North Broward Hospital District where the short-term and long-term measures fall on the scale (highlighted in gray) for the most recent year. All numbers are in thousands.

North Broward Hospital District (in thousands)		
	Jun-14	Jun-13
Current Assets	\$743,143	\$698,812
Total Assets	\$1,413,390	\$1,334,995
Current Liabilities	\$170,165	\$178,421
Total Liabilities	\$530,780	\$523,072
Net Assets	\$882,610	\$811,923
Total Revenues	\$971,162	\$952,919
Excess of Revenues Over Expenses	\$70,580	\$55,990
Cash Flow from Operations	(\$80,688)	(\$28,053)
Short-Term Analysis		
Current Ratio (CA/CL)	4.4	3.9
Cash Flow to Current Liabilities (CFO/CL)	-47.42%	-15.72%
Long-Term Analysis		
Long-Term Debt to Net Assets (TL-CL/NA)	40.9%	42.4%
Total Margin (ER/TR)	7.27%	5.88%
Measure of Available Funding		
Working Capital	\$572,978	\$520,391

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

Capital Requirements and Funding:

The applicant lists \$83,053,759 for capital projects which include CECH P2, other capitalization, equipment, furnishings, renovations, maturities of long-term debt, the CON currently being reviewed, a CON application submitted simultaneously (10389), OP CT scanner replacement, pediatric pharmacy, and a proposed 2016 budget for equipment and construction. The project will be funded by cash on hand.

Staffing:

The applicant's Schedule 6A indicates no FTEs added for the proposed project, at least for the four year period of projected service ending March 30, 2021 (March 30, 2021 is shown on page 4 of 4 on Schedule 6A, with all other year ending dates on this schedule indicating March 31). In the Schedule 6A notes, BHMC indicates that due to the very low volume of pediatric procedures forecast, it is not expected that any new staff will be hired to support the pediatric program.

Conclusion:

Funding for this project should be available as needed.

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

The immediate and long-term financial feasibility of each co-batched project is tied to expected profitability. The purpose of our analysis for this section is to evaluate the reasonableness of the applicant's profitability projections and, ultimately, whether profitability is achievable for this project. Our analysis includes an evaluation of net revenue per patient day (NRPD), cost per patient day (CPD), and profitability. We compared the NRPD, CPD, and profitability to actual operating results from teaching hospitals as reported on Florida Hospital Uniform Reporting System reports. For our comparison group, we selected hospitals from the same group (Group 7: Large Urban Hospital Group) to the utilization projected by the applicant on a per patient day basis (PPD). Comparison group data was adjusted for inflation to match the second year projection (inflation factor was based on the New CMS Market Basket Price Index as published in the 1st Quarter 2015, Health Care Cost Review).

NRPD, CPD and profitability or operating margin that fall within the group range are considered reasonable projections. Below is the result of our analysis.

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**South Broward Hospital District d/b/a Memorial Regional Hospital
(CON application #10386):**

	PROJECTIONS PER APPLICANT		COMPARATIVE GROUP VALUES PPD		
	Total	PPD	Highest	Median	Lowest
Net Revenues	825,201,115	2,633	3,674	2,518	2,069
Total Expenses	796,133,000	2,540	3,247	2,353	2,118
Operating Income	29,068,115	93	355	37	-86
Operating Margin	3.52%		Comparative Group Values		
	Days	Percent	Highest	Median	Lowest
Occupancy	185,882	67.3%	71.0%	57.8%	39.7%
Medicaid	40,070	21.6%	25.8%	16.6%	8.7%
Medicare	31,241	16.8%	56.5%	31.9%	20.0%

NRPD, CPD and operating margin all fall within the control group range. Overall, the project appears profitable.

Conclusion:

The project appears reasonable.

**North Broward Hospital District d/b/a Broward Health Medical
Center (CON application #10387):**

	PROJECTIONS PER APPLICANT		COMPARATIVE GROUP VALUES PPD		
	Total	PPD	Highest	Median	Lowest
Net Revenues	509,371,804	2,057	3,424	2,346	1,928
Total Expenses	516,794,149	2,087	3,026	2,193	1,974
Operating Income	-7,422,345	-30	355	37	-86
Operating Margin	-1.46%		Comparative Group Values		
	Days	Percent	Highest	Median	Lowest
Occupancy	152,443	58.3%	71.0%	57.8%	39.7%
Medicaid	39,120	25.7%	25.8%	16.6%	8.7%
Medicare	29,752	19.5%	56.5%	31.9%	20.0%

NRPD, CPD and operating margin all fall within the control group. The applicant appears to list the incorrect amount for net patient service revenue in year two. However, going forward the applicant appears to use the correct amount for calculations of net operating revenue and net income. Additionally, the applicant listed 1,432 beds for the first year of combined projected patient day data. The applicant is only licensed for

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716 beds and lists that in the second year of projected operations. When determining the occupancy percentage for the first year of projected data, the Agency used the number of licensed beds.

Conclusion:

Overall, the projections appear reasonable.

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

For **each** co-batched application, the answer is no. Due to the health care industry's existing barriers in consumer based competition, this project will not likely foster the type competition generally expected to promote quality and cost-effectiveness.

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

The User and Purchaser of Health Care are Often Different – Roughly 86.5 percent of hospital charges in Florida are from Medicare, Medicaid, and HMO/PPOs. The individuals covered by these payers pay little to none of the costs for the services received. Since the user is not paying the full cost directly for service, there is no incentive to shop around for the best deal. This further makes price-based competition irrelevant.

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

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

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demand in which excess supply leads to lower price in a competitive market. The study illustrates the weakness in the link between supply and demand and suggests that more choices lead to higher utilization in the health care industry as consumers explore all alternatives without regard to the overall cost per treatment or the quality of outcomes.

South Broward Hospital District d/b/a Memorial Regional Hospital (CON application #10386):

Price-Based Competition is Limited - Medicare and Medicaid account for 64.0 percent of hospital charges in Florida, while HMO/PPOs account for approximately 22.5 percent of charges. While HMO/PPOs negotiate prices, fixed price government payers like Medicare and Medicaid do not. Therefore price-based competition is limited to non-government payers. Price-based competition is further restricted as Medicare reimbursement in many cases is seen as the starting point for price negotiation among non-government payers. In this case 38.4 percent of patient days are expected to come from Medicare and Medicaid with 49 percent from HMO/PPOs.

Conclusion:

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

North Broward Hospital District d/b/a Broward Health Medical Center (CON application #10387):

Price-Based Competition is Limited - Medicare and Medicaid account for 64.0 percent of hospital charges in Florida, while HMO/PPOs account for approximately 22.5 percent of charges. While HMO/PPOs negotiate prices, fixed price government payers like Medicare and Medicaid do not. Therefore price-based competition is limited to non-government payers. Price-based competition is further restricted as Medicare reimbursement in many cases is seen as the starting point for price negotiation among non-government payers. In this case 68.9 percent of patient days are expected to come from Medicare and Medicaid with 15.3 percent from HMO/PPOs.

Conclusion:

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

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

Neither co-batched project involves construction or renovation.

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

The reviewer notes that statewide during CY 2014, two (22.22 percent) of the pediatric kidney transplantations were compensated through Medicaid.⁵ Agency data indicates that these two procedures were performed by non-TSA 4 providers.

Below is a chart to account for **each** co-batched applicant's and the district's Medicaid and charity care percentages for CY 2013.

**Medicaid and Charity Care for
South Broward Hospital District d/b/a
Memorial Regional Hospital/CON application #10386 and
North Broward Hospital District d/b/a
Broward Health Medical Center/CON application #10387
Compared to the District for FY 2013**

Applicant	Medicaid and Medicaid HMO Days	Charity Percentage Service	Combined Medicaid and Charity Care
South Broward Hospital District d/b/a Memorial Regional Hospital*	30.00%	9.16%	39.16%
North Broward Hospital District d/b/a Broward Health Medical Center**	38.47%	9.92%	48.39%
District 10 Average	20.85%	5.67%	26.52%

Source: Fiscal Year 2013 Agency for Health Care Administration Actual Hospital Budget Data

Note: * For this review, Memorial Regional Hospital's fiscal year ended 04/30/2013

** For this review, Broward Health Medical Center's fiscal year ended 06/30/2013

The table below illustrates MRH's and Broward Health Medical Center's FY 2014-2015 low-income pool (LIP) and disproportionate share hospital (DSH) program participation, as of May 21, 2015.

⁵ Based on the Agency's Florida Center for Health Information and Policy Analysis hospital discharge data for CY 2014

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South Broward Hospital District d/b/a Memorial Regional Hospital/CON application #10386 and North Broward Hospital District d/b/a Broward Health Medical Center/CON application #10387 LIP and DSH Program Participation FY 2014-2015		
Applicant/Program	Annual Total Allocation	Year-to-Date Total Allocation As of May 21, 2015
Memorial Regional Hospital/LIP	\$133,569,165	\$99,287,449
Memorial Regional Hospital/DSH	\$19,571,056	\$14,678,293
Broward Health Medical Center/LIP	\$137,802,189	\$102,664,575
Broward Health Medical Center/DSH	\$23,423,210	\$17,567,408

Source: Agency Division of Medicaid, Office of Program Finance

South Broward Hospital District d/b/a Memorial Regional Hospital (CON application #10386) states that the South District serves as the safety net provider for charity care patients in the south Broward service area. The applicant also states that MRH and the South District as a whole have a long history of providing care to medically indigent patients, regardless of their ability to pay. According to the applicant, in FY 2015 (ending April 30, 2015), Medicaid accounted for 30.2 percent (9,689 cases of 32,084 cases) of total patients discharged from MRH. The applicant further states that in FY 2013, the South District provided approximately \$784.1 million in uncompensated care to the medically indigent population of Broward County, which included charity care and uncollected accounts. Additionally, MRH maintains that the district provided approximately \$1.9 billion in care to Medicaid patients.

According to Schedule 7A of the application, incrementally, 26.9 percent of the proposed project's annual patient days will be self-pay/other payers, followed by 11.5 percent to other managed care and 61.8 percent to Medicare, for year one ending October 31, 2017. Schedule 7A also indicates that again, incrementally, 23.5 percent of the proposed project's patient days will be self-pay/other payers and other managed care equally, followed by 53.0 percent to Medicare, for year two ending October 31, 2018.

Memorial Regional Hospital offers no Medicaid or charity care conditions to the proposed project. However, the applicant does condition to accept and provide care to any and all pediatric kidney transplant patients (ages 0-14) from TSA 4 regardless of their ability to pay.

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North Broward Hospital District d/b/a Broward Health Medical Center (CON application #10387) indicates a strong and proven history of providing health services to Medicaid patients and the medically indigent. The applicant states that this is shown by the fact that during FY 2014, approximately \$234 million in charity care was provided by the North District operations. BHMC states that in addition, approximately 12 percent of the North District's gross patient revenue was derived under the Medicaid program and that the district provided more than \$320 million in community benefits at cost during 2013. BHMC further explains that BHMC alone provided 10 percent of its gross revenue to charity care patients, plus an additional 38 percent of its patient day volume to Medicaid patients during 2013.

According to Schedule 7A of the application, 75.0 percent of the proposed project's total annual patient days will be commercial insurance, followed by 25.0 percent to Medicaid, for each of the first four years of planned services (with year one ending March 31, 2017).

BHMC offers no Medicaid or charity care conditions to the proposed project.

F. SUMMARY

South Broward Hospital District d/b/a Memorial Regional Hospital (CON application #10386) proposes to establish a pediatric kidney transplantation program within MRH at JDCH, in Hollywood, Broward County, Florida, District 10, TSA 4.

MRH is a 757-bed general hospital, licensed for 621 acute care, 22 Level II NICU, 42 Level III NICU, 45 adult psychiatric, 10 child/adolescent psychiatric, 11 adult substance abuse and six CMR beds. MRH offers pediatric cardiac catheterization, pediatric open heart surgery and pediatric and adult heart transplantation programs, as well as Level II adult cardiovascular services and is a Comprehensive Stroke Center. MRH is a Level I Trauma Center.

In this batching cycle, MRH is also seeking approval to establish an adult kidney transplantation program (CON application #10388).

Project costs total \$217,060. These costs include equipment, project development and start-up costs. There is no reported construction or renovation associated with the project.

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In addition to the project location at 3501 Johnson Street, Hollywood, Florida 33021, Schedule C includes the following conditions:

- (1) The MRH pediatric kidney transplant program will comply at all times with Medicare conditions of participation and meeting Medicare specified transplant patient survival standards.
- (2) Although kidney transplantation programs can continue to operate following the loss of Medicare certification MRH agrees that, in the event it loses Medicare certification, it will not continue to operate the program.
- (3) South Broward Hospital District d/b/a Memorial Regional Hospital stipulates that consistent with its mission and vision, it is committed to accept and provide care TO ANY AND ALL pediatric kidney transplant patients (ages 0-14) from Organ Transplant Service Area 4 (Monroe Miami-Dade, Broward, Palm Beach, and Collier Counties) regardless of their ability to pay.

North Broward Hospital District d/b/a Broward Health Medical Center (CON application #10387) proposes to establish a pediatric kidney transplantation program at BHMC, in Fort Lauderdale, Broward County, Florida, District 10, TSA 4.

BHMC is a 716-bed general hospital, licensed for 570 acute care, 36 Level II NICU, 27 Level III NICU and 83 adult psychiatric beds. BHMC offers Level II adult cardiovascular services, is a Comprehensive Stroke Center, a Level I Trauma Center and provides adult liver transplantations.

In this batching cycle, BHMC is also seeking approval to establish an adult kidney transplantation program (CON application #10389).

Project costs total \$527,650. These costs include equipment, project development and start-up costs. There is no reported construction or renovation associated with the project.

The applicant's pediatric kidney transplant program is expected to be licensed in March 2016 with initiation of service in April 2016.

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The applicant includes the following conditions in its Schedule C:

- (1) BHMC conditions this application such that if the companion adult kidney transplant program is not ultimately approved, this pediatric program will not be developed as a stand-alone pediatric kidney transplant program.
- (2) BHMC conditions this application such that an outpatient pediatric dialysis service will be established by BHMC's dialysis partner – DaVita (DVA Healthcare Renal Care) – in an existing DaVita dialysis center located proximate to BHMC. The outpatient pediatric dialysis service will provide a centralized, pediatric focused dialysis service in support of the outpatient needs of BHMC's pediatric kidney transplant patients. Compliance with this condition will be documented by an annual report to AHCA presenting documentation regarding the operation of the outpatient pediatric dialysis service.

Need:

Need is not published by the Agency for pediatric kidney transplants. It is the applicant's responsibility to demonstrate need. The planning for organ transplantation programs in Florida is done on a regionalized basis covering four regions defined by rule.

South Broward Hospital District d/b/a Memorial Regional Hospital (CON application #10386) contends that project approval is warranted based on the following reasons:

- There is a growing waiting list for pediatric kidney transplants at Florida Centers. The waiting list from TSA 4 transplant centers is growing at a faster rate than other service areas.
- The number of donor kidneys procured in Florida is significantly greater than the number of pediatric kidney transplants performed in Florida. From 2012 to 2014, the TSA 4 OPO was the only OPO where the number of pediatric kidneys procured increased.
- There is a growing number of ESRD patients on dialysis in Florida, with TSA 4 having the highest prevalence of pediatric ESRD cases of all TSAs.
- The pediatric population (ages 0-14) in TSA 4 is projected to grow three percent by 2020 – from 1.0 million to 1.1 million pediatric residents.
- The demand for kidney transplantation in TSA 4 will continue to increase through 2020 given the projected population growth in the region and the expectation that the prevalence of ESRD will continue on an upward trend.

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- MRH/JDCH also shows recent higher pediatric (ages 0-17) discharges, patient days, ALOS and average case mix index figures along with higher ED pediatric (age 0-17) visits and admits than co-batched CON application #10387.
- Given the comprehensive range of specialized services offered by MRH and JDCH with its Pediatric Nephrology and Hypertension Program, its pediatric-only dialysis center, its Chronic Kidney Disease Clinic devoted to caring for children with chronic kidney disease, the program's 10 years' experience treating pre- and post-kidney transplant patients, and the fact that five of the 15 patients currently being seen in Chronic Kidney Disease Clinic have stage 4 or stage 5 chronic kidney disease, it is reasonable to expect that the proposed project will meet minimum volume requirements.

North Broward Hospital District d/b/a Broward Health Medical Center (CON application #10387) contends that project approval is warranted based on the following reasons:

- In CY 2014, Jackson Memorial Hospital performed more pediatric kidney transplants (13 procedures) than any other single provider, statewide and this same provider averaged 19.7 such procedures for the three year period 2012 -2014.
- Jackson Memorial Hospital would remain above the 10 case minimum for existing programs if the area market remained stable and five cases were shifted to the proposed project.
- In 2013, Broward County and Palm Beach County, together, realized 50 percent of the live births in the service area.
- In 2013, Broward County and Palm Beach County, together, realized 54 percent of the pediatric (age 0-14) inpatient hospital discharges for the service area.
- Broward County alone could support the proposed project case volume of six cases and Broward and Palm Beach County together could support a case volume of nine to 10 pediatric kidney cases.
- The proposal would significantly reduce travel time and costs in traveling to Miami from Broward or Palm Beach for care.
- The small pediatric case volume alone would prove problematic to operate an efficient program but the companion application (CON application #10389) will have adequate volume to operate an efficient and effective pediatric kidney transplant program.

Quality of Care:

Each co-batched applicant described their ability to provide quality care.

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South Broward Hospital District d/b/a Memorial Regional Hospital (CON application #10386) references many awards and recognitions.

Agency complaint records indicate, for the three-year period ending June 1, 2015, Memorial Regional Hospital had no substantiated complaints and for the same period, South Broward Hospital District had no substantiated complaints. South Broward Hospital District operates five Broward County hospitals with 1,900 beds.

North Broward Hospital District d/b/a Broward Health Medical Center (CON application #10387) references many awards and recognitions.

Agency complaint records indicate, for the three-year period ending June 1, 2015, Broward Health Medical Center had one substantiated complaint. North Broward Hospital District operates four Broward County hospitals with 1,529 beds. Agency complaint records indicate, for the three-year period ending June 1, 2015, North Broward Hospital District had five substantiated complaints.

Financial/Cost:

Both co-batched **South Broward Hospital District d/b/a Memorial Regional Hospital (CON application #10386)** and **North Broward Hospital District d/b/a Broward Health Medical Center (CON application #10387)** show that funding for **each** project should be available as needed and **each** project appears financially reasonable.

Neither project is likely to have a material impact on competition to promote quality and cost-effectiveness.

Medicaid/Indigent Care:

South Broward Hospital District d/b/a Memorial Regional Hospital (CON application #10386): According to the Agency's 2013 Financial Data Report, MRH provided 30.00 percent of its total annual patient days to Medicaid/Medicaid HMO patients and 9.16 percent to charity care patients in FY 2013.

MRH is a LIP and a DSH participating hospital. As of May 21, 2015, for state fiscal year 2014-2015, MRH received \$99,287,449 in LIP payments and \$14,678,293 in DSH payments.

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According to Schedule 7A, MRH intends to provide incrementally with the proposed project, 0.00 percent of its proposed pediatric kidney transplantation program's patient days to Medicaid in year one (ending October 31, 2017) and 0.00 percent in year two (ending October 31, 2018). According to the same schedule for the same service and years (year one and year two), 26.9 percent and 23.5 percent, respectively, of annual patient days, are to self-pay/other payers.

MRH offers no Medicaid or charity care conditions to the proposed project. However, the applicant does condition to accept and provide care to any and all pediatric kidney transplant patients (ages 0-14) from TSA 4 regardless of their ability to pay.

North Broward Hospital District d/b/a Broward Health Medical Center (CON application #10387): According to the Agency's 2013 Financial Data Report, BHMC provided 38.47 percent of its total annual patient days to Medicaid/Medicaid HMO patients and 9.92 percent to charity care patients in FY 2013.

BHMC is a LIP and a DSH participating hospital. As of May 21, 2015, for state fiscal year 2014-2015, BHMC received \$102,664,575 in LIP payments and \$17,567,408 in DSH payments.

According to Schedule 7A of the application, 25.0 percent of the applicant's total annual patient days shall be provided to Medicaid, for each of the first four years of planned services (with year one ending March 31, 2017).

BHMC offers no Medicaid or charity care conditions to the proposed project.

G. RECOMMENDATION

Approve CON #10386 to establish a pediatric kidney transplantation program in Broward County, District 10, Organ Transplantation Service Area 4. The total project cost is \$217,060. The project involves no construction or renovation.

CONDITIONS:

- (1) The MRH pediatric kidney transplant program will comply at all times with Medicare conditions of participation and meeting Medicare specified transplant patient survival standards.
- (2) Although kidney transplantation programs can continue to operate following the loss of Medicare certification MRH agrees that, in the event it loses Medicare certification, it will not continue to operate the program.
- (3) South Broward Hospital District d/b/a Memorial Regional Hospital stipulates that consistent with its mission and vision, it is committed to accept and provide care TO ANY AND ALL pediatric kidney transplant patients (ages 0-14) from Organ Transplant Service Area 4 (Monroe Miami-Dade, Broward, Palm Beach, and Collier Counties) regardless of their ability to pay.

Deny CON #10387.

AUTHORIZATION FOR AGENCY ACTION

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

DATE: _____

Marisol Fitch
Health Services and Facilities Consultant Supervisor
Certificate of Need