

**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 #10388**
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 #10389**
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 co-batched proposals.

Letters of Support

South Broward Hospital District d/b/a Memorial Regional Hospital (CON application #10388): 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, physicians, many of whom indicate affiliation with Memorial Healthcare

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System, 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:

- High population density, high demand and a large number of patients on kidney transplant waiting lists
- Memorial Regional Hospital having a 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
 - 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
 - YMCA of South Florida

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- Chief Medical Officer
 - 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
- Administrator
 - Johnson Dialysis Center
- Chief Operating Officer
 - Jewish Federation of Broward County
- Director of Programs/Operations
 - National Kidney Foundation of Florida
 - Russian American Chamber of South Florida
- Associate Professor/Coordinator of Clinical Services-College of Nursing
 - Nova Southeastern University

North Broward Hospital District d/b/a Broward Health Medical Center (CON application #10389): The applicant submitted a very large number of letters of support and the Agency received one independently. The predominant majority of 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, 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 not being new to the field of organ transplantation, having 10 years of experienced in successful liver transplantation
- That the proposed project would add to the applicant's existing transplantation services

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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
- 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)
- Mayor of:
 - City of Coral Springs
 - City of Tamarac
- City Commissioner of:
 - City of Lauderhill
- President/CEO of
 - 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

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- Board Chair and Board Vice Chair
 - Children's Diagnostic and Treatment Center
- Executive Director
 - Children's Diagnostic and Treatment Center
 - Aging & 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 indicate being a patient (or former patient) 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 and 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 and 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 #10388), also referenced as Memorial Regional, MRH or the applicant, proposes to establish an adult kidney transplantation program at MRH, in Hollywood, Broward County, Florida, District 10, TSA 4. South Broward Hospital District, also known as Memorial Health System or the District, operates MRH, 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/adult heart transplantation programs, as well as Level II adult cardiovascular services and is a Comprehensive Stroke Center. 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 a pediatric kidney transplantation program (CON application #10386).

Project costs total \$229,240. These costs include equipment, project development and start-up costs. There is no reported construction or renovation associated with the project. The proposed adult kidney transplant program is expected to be licensed in October 2016 with initiation of service in November 2016.

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

- (1) The MRH adult kidney transplant program will comply at all times with Medicare conditions of participation, including the requirement of providing a minimum average annual volume to 10 kidney transplants in a one year period 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 adult kidney transplant patients 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 #10389), referenced as BHMC or the applicant, proposes to establish an adult 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. Broward Health Medical Center offers Level II adult cardiovascular services, is a Comprehensive Stroke Center, a Level I Trauma Center² and provides adult liver transplantations.

The applicant was previously CON approved to establish an adult kidney transplantation program (CON application #10152). However, North Broward Hospital District did not implement the CON by the required date and therefore it expired. In this batching cycle, Broward Health Medical Center is also seeking approval to establish a pediatric kidney transplantation program (CON application #10387).

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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Project costs total \$712,399. These costs include equipment, project development and start-up costs. There is no reported construction or renovation associated with the project. The proposed adult kidney transplant program is expected to be licensed in March 2016 with initiation of service in April 2016.

The applicant includes the following conditions in its Schedule C:

- BHMC conditions this application such that \$50,000 per year, for the first two years of operation, will be provided in support of kidney transplant education and awareness programs, including a targeted focus on expanding organ donation activity within Broward County and within the larger TSA 4.

This condition will be met whether just this adult kidney transplant is approved or whether both this adult project and the companion pediatric project are approved.

The intent of this condition and this funding opportunity is twofold. First, to ensure that all local residents are aware of available kidney transplant resources, including ensuring access to the pre-transplant evaluation process whereby a patient would potentially gain access to an ultimate transplant. Second, this funding is intended to expand organ donor awareness and the dramatic need for increased organ donation within the community. The ultimate goal of this funding is to enhance access to transplant care and to expand the pool of available organs to increase eventual transplant volumes.

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.

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

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

As part of the fact-finding, the consultant Steve Love, analyzed the applications in 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 adult 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 adult 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 two operational adult kidney transplant programs – Cleveland Clinic Hospital (Broward County, District 10) and Jackson Memorial Hospital (Miami-Dade County,

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District 11). During CY 2014, TSAs 1, 2 and 3 also each had two adult kidney transplantation programs.

Data reported to the Agency by the local health councils for CY 2014 show the following adult kidney transplant utilization, by facility, service area and district:

Florida Adult Kidney Transplantation Program Utilization January 2014 – December 2014			
Hospital	Service Area	District	Total Procedures
UF Health Shands Hospital	1	3	82
Mayo Clinic	1	4	147
Tampa General Hospital	2	6	204
Gulf Coast Medical Center/Lee Memorial Health System	2	8	55
Halifax Health Medical Center	3	4	4
Florida Hospital	3	7	124
Cleveland Clinic Hospital	4	10	31
Jackson Memorial Hospital	4	11	345
TOTAL			992

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

As shown in the table above, in CY 2014, among TSA 4 providers, Cleveland Clinic Hospital (Broward County) provided 31 and Jackson Memorial Hospital (Miami-Dade County) provided 345 adult kidney transplantation procedures (combined this is 376 procedures). Additionally, as shown above, Jackson Memorial Hospital provided the most procedures of any single provider. Below is a five year chart to account for adult kidney transplantation utilization, by service area, county and facility, CY 2010 through CY 2014.

Florida Adult Kidney Transplantation Utilization CY 2010—2014								
Service Area	County	Facility	2010	2011	2012	2013	2014	Total
1	Alachua	UF Health Shands Hospital	146	154	86	90	82	558
1	Duval	Mayo Clinic	117	139	161	160	147	724
1	Duval	UF Health Jacksonville*	29	1				30
2	Hillsborough	Tampa General Hospital	197	223	191	206	204	1021
2	Lee	Gulf Coast Medical Center Lee Memorial Health System	35	28	29	37	55	184
3	Orange	Florida Hospital	176	148	171	161	124	780
3	Volusia	Halifax Health Medical Center	14	14	19	13	4	64
4	Broward	Cleveland Clinic Hospital**				7	31	38
4	Miami-Dade	Jackson Memorial Hospital	238	280	286	299	345	1448
		Total	952	987	943	973	992	4847

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

Notes: * UF Health Jacksonville's program was terminated effective 1/12/2011

** Cleveland Clinic Hospital's program was effective 7/29/2013

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During the five-year period shown above, Jackson Memorial Hospital in TSA 4 performed the most adult kidney transplants in Florida (29.87 percent), followed by Tampa General Hospital in TSA 2 (21.06 percent), then Florida Hospital in TSA 3 (16.09 percent). Cleveland Clinic Hospital in TSA 4 performed 0.78 percent of all adult kidney transplants for Florida during the five-year period identified above.

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

The reviewer notes that the Organ Procurement Transplantation Network (OPTN), the national database of patient waiting lists for organ transplantation in the United States, shows 4,797 adults 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 Registrants
Based on OPTN Data as of May 15, 2015**

	Kidney
Total	4,797
< 30 Days	167
30 to < 90 Days	317
90 Days to < 6 Months	309
6 Months to < 1 Year	765
1 Year to < 2 Years	1,299
2 Years to < 3 Years	972
3 Years to < 5 Years	620
5 or More Years	348

Source: <http://optn.transplant.hrsa.gov/latestData/rptData.asp>, as of May 19, 2015

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

**Florida Kidney Donors Recovered
January 1, 2009 - December 31, 2014
Based on OPTN Data as of May 19, 2015**

	2009	2010	2011	2012	2013	2014
All Donor Types	647	729	737	739	750	715
Deceased Donor	443	488	517	500	477	490
Living Donor	204	241	220	236	273	225

Source: <http://optn.transplant.hrsa.gov/latestData/rptData.asp>, as of May 19, 2015

³ As of May 19, 2015 per the OPTN website @ <http://optn.transplant.hrsa.gov>.

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As shown above, there were 715 Florida kidney donors in 2014. Florida Center for Health Information and Policy Analysis data indicates there were a total of 888 adult kidney transplants performed at Florida hospitals in CY 2014. The total procedures (888 adult kidney transplants) were greater than the donor recovery total of 715 (a difference of 173 fewer donors than adult kidney transplant procedures, in CY 2014).

Agency data indicates that 828 of 888 (or 93.24 percent) of the adult patients (15 years of age or older) receiving kidney transplants performed in Florida in CY 2014 were Florida residents⁴. The remaining 60 adult patients had an unknown residence. TSA 4 residents accounted for 349 of the 888 procedures, or 39.30 percent. Below is a chart to account for these totals.

**Adult Kidney Transplants at Florida Hospitals
By Patient Residence
CY 2014**

Service Area	Transplants Performed	Percent of Total
1	147	16.55%
2	194	21.85%
3	138	15.54%
4	349	39.30%
Unknown	60	6.76%
Total	888	100.00%

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

TSA 4 residents generally do not migrate outside their home service area for adult kidney transplantation. This is verified for CY 2014. Below is a chart to account for these procedures.

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

Facility/Organ Transplant Service Area	Patient Total	Patient Percent
Jackson Memorial Hospital (Service Area 4)	282	80.80%
Cleveland Clinic Hospital (Service Area 4)	25	7.16%
Gulf Coast Medical Center Lee Memorial Health System (Service Area 3)	16	4.58%
Florida Hospital-Orlando (Service Area 3)	9	2.58%
Tampa General Hospital (Service Area 2)	7	2.01%
Mayo Clinic (Service Area 1)	5	1.43%
UF Health Shands Hospital (Service Area 1)	5	1.43%
Service Area 4 Total	349	100.00%

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

⁴ There were 992 total adult 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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The above chart indicates that in CY 2014, 323 (92.55 percent) of TSA 4 residents who had adult kidney transplants remained in TSA 4 for the procedure. Jackson Memorial Hospital's service to TSA 4 residents included procedures for 85 Broward County residents and 46 Palm Beach County residents. Cleveland Clinic Hospital's service to TSA 4 residents included procedures for 13 Palm Beach County residents and 10 Broward County residents. Gulf Coast Medical Center Lee Memorial Health System's service to TSA 4 residents included five residents from Broward County and Palm Beach County (each).

For the five-year period ending December 31, 2014, given noticeable rising demand for adult kidney transplantation at TSA 4's existing adult kidney transplantation providers as a whole (from 238 procedures in CY 2010 to 376 procedures in CY 2014), and relatively low 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 would not likely reduce demand significantly at the existing TSA 4 adult kidney transplant providers.

The two TSA 4 providers of adult kidney transplantation averaged 188 procedures in CY 2014, though in this case, averaging significantly under-represents procedure volume at Jackson Memorial Hospital and significantly over-represents procedure volume at Cleveland Clinic Hospital.

South Broward Hospital District d/b/a Memorial Regional Hospital (CON application #10388) expects to perform 14 adult kidney transplantations in year one of operation (ending October 31, 2017), and 30 procedures in year two (ending October 31, 2018).

North Broward Hospital District d/b/a Broward Health Medical Center (CON application #10389) 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.

BRMC expects to perform 15 adult kidney transplantations in year one of operation (ending March 31, 2017), 30 procedures in year two , 40 procedures in year three and 50 procedures in year four.

b. Determination of Need.

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

- 1. Each existing kidney transplantation provider in the applicable service area performed a minimum of 30 transplants in the most recent calendar year preceding the application deadline, and no additional program has been approved for the same service planning area.**

Cleveland Clinic Hospital and Jackson Memorial Hospital are the existing adult kidney transplantation providers in TSA 4. Cleveland Clinic Hospital performed 31 and Jackson Memorial Hospital performed 345 adult kidney transplants during the 12-month period ending December 31, 2014.

There are no additional adult kidney transplant programs approved for TSA 4.

- 2. The application shall include documentation that a minimum of 15 kidney transplants per year will be performed within two years of program operation. 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 #10388) indicates plans for 30 adult kidney transplantations in 2018, the second year of planned operations. According to the applicant, this estimate is based on the following factors:

- The number of adult kidney transplants performed at centers in TSA 4 increased sharply between 2012 and 2014
- The number of adult kidney transplants received by residents of TSA 4 has also steadily increased from 274 in the 12 months ending September 2012 to 346 in the 12 months ending September 2014--a jump of 26 percent

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- A significant number of adult kidney transplant recipients who reside in TSA 4 currently travel outside the service area for transplantation services – 141 in the past three years

Using Agency inpatient hospital data for the three years ending September 30, 2014, MRH indicates several important observations about adult (age 15+) transplant patients who reside in Broward or Palm Beach County:

- 31 percent (280) of the 915 transplant patients from TSA 4 during the period reside in Broward County
- 13 percent (36) of the Broward County patients traveled outside of TSA 4 for their transplant
- 21 percent (196) of the 915 transplant patients in TSA 4 resided in Palm Beach County
- 33 percent (65) of the Palm Beach County patients traveled outside TSA 4 for their transplant

See the figure below.

**Transplant Center Location vs. County of Patient Residence in OTSA 4
Adult (Age 15+) Kidney Transplants
Performed at Florida Transplant Centers
36 Months Ending September 30, 2014**

Patient Resident Location	Transplant Center Location				Total	Transplant Recipients Leaving OTSA 4	Outmigration Percentage from OTSA 4
	OTSA 1	OTSA 2	OTSA 3	OTSA 4			
Broward	13	15	8	244	280	36	13%
Collier	2	19	1	7	29	22	76%
Miami-Dade	7	10	1	388	406	18	4%
Monroe				4	4	0	0%
Palm Beach	27	17	21	131	196	65	33%
OTSA 4	49	61	31	774	915	141	15%

Source: CON application #10388, page 38, Figure 8

- A new transplant program at MRH would significantly shorten the travel distance of residents of TSA 4 who now travel to other service areas for their transplant and would also shorten the travel distance of residents of Palm Beach County who now receive their transplants at Jackson Memorial
- There is a growing waiting list for adult kidney transplants at Florida Centers. The waiting list from TSA 4 transplant centers is growing at a faster rate than other service areas.

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Using Scientific Registry of Transplant Recipients (SRTR) program-specific reports data, the applicant indicates a 57 percent increase (from 2012 to 2014) and a 25 percent annual rate of growth for adult kidney waiting list candidates in TSA 4, with TSA 4 having the largest number of persons on the waiting list (1,745 as of June 30, 2014) and the fastest rate of growth of any TSA. See the figure below.

**Number of Persons on Adult (Age 18+) Kidney Transplant Waiting List
By TSA Region
June 30, 2014 versus June 30, 2012**

Region	As of 6/30/2012	As of 6/30/2014	Change 2012-2014	Percent Change 2012-2014	Annual Rate of Growth 2012-2014
TSA 1	1,026	1,266	240	23%	11%
TSA 2	679	945	266	39%	18%
TSA 3	552	559	7	1%	1%
TSA 4	1,113	1,745	631	57%	25%
Total	3,370	4,514	1,144	34%	16%

Source: CON application 10388, page 41, Figure 12

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

Using Agency inpatient hospital discharge data and SRTR OPO-specific reports, the applicant indicates that adult kidney recovery cases were 942 (in 2012) to 936 (in 2014) and that these totals are greater than total adult kidneys transplants in Florida (from 863 in 2012 to 867 in 2014) and also greater than the total organs procured but not transplanted (from 79 in 2012 to 69 in 2014). MRH also notes about 250 adult kidney recovery cases in TSA 4 from 2012 to 2014. MRH points out that in both 2013 and 2014, there were approximately 70 more adult kidneys recovered than adult kidneys transplanted in Florida. See the figure below.

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Number of Adult (18+) Kidneys Recovered by Organ Procurement Organizations in Florida, 12 Months Ending June 30, 2012-2014

OPO	Number of Adult Kidneys		
	2012	2013	2014
Life Quest Organ Recovery Services (OTSA 1)	232	222	238
LifeLink of Florida (OTSA 2)	275	293	320
TransLife Organ & Tissue Donation Services (OTSA 3)	187	176	128
Life Alliance Organ Recovery Agency (OTSA 4)	248	256	250
Total	942	947	936
Total Adult Kidneys Transplanted in Florida (1)	863	878	867
Total Organs Procured, but Not Transplanted	79	69	69

(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, Adult –specific data is estimated based on the percentage of adult donors to total donors as outlined by SRTR.

Source: CON application #10388, page 42, Figure 13

- There is a growing number of end stage renal disease (ESRD) patients on dialysis in Florida and a much higher number of ESRD patients per transplant program in TSA 4 than in other service areas.

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 #103886, page 43, Figure 14

The applicant maintains that as of December 30, 2012-2013 and March 2015, 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.

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MRH proceeds by stating that according to Florida Medical Quality Assurance, Inc. – ESRD Network 7 data, as of March 2015 there was an estimated 28,640 ESRD patients age 15+ in Florida and that TSA 4 has more adult ESRD patients than any other service areas – 9,629 accounting for 34 percent of all adult dialysis patients in the state. See the figure below.

ESRD Patients on Dialysis by TSA, as of March 2015

County	All Ages Cases	Ages 0-14 Cases	Ages 15+ Cases	Percent of 15+ ESRD Cases of Total 15+ 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 0-15 and ages 15+ ESRD cases.

Source: CON application #10388, page 44, Figure 16

- The applicant maintains that despite having by far the largest number of adult patients with ESRD, TSA 4 has only two operational kidney transplant programs--the same number as the other three service areas.
- There has been a steady increase from 2012 -2104 in adult kidney transplant rates in TSA 4.

Using Agency data through September 30, 2014, MRH states that the adult kidney transplant use rate situation in TSA 4 is very different from elsewhere in the State. According to the applicant, the adult kidney transplant rate in TSA 4 jumped 24 percent between 2012 and 2014 compared to the statewide increase of four percent. The applicant also states that the most recent estimate of the transplant rate in TSA 4 (67.6 per million in 2014) far exceeds the transplant rate in every other region (which ranges from 41.2 to 45.4 per million). Though the applicant includes transplants performed data and adult population data, the reviewer presents only the transplants per million portion of MRH's figure below.

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**Adult (Ages 15+) Kidney Transplant Rates by OTSA
36 Months Ending September 30, 2012-2014**

Patient Resident Location	Transplants per Million			Percent Change	Annual Rate of Growth
	2012	2013	2014	2012-2014	2012-2014
OTSA 1	40.6	40.3	41.2	1%	1%
OTSA 2	46.5	47.0	43.5	- 6%	- 3%
OTSA 3	52.5	54.9	45.4	- 13%	- 7%
OTSA 4	54.6	58.2	67.6	24%	11%
Florida	49.0	50.7	51.0	4%	2%

Source: CON application #10388, page 46, Figure 18

- The ESRD conversion rate is lower in Broward and Palm Beach Counties than in Miami-Dade County.

Using Florida Medical Quality Assurance, Inc., ESRD Network 7 and Agency data, the applicant indicates for the 12 months ending September 30, 2014, Broward County and Palm Beach County have higher ESRD adult dialysis to transplant conversion rates, 3.5 percent and 3.2 percent, respectively, after Miami-Dade County's highest rate (3.9 percent) in TSA 4. See the figure below.

**Conversion of ESRD Patients (Age 15+) on Dialysis to Transplant Recipient
12 Months Ending September 30, 2014**

County	Ages 15+ ESRD Cases	Ages 15+ Transplants	Conversion Rate
Broward	2,910	103	3.5%
Collier	384	10	2.6%
Miami-Dade	4,160	164	3.9%
Monroe	45	1	2.2%
Palm Beach	2,131	68	3.2%
OTSA 4	9,629	346	3.6%
Florida	28,640	825	2.9%

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 0-15 and ages 15+ ESRD cases.

Source: CON application #10388, page 47, Figure 19

The reviewer notes that in the above figure, the applicant's note indicates "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". CON application #10388 seeks approval for an adult program.

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- The adult population (ages 15+) in TSA 4 is projected to grow almost seven percent by 2020 – from 5.1 million to 5.5 million adult residents.

Using Agency population estimates, MRH estimates 5,114,584 adult (age 15+) residents in TSA 4, in 2014, to 5,461,865 by 2020, an increase of 347,281 adult residents, with a growth rate of 6.8 percent. The reviewer presents the total TSA 4 age-specific resident totals only, without the individual county totals. See the figure below.

**TSA 4 Adult (Ages 15+) Current and Projected Population
2014-2020**

	2014	2015	2016	2017	2018	2019	2020	Change 2014- 2020	Percent Change 2014- 2020
Total	5,114,584	5,167,453	5,224,625	5,284,211	5,344,135	5,403,720	5,461,865	347,281	6.8%

Source: CON application #10388, page 48, Figure 20

- 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 & Solutions, Inc., MRH provides estimated adult kidney transplants for residents of TSA 4. In making its estimate, MRH indicates use of the following:

- The population growth projections shown in CON application #10388, Figure 20
- A five percent per year increase in the ESRD rate
- No change in the ESRD to transplant conversion rate

MRH estimates TSA 4 resident adult kidney transplants ranging from 346 (in 2015) to 467 (in 2020). See the figure below.

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**Projected Number of Adult (Ages 15+) Kidney Transplants
Provided to Residents of OTSA 4**

	2015	2016	2017	2018	2019	2020
Adult Population	5,167,453	5,224,625	5,284,211	5,344,135	5,403,720	5,461,865
Annual % Change in Adult Population		1.1%	1.1%	1.1%	1.1%	1.1%
Annual % Change in ESRD Rates		5.0%	5.0%	5.0%	5.0%	5.0%
Adult ESRD Cases per Million	1,863	1,956	2,054	2,157	2,264	2,378
Adult ESRD Cases	9,629	10,220	10,854	11,525	12,237	12,987
Annual % Change in Conversion Rate		0.0%	0.0%	0.0%	0.0%	0.0%
Conversion Rate	3.6%	3.6%	3.6%	3.6%	3.6%	3.6%
Transplants Performed	346	367	390	414	440	467
Adult Kidney Transplants per Million	67.0	70.2	73.8	77.5	81.4	85.5

Source: CON application #10388, page 49, Figure 21

According to MRH, given the growing demand for adult kidney transplantation and that MRH will be more readily accessible than Cleveland Clinic Florida and Jackson Memorial Hospital to transplant candidates who live in Palm Beach and parts of Broward Counties, it is reasonable to expect that the proposed project will meet minimum volume requirements.

MRH contends that regarding impact on the transplant program at Jackson Memorial Hospital and Cleveland Clinic Florida, the District is committed to collaborate with transplant programs at these two hospitals in identifying patients to assure that every patient is cared for in the most appropriate setting and location. MRH expects transplant activity levels at Jackson Memorial Hospital and Cleveland Clinic Florida to continue to grow, even if the proposed project opens at MRH.

North Broward Hospital District d/b/a Broward Health Medical Center (CON application #10389) indicates plans for 30 adult 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 for 2012, Jackson Memorial Hospital performed 286 adult kidney transplants and for 2014, Cleveland Clinic Hospital and Jackson Memorial Hospital, together, performed 376 such procedures. The applicant indicates that this is a case growth of 90 cases for TSA 4 and a growth rate of 31 percent. See below.

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**Adult Kidney Transplant Volume
2012-2014**

	2012	2014	Case Growth	Percent Growth
Cleveland Clinic	0	31	+31	N/A
Jackson Memorial	286	345	+59	+21%
Total SPA 4	286	376	+90	+31%
Total FL	943	992	+49	+5

Source: CON application #10389, page 19

BHMC discusses the number of adult kidney transplants by facility in CY 2014. The applicant notes that in CY 2014, Jackson Memorial Hospital performed more adult kidney transplants than any other single provider, statewide. Further, the applicant notes that Tampa General Hospital performed 204 of these same procedures, having the second highest volume for adult kidney transplants statewide. Other decreasing volume adult kidney transplant provider facilities are mentioned.

BHMC contends that even assuming no additional adult kidney transplant growth volume in TSA 4, demand is more than adequate to support the two existing programs even with the proposed project operational, indicating that Jackson Memorial Hospital would still be by far the largest volume program in Florida.

Using Agency inpatient hospital discharge data for 2013, BHMC provides an adult kidney transplantation volume by county of residence. BHMC contends that with Broward County resident kidney transplant volume only, there is currently adequate volume (97 cases) to support both the proposed project and the existing Cleveland Clinic Hospital program. The applicant contends that the addition of Palm Beach County resident volume (63 cases) further supports the position that there is adequate market volume to support both programs. See below.

**2013 Kidney Transplant Volume
Residents of TSA 4 Counties**

	Resident 2013 Kidney Transplants	Percent of TSA 4 Total
Miami-Dade	135	43%
Broward	97	32%
Palm Beach	63	20%
Collier	13	4%
Monroe	3	1%
TOTAL SPA 4	331	

Source: CON application #10389, page 20

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Again using Agency inpatient hospital discharge data for 2013, BHMC states that 57 residents of the service area (or 18 percent) received kidney transplantation outside the service area. BHMC contends that the outmigration volume is larger than the proposed year four case volume forecast. See below.

**2013 Kidney Transplant Volume
Residents of TSA 4 Counties Transplanted Outside of TSA 4**

	Resident 2013 Kidney Transplants	Number Transplanted Outside of SPA 4	Percent Transplanted Outside of SPA 4
Miami-Dade	135	9	7%
Broward	97	13	13%
Palm Beach	63	25	40%
Collier	13	10	77%
Monroe	3	0	0%
TOTAL TSA 4	311	57	18%

Source: CON application #10389, page 21

The reviewer notes that more recent Agency inpatient hospital discharge data than CY 2013 was available for the applicant to reach more current conclusions.

BHMC asserts that based on a review of the percent of total Broward County resident renal failure inpatients that were treated at a Broward Health inpatient facility, the 2013 data from Agency hospital discharge data show that Broward Health facilities treated 29 percent of all Broward County residents discharged from a hospital for treatment of renal failure.

The applicant offers a narrative discussion in reaching a conservative estimate that BHMC would perform a total of 35 kidney transplants by its second year of operation. However, the reviewer notes that previously, BHMC indicated 30 adult kidney transplants by year two of planned operation. The reviewer notes that whether year two procedures totaled 30 or 35, these estimates meet the minimum volume requirement for year two operations.

BHMC offers discussion of and maintains that its year one and year two volume estimates compare to those of Cleveland Clinic Hospital's actual adult kidney procedures during its start-up.

CON application #10389, pages 23 – 28, 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 #10388) states being the flagship and tertiary hospital of the district and that MRH has the requisite staff and resources currently in place to provide expert care to patients with chronic and end-stage renal failure. The applicant also points out that staff on the general nursing units and critical care units 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

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applicant assures that education will be made available related to specifics of adult kidney transplantation during the lead up to program establishment and inception.

MRH states plans to utilize a multidisciplinary approach involving the medical director (David Metz, MD, board-certified in nephrology). According to the applicant, Dr. Metz is a member of the Life Alliance Organ Recovery Agency clinical team, has provided medical care for kidney, liver, intestine, pancreas and cardiac transplant patients and has also been on the staff at Memorial Health System since 2005.

MRH indicates plans to recruit an experienced transplant surgical director, transplant surgeons, transplant nephrologists and surgical team and all necessary staff as required. MRH provides detailed descriptions of these and other staff, as well as transplant services (CON application #10388, pages 52 – 60).

North Broward Hospital District d/b/a Broward Health Medical Center (CON application #10389) states having the necessary staff and other resources needed to care for kidney transplant patients' chronic illness prior to, during and after the transplant procedure. BHMC further states having 24-hour availability of all required inpatient and outpatient services and facilities necessary to support kidney transplant patients.

BHMC states having nephrologists on staff, and that while a transplant nephrologist is not yet on staff that the resource is currently being recruited and commits that this resource will be in place prior to program initiation. The applicant contends 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 #10389, Volume 2, Appendix 10). The reviewer notes that no physician CVs are included in this appendix.

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The applicant indicates that diagnostic and treatment services 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 at BHMC, will be provided via contract with existing programs.

BHMC contends having two kidney transplant surgeons currently committed to support the proposed projects, and a third surgeon currently being recruited, plus all other necessary transplant medical resources currently available at BHMC and that the transplantation portion of the patient's care will be provided.

The reviewer notes CON application #10389, 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 American Society of Transplant Surgeons (ASTS) multi-organ transplant in transplant center, Cleveland Clinic Foundation, Cleveland, Ohio and among other professional society memberships is a member of the 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.

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- 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 #10388) includes a June 2009, written agreement between South Broward Hospital District and Life Alliance Organ Recovery Agency in CON application #10388, Volume II, Attachment H. According to MRH, this agreement is to coordinate procurement of suitable donor kidneys to MRH in accordance with organ allocation policies and procedures established by the United Network of Organ Sharing (UNOS).

MRH provides a narrative description of coordinating functions between the Kidney Transplant Team, the Transplant Donor Coordinator, the surgeon and related team members (CON application #10388, pages 61 – 62).

The applicant states 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 services: nephrology, hospitalist, vascular surgeon, urology, OR team, perfusion, cardiac anesthesia, cardiologist and sonographer. The applicant advises the call schedule already has the on call transplant coordinator/donor coordinator service, heart transplant surgeon and transplant cardiologist. It is also stated that there is in place a 24-hour/seven day per week call schedule if a patient requires support at that level either pre-operative or post-transplant.

North Broward Hospital District d/b/a Broward Health Medical Center (CON application #10389) states that cadaveric transplantation will be part of the proposed program. BHMC provides a support letter (CON application #10389, 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.

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The reviewer notes that this support letter specifically states support for the applicant's pediatric kidney transplantation proposal but not adult kidney transplantation, the subject of this review. The reviewer further 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 #10388) indicates having a total of 62 adult critical care beds on the second floor intensive care unit (ICU). Further, the applicant states that the ICU has the ability to provide reverse isolation when indicated. MRH's ICU intensivists and other related staff and services are discussed (CON application #10388, pages 63 – 64).

North Broward Hospital District d/b/a Broward Health Medical Center (CON application #10389) states that the existing 24-bed ICU, Atrium ICU, will be used in support of the proposed project. BHMC also states that this ICU includes facilities for prolonged reverse isolation and is the same unit used to support the existing liver transplant program.

- 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 #10388) states having the Memorial Cardiac and Vascular Institute (MCVI) Transplant Selection Committee (the committee) for the adult heart transplant program. According to MRH, this is the clinical review committee and currently functions for

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evaluation and decision-making regarding the suitability of a transplant candidate. The applicant maintains that the proposed project will be developed based on the existing committee structure to determine suitability. The committee is stated to be under the leadership of Dr. David Metz. The committee is indicated to meet weekly or as needed.

MRH states that there are three possible outcomes resulting from a committee evaluation – accepted, not suitable for transplant or tabled. According to the applicant, once committee-approved, a candidate will be placed on the waiting list as maintained by UNOS. Also, 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.

North Broward Hospital District d/b/a Broward Health Medical Center (CON application #10389) 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 #10389, 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 #10152 to establish an adult kidney transplantation program on August 17, 2012, 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.

- 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 #10388) plans to establish written protocols for selection and management of adult kidney transplant patients. According to MRH, these protocols will be modeled after similar protocols developed and successfully utilized for the existing adult heart transplant program and those of other existing nationally renowned adult kidney transplant facilities. MRH maintains that these protocols include identification of patient selection criteria, patient inclusion/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 adult heart transplant information (CON application #10388, Volume II, Attachment L).

North Broward Hospital District d/b/a Broward Health Medical Center (CON application #10389) 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 #10389, 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 #10388) states it will model protocols after similar protocols developed and successfully utilized by MHR's existing adult heart transplantation protocols and those of other existing nationally renowned adult heart transplant facilities. The applicant offers its existing adult heart transplant information (CON application #10388, Volume II, Attachment L).

MRH stresses protocols will be developed and based on the experience and outcomes from the adult heart transplant program under the administration of Enrique Gongora, MD and Ioana Dumitru, MD.

North Broward Hospital District d/b/a Broward Health Medical Center (CON application #10389) asserts that detailed therapeutic and evaluative procedures for the acute and long-term management of 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 #10388) 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.

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MRH states that as a Level I Trauma Center it is 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 #10389) 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 #10388) provides a signed May 2013 letter of agreement in the provision of laboratory and blood product support (CON application #10388, Volume II, Attachment M) from LifeLink®. MRH states that the laboratory meets the requirements of the American Society of Histocompatibility.

North Broward Hospital District d/b/a Broward Health Medical Center (CON application #10389) states that it currently 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 the applicant, this existing relationship will be expanded to include support for the proposed project. The applicant states that a letter of support for the proposed program from Dr. Phillip Ruiz, Lab Director, has been received. 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 #10388) indicates that MRH's laboratory and staff will provide the expertise and resources required for pathology and laboratory support for the proposed project. The applicant 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 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 adult and pediatric trauma center, NICU, open heart surgery unit, pediatric specialty center, breast cancer center, adult and pediatric heart transplant and Memorial's oncology center. MRH reports that the main laboratory, located on the fifth floor of the hospital, 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.

Memorial Regional Hospital reports seven pathologists having 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 #10388, Volume II, Attachment R).

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North Broward Hospital District d/b/a Broward Health Medical Center (CON application #10389) maintains that all required pathology services are currently available within BHMC laboratories. The applicant offers a profile of BHMC's Laboratory Services (CON application #10389, 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 #10388) states that it has blood banking facilities and services necessary to support the proposed project. The applicant states that MRH and OneBlood, Inc., have enjoyed a strong working relationship since 2004, and currently have an agreement for blood and blood components supply. MRH provides a December 2013, 18 page agreement, with OneBlood and Memorial Healthcare System (no signature dates) and a signed January 2014 four page signed addendum to this agreement. According to the OneBlood support letter, OneBlood is confident that it will have the blood supply and blood product resources available at all times for MRH's transplant program (CON application #10388, Volume II, Attachment Q).

MRH indicates that the blood bank/transfusion medicine service is located on the second floor of MRH, 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 #10388, pages 74 – 78).

North Broward Hospital District d/b/a Broward Health Medical Center (CON application #10389) 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 Procedures Manual/Laboratory Scope of Service (CON application #10389, 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 #10388) states that David Metz, MD, is the medical director for the proposed project and is also Medical Director, Davita South Florida Dialysis. This physician is also stated to be a board-certified nephrologist.

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, RN, DNP-BC, CCTC, Clinical Manager for Adult Heart and Mechanical Assist Device program at MRH will service as coordinator.

The applicant maintains that comprehensive training will be provided to the staff on all aspects of kidney transplant including: transplant evaluation, diagnosis suitable for transplant, psychosocial evaluation/support for the transplant patient and family, pre-transplant management strategies, anticipated wait list times by listing status/blood type, management of elevated panel reactive antibody, 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.

MRH states that the education will be done collectively by the very experienced adult transplant team members on staff which include David Metz, MD. MRH assures that competencies, based on the current pediatric and cardiac 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.

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Applicable topics are to be covered weekly, set to commence 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 ICU will attend national conferences on kidney transplant and transplant 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 adult program as well.

North Broward Hospital District d/b/a Broward Health Medical Center (CON application #10389) maintains that a program for the education and training of staff regarding the special care of 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 #10389, 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 #10388) states MRH will develop a patient handbook for the program (a version of the current manual used by the adult heart transplant team). MRH offers the patient education manual (CON application #10388, Volume II, Attachment P). The reviewer notes that this attachment is available in Spanish.

MRH assures that it will be a priority of the transplant 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 the addition of adult kidney transplant to the hospital's scope of service will be formally announced to the community, primary care physicians, nephrologists and staff physicians.

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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 MRH, 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 #10388, Volume II, Attachment P).

North Broward Hospital District d/b/a Broward Health Medical Center (CON application #10389) indicates that educational programs for patients, their families and the patient's primary care physician regarding after-care for transplantation patients will be established. The applicant maintains that similar education programs are currently in place for the liver transplant program. The applicant references CON application #10389, 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 #10388) states having 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/complement the existing adult heart transplant program and will support the proposed adult kidney transplant program. MRH states that there are 28

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board-certified adult nephrologists with active medical staff privileges at Memorial Healthcare System's sister hospitals.

MRH ensures that all required physicians with the expertise in caring for patients with ESRD are in place such as the medical director, transplant physician and transplant surgeons. MRH again discusses the medical director (David Metz, MD), transplant physician, transplant surgeon, adult infectious disease physicians and other physicians (CON application #10388, pages 83 – 84).

North Broward Hospital District d/b/a Broward Health Medical Center (CON application #10389) states that all required physicians necessary to support the ESRD medical needs of kidney transplant patients are currently in-place and active at BHMC. The applicant states 30+ nephrologists, multiple infectious disease specialists, urologists, endocrinologists, cardiologists and every other specialist or subspecialist that may be required to support the kidney transplant patients on staff at BHMC noting that adequate patient support will be provided.

BHMC states that the required transplant nephrologist is currently being recruited with this resource to be in place by program initiation. The applicant references attention to CON application #10389, Volume 2, Appendix 14, for the CVs of the two transplant surgeons. The reviewer notes that this appendix includes a CV for Galal Hussein El-Gazzaz, MD and a CV for Roysuke Misawa, BS, MD, PhD.

- 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 #10388) reports plans, upon project approval, to recruit an adult kidney transplant surgeon who will serve as surgical director of the program (David Metz, MD, was previously indicated as the medical director).

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The applicant indicates being prepared to implement the project within 12 to 14 months. Further, MRH states plans to seek UNOS certification for adult kidney transplant within this period. The applicant maintains having been able to commence both 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 #10389) states that a program director with all required training and experience in kidney transplantation is currently being recruited and that the position will be filled by program 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 #10388) states having staff nurses expert in the care of chronically ill patients with a focus on the patient/family unit. MRH asserts that the staff is well versed in the care of the chronic medical issues experienced by patients with acute and longstanding renal disease. MRH maintains that it will recruit a transplant advance registered nurse practitioner (ARNP) to assist the medical director with daily rounds, evaluation and post-transplant care. The applicant also discusses specific duties of the transplant ARNP.

North Broward Hospital District d/b/a Broward Health Medical Center (CON application #10389) indicates that BHMC's current staff of nurses and nurse practitioners have extensive experience in the care and support of chronically ill patients, specifically chronically-ill renal disease patients and their families. BHMC maintains that the current nurses and support staff within BHMC's existing transplant clinic have 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 #10388) 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 #10389) indicates that existing resources within BHMC's blood bank systems are capable and available to meet the unique needs of the applicant's kidney transplant patients.

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

South Broward Hospital District d/b/a Memorial Regional Hospital (CON application #10388) states having clinical dietitians with experience and expertise in the nutritional needs of patient with chronic and ESRD and transplant patients. MRH notes having a registered dietician for the adult heart transplant program who will do the same for the proposed project – Elizabeth LaFrocia, RD, LD/N. According to the applicant, Ms. LaFrocia has experience in the field of transplantation. Ms. LaFrocia's CV is located in CON application #10388, Volume II, Attachment F. The reviewer notes that the CV supports the applicant's statement that Ms. LaFrocia has experience in transplantation.

North Broward Hospital District d/b/a Broward Health Medical Center (CON application #10389) states that nutritionists are available at BHMC with expertise in the nutritional needs of transplant patients and will be available to support this 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 #10389, Volume 2, Appendix 15). According to the applicant, Ms. Fernandez Ashley is one of the clinical dietitians who support 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 #10388) states employing 101 respiratory therapists, two thirds of which have experience and training in caring for critically ill patients. The applicant also indicates that the patient population of its ICU's includes Level I trauma patients, cardiac, infectious disease, neuro-interventional, multi-system organ failure patients and services for many more sub-specialties.

Memorial Regional Hospital states that Darlene Moretti, RRT, MSN, RN, is the director of nursing and respiratory therapy, with over 20 years of respiratory care experience and has specific expertise in the care of critically ill patients requiring respiratory support. Ms. Moretti's CV is located in CON application #10388, Volume II, Attachment F.

North Broward Hospital District d/b/a Broward Health Medical Center (CON application #10389) notes that respiratory therapists with expertise and experience in the needs of kidney transplant patients, are available at BHMC to support this patient population. The applicant states that an overview of BHMC's Respiratory Services Program is provided. The reviewer notes that the BHMC Individual Department Plan Respiratory Care Services and the CV of Gary J. Richmond, MD, FACP, FCCP is provided (CON application #10389, 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 #10388) states that MRH 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 they provide the arrangements of all discharges, including home health, medications, follow-up care coordination, clinical assessment/referral as needed, arrangement for educational and support groups for patients and their families and work with patients, families, community resources and insurance companies to ensure that client needs are met in a complete and timely manner. In addition, MRH notes that the social worker for the transplant team will assist with timely financial referrals for Medicaid and coordination of services through patient's insurance.

MRH 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.

North Broward Hospital District d/b/a Broward Health Medical Center (CON application #10389) states that practitioners referenced in this rule staffing requirement are currently available at BHMC and will be used in support of the future kidney transplant program.

BHMC notes 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 #10389, 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 #10388) states having 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 OPTN. Memorial Regional Hospital also reports it currently has licensing and is utilizing the organ transplant service platform EPIC™. According to MRH, 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 #10389) 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.**

South Broward Hospital District d/b/a Memorial Regional Hospital (CON application #10388) states providing onsite renal dialysis 24 hours per day and pre- and post-operative care under the direction of David Metz, MD.

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North Broward Hospital District d/b/a Broward Health Medical Center (CON application #10389)

contends 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 kidney transplant program. The applicant maintains that inpatient renal dialysis, either bedside or at the dialysis unit, is available at BHMC 24 hours per day and is under appropriate nephrologist supervision.

- 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 #10388)

maintains that it currently provides outpatient services which include renal dialysis services via a contractual arrangement with Davita Dialysis of Broward. According to MRH, this agreement is currently in place and includes renal clinic services. The reviewer notes that a copy of this agreement is not included for Agency review.

North Broward Hospital District d/b/a Broward Health Medical Center (CON application #10389)

states that all required outpatient services in support of the proposed project is available at BHMC. The applicant indicates that outpatient renal clinic services are included in this availability. BHMC contends that outpatient dialysis care is typically provided at outpatient dialysis centers but can be provided within BHMC's dialysis capabilities.

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- 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 #10388) states having a broad array of ancillary services to meet all the needs of kidney transplant candidates and patients throughout the entire continuum of care, beginning with evaluation, transplantation and post transplantation phases of the process. MRH reiterates portions of its application regarding dietary/nutritional services, its clinical laboratory and pathologists.

MRH discusses its Radiology and Imaging Services Department, described as providing diagnostic, therapeutic and noninvasive procedures using computer tomography, magnetic resonance imaging (MRI), ultrasound and nuclear medicine.

North Broward Hospital District d/b/a Broward Health Medical Center (CON application #10389) notes that each of these listed ancillary services is currently available at BHMC. The applicant states that nursing services in support monitoring and support during dialysis are currently available as is nursing support used in assisting vascular access and home dialysis management.

(b) Staffing Requirements for Adult Kidney Transplantation Programs.

- 1. The kidney transplantation program shall be under the direction of a physician with experience in physiology, immunology and immune-suppressive therapy relevant to kidney transplantation.**

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South Broward Hospital District d/b/a Memorial Regional Hospital (CON application #10388) states that David Metz, MD, is the medical director for the proposed project and is Medical Director, Davita South Florida Dialysis. MRH indicates that it will recruit an experienced transplant surgical director, surgeons and surgical team, upon project approval. This physician is stated to be a board-certified nephrologist.

North Broward Hospital District d/b/a Broward Health Medical Center (CON application #10389) states that the required physician is currently being recruited and will be on-site and part of the kidney transplant team prior to program initiation.

- 2. The transplant surgeon shall be board-certified in surgery or a surgical subspecialty, and shall have a minimum of 18 months training in a transplant center.**

South Broward Hospital District d/b/a Memorial Regional Hospital (CON application #10388) states that it will recruit experienced transplant surgeons who will be board-certified in surgery or a surgical subspecialty with a minimum of 18 months of training in a transplant center. MRH states that it was able to commence its adult heart transplant program and receive UNOS approval in a timely manner.

North Broward Hospital District d/b/a Broward Health Medical Center (CON application #10389) reiterates having two transplant surgeons in support of the proposed project and that both will have completed a formal ASTS/UNOS qualified transplant training fellowship prior to program initiation. The applicant states that a third transplant surgeon is being recruited.

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- 3. The transplant team performing kidney transplantation shall include physicians who are board-certified or board-eligible in the areas of anesthesiology, nephrology, psychiatry, vascular surgery and urology.**

South Broward Hospital District d/b/a Memorial Regional Hospital (CON application #10388)

provides discussion (CON application #10388, pages 98 -100) and physician names and CVs (CON application #10388, Volume II, Attachment F) to show compliance with this criterion.

North Broward Hospital District d/b/a Broward Health Medical Center (CON application #10389)

provides discussion (CON application #10389, page 36) and CVs in Volume 2, Appendix 17 and 18, to show compliance with this criterion.

- 4. Additional support personnel which shall be available include a nephology nurse with experience in nursing care of patients with permanent kidney failure and a renal dietician.**

South Broward Hospital District d/b/a Memorial Regional Hospital (CON application #10388)

states having existing nursing staff with experience in caring for patients with both acute and chronic kidney failure. MRH notes having staff in the general nursing units and critical care units with extensive experience in the care of patients with chronic kidney disease. MRH maintains having clinical dieticians with experience and expertise in the nutritional needs of chronic and ESRD and transplant patients.

North Broward Hospital District d/b/a Broward Health Medical Center (CON application #10389)

indicates having an active nephrology service, including nephrology nurses with expertise in supporting patients with permanent kidney failure, including the dialysis care for these patients as well as dieticians with experience in supporting patients with renal and ESRD. The applicant provides the BHM Nutrition Services Department Scope of Service and

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the CV of Lisa Fernandez Ashley, RD, LD/N, CDE. According to the applicant, Ms. Fernandez Ashley is currently a clinical dietician active in supporting the existing liver transplant program.

- 5. A laboratory with the capability of performing and promptly reporting bacteriologic, biochemical and pathologic analysis.**

South Broward Hospital District d/b/a Memorial Regional Hospital (CON application #10388)

previously presented the qualifications of hospital laboratory capabilities in response to this criterion.

North Broward Hospital District d/b/a Broward Health Medical Center (CON application #10389)

previously presented the qualifications of hospital laboratory capabilities in response to this criterion.

- 6. An anesthesiologist experienced in kidney transplantation.**

South Broward Hospital District d/b/a Memorial Regional Hospital (CON application #10388)

states having adult anesthesiologists who are trained and experienced in transplant anesthesiology with the existing adult heart transplantation program. MRH references Dr. Robert Brooker. According to his CV (CON application #10388, Volume II, Attachment F), Robert Brooker, MD, is board-certified by the American Board of Anesthesia and is Chief, Cardiac Anesthesia Services, at MRH.

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North Broward Hospital District d/b/a Broward Health Medical Center (CON application #10389)

states having staff anesthesiologists with experience in kidney transplantation. The applicant offers CVs of these transplant anesthesiologists (CON application #10389, Volume 2, Appendix 18). According to the CV of Naveen S. Gandretti, MD, FASE, he is the Director, Anesthesia Transplant Services, Benson Ford Transplant Institute, Henry Ford Health System, Detroit, Michigan. The CV of Joshua J. Livingstone indicates a State of Florida medical training license. The reviewer notes that neither of these CVs indicate that the practitioner is on staff at BHMC.

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 adult kidney transplant providers, within 321 miles or less, from the proposed locations for co-batched proposals CON application #10388 and CON application #10389.

Driving Distances in Miles – CON application #10388 (Memorial Regional Hospital), CON application #10389 (Broward Health Medical Center) and Florida Adult Kidney Transplantation Providers *									
Facility	Memorial Regional Hospital	Broward Health Medical Center	Cleveland Clinic Hospital	Jackson Memorial Hospital	Gulf Coast Medical Center	Florida Hospital -Orlando	Halifax Health Medical Center	Tampa General Hospital	UF Health Shands Hospital
Memorial Regional Hospital		8.85	16.72	19.15	134.69	221.66	243.05	266.55	320.81
Broward Health Medical Center	8.85		18.72	26.03	132.19	215.95	240.12	264.05	315.11
Cleveland Clinic Hospital	16.72	18.72		30.84	120.46	222.83	244.78	251.68	321.58
Jackson Memorial Hospital	19.15	26.03	30.84		145.86	235.74	256.04	279.06	334.48
Gulf Coast Medical Center	134.69	132.19	120.46	145.86		175.63	225.48	139.35	259.51
Florida Hospital-Orlando	221.66	215.95	222.83	235.74	175.63		50.70	88.29	115.03
Halifax Health Medical Center	243.05	240.12	244.78	256.04	225.48	50.70		13.10	101.80
Tampa General Hospital	266.55	264.05	251.68	279.06	139.35	88.29	138.10		131.14
UF Health Shands Hospital	320.81	315.11	321.58	334.48	259.51	115.03	101.80	131.14	

Source: www.Mapquest.com

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The chart above illustrates that from the proposed **CON application #10388**, the nearest adult kidney transplant provider (Cleveland Clinic Hospital) is 16.72 miles and from the proposed **CON application #10389**, the nearest adult kidney transplant provider (Cleveland Clinic Hospital) is 18.72 miles. Also, the next nearest and also the largest volume TSA 4 adult kidney transplant provider (Jackson Memorial Hospital) is 19.15 miles from **CON application #10388** and 26.03 miles from **CON application #10389**.

Agency data has also previously shown that TSA 4 adult kidney transplant recipients, in CY 2014, generally did not migrate outside of their home service area for this procedure. In fact, 323 (or 92.55 percent) of TSA 4's adult kidney transplant patients remained in TSA 4 for transplant services (282 at Jackson Memorial Hospital, 25 at Gulf Coast Medical Center Lee Memorial Health System and 16 at Cleveland Clinic Hospital) in CY 2014.

South Broward Hospital District d/b/a Memorial Regional Hospital (CON application #10388) states that the proposed project will have a positive effect on the overall availability of adult 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 and financial accessibility issues faced by many residents of TSA 4, especially those residing in Palm Beach and Broward Counties, with travel distances and travel times being greatly reduced. The applicant asserts that, more importantly, access to the proposed program at MRH 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.

North Broward Hospital District d/b/a Broward Health Medical Center (CON application #10389) indicates that the proposed project will enhance geographic and financial access to kidney transplantation care by providing a local alternative as a majority of Broward County residents travel to Miami for kidney transplant care. According to BHMC, the proposed project will reduce travel time, associated travel costs and enhance the continuum of care that will be collaboratively provided by the physicians and staff of BHMC. The applicant asserts that it is 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 #10388) states being 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 district's facilities are board-certified or board-qualified in their specialties. The applicant includes recognitions and awards at its District hospitals (CON application #10388, pages 106 - 109) and awards specific to MRH including:

- 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 further states 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 selected from more than 5,000 hospitals as the national model for improving the health of the community. The applicant discusses that in 2006, the district launched a community

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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 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 #10388, page 111).

MRH provides discussion regarding its existing adult heart transplantation program (CON application #10388, pages 111 – 113) and also the Memorial Physician Group, the Memorial Health Network (Clinically Integrated Network) and the Organ Donor Kiosks (CON application #10388, pages 117 – 118).

Agency complaint records indicate, for the three-year period ending June 1, 2015, MRH 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 #10389) asserts a long and proven history of providing high quality of care to all segments of patients. BHMC indicates having strengths among numerous clinical services lines that provide proven high quality care throughout many sectors of the community. The applicant notes the following quality features at BHMC (CON application #10389, pages 39 – 40):

- Recognized by *US News & World Report* as a Best/Top Performing Regional Hospitals in two adult specialties – Cardiology and 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
- 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

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- 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

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

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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.

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.

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South Broward Hospital District d/b/a Memorial Regional Hospital (CON application #10388): 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%

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 #10386, and the CON currently under review.

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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 October 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 #10388 Adult 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	1.0	1.8
SOCIAL SERVICES		
Other: All Other	1.5	2.5
GRAND TOTAL	5.8	7.6

Source: CON application #10388, Schedule 6A

Conclusion:

Funding for this project should be available as needed.

North Broward Hospital District d/b/a Broward Health Medical Center (CON application #10389):

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.

CON Action Numbers: 10388 and 10389

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 (10387), 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 Broward Health Medical Center's projected staffing, at least for the four-year period of projected service ending March 30, 2020 (March 30, 2020 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 an

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already operating adult liver transplant program, the applicant will be able to utilize personnel from that program to assist in the operation and management of the proposed project. The applicant expects the FTE count to remain the same for each referenced year. The table below accounts for FTEs to be added as a result of the proposed project.

North Broward Hospital District d/b/a Broward Health Medical Center CON application #10389 Adult Kidney Transplantation Program Staffing Patterns				
	Year One Ending 3/31/17	Year Two Ending 3/31/18	Year Three Ending 3/31/19	Year Four Ending 3/30/20
ADMINISTRATION				
Director of Nursing	1.0	1.0	1.0	1.0
Bookkeeper	1.0	1.0	1.0	1.0
Nursing				
RN	3.0	3.0	3.0	3.0
Nurse's Aides	1.0	1.0	1.0	1.0
Ancillary				
Other: Pharmacist	0.5	0.5	0.5	0.5
Dietary				
Dietary Supervisor	0.5	0.5	0.5	0.5
GRAND TOTAL	7.0	7.0	7.0	7.0

Source: CON application #10389, Schedule 6A

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).

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

South Broward Hospital District d/b/a Memorial Regional Hospital (CON application #10388):

	PROJECTIONS PER APPLICANT		COMPARATIVE GROUP VALUES PPD		
	Total	PPD	Highest	Median	Lowest
Net Revenues	828,056,309	2,638	3,674	2,518	2,069
Total Expenses	798,448,000	2,544	3,247	2,353	2,118
Operating Income	29,608,309	94	355	37	-86
Operating Margin	3.58%		Comparative Group Values		
	Days	Percent	Highest	Median	Lowest
Occupancy	186,143	67.4%	71.0%	57.8%	39.7%
Medicaid	40,070	21.5%	25.8%	16.6%	8.7%
Medicare	31,456	16.9%	56.5%	31.9%	20.0%

NRPD, CPD and operating margin all fall within the control group range. Overall, the project appears profitable. The applicant appears to list the incorrect amount for net patient service revenue in year two. This incorrect amount was used to calculate the net profit from operations on Schedule 8. The Agency used the correct amount from Schedule 7 to calculate net revenues and operating income.

North Broward Hospital District d/b/a Broward Health Medical Center (CON application #10389):

	PROJECTIONS PER APPLICANT		COMPARATIVE GROUP VALUES PPD		
	Total	PPD	Highest	Median	Lowest
Net Revenues	511,445,010	2,065	3,424	2,346	1,928
Total Expenses	518,502,658	2,093	3,026	2,193	1,974
Operating Income	-7,057,648	-28	355	37	-86
Operating Margin	-1.38%		Comparative Group Values		
	Days	Percent	Highest	Median	Lowest
Occupancy	152,615	58.4%	71.0%	57.8%	39.7%
Medicaid	39,123	25.6%	25.8%	16.6%	8.7%
Medicare	29,889	19.6%	56.5%	31.9%	20.0%

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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.

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,

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equipment, specialist, etc.) was highly correlated with higher cost per patient. Despite the higher costs, the study also found slightly lower quality outcomes. This is contrary to the economic theory of supply and demand in which excess supply leads to lower price in a competitive market. The study illustrates the weakness in the link between supply and demand and suggests that more choices lead to higher utilization in the health care industry as consumers explore all alternatives without regard to the overall cost per treatment or the quality of outcomes.

South Broward Hospital District d/b/a Memorial Regional Hospital (CON application #10388):

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 #10389):

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 45.2 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 Agency recognizes that most patients who receive a kidney transplant qualify for Medicare coverage as a result of being disabled due to their ESRD status, therefore few adult kidney transplants are provided to Medicaid or charity care patients. The reviewer notes that statewide during CY 2014, there were six Medicaid patients that received adult kidney transplantation.⁵ Medicaid accounted for 0.72 percent of total adult kidney transplantation procedures for Florida residents in CY 2014. These six procedures occurred at Jackson Memorial Hospital.

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 #10388 and
North Broward Hospital District d/b/a
Broward Health Medical Center/CON application #10389
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

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

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

South Broward Hospital District d/b/a Memorial Regional Hospital/CON application #10388 and North Broward Hospital District d/b/a Broward Health Medical Center/CON application #10389 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 #10388) states that the 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 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 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, 21.8 percent of the proposed project’s patient days will be other managed care and 78.2 percent to Medicare, for year one ending October 31, 2017. Schedule 7A also indicates that again, incrementally, 23.7 of the proposed project’s patient days will be other managed care, followed by 76.3 percent to Medicare, for year two ending October 31, 2018.

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 adult kidney transplant patients 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 #10389) notes 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 district operations. BHMC states that in addition, approximately 12 percent of the 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. The applicant 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, 66.0 percent of the proposed project's patient days will be Medicare, followed by 28.0 percent commercial insurance and 6.0 percent Medicaid, for each of the first four years of planned services.

Broward Health Medical Center 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 #10388) proposes to establish an adult kidney transplantation program at MRH, 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. Memorial Regional Hospital is a Level I Trauma Center.

In this batching cycle, MRH is also seeking approval to establish a pediatric kidney transplantation program (CON application #10386).

Project costs total \$229,240. 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 adult kidney transplant program will comply at all times with Medicare conditions of participation, including the requirement of providing a minimum average annual volume to 10 kidney transplants in a one year period 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 adult kidney transplant patients 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 #10389) proposes to establish an adult kidney transplantation program at Broward Health Medical Center, in Fort Lauderdale, Broward County, Florida, District 10, TSA 4.

The applicant was previously CON approved to establish an adult kidney transplantation program (CON application #10152). However, North Broward Hospital District allowed the CON to terminate due to failure to implement the program. The applicant offered no explanation for failure to implement the approved program.

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, Broward Health Medical Center is also seeking approval to establish a pediatric kidney transplantation program (CON application #10387). The applicant's adult kidney transplant program, if approved, is expected to be licensed in March 2016 with initiation of service in April 2016.

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Project costs total \$712,399. These costs include equipment, project development and start-up costs. There is no reported construction or renovation associated with the project.

The applicant includes the following conditions in its Schedule C:

- BHMC conditions this application such that \$50,000 per year, for the first two years of operation, will be provided in support of kidney transplant education and awareness programs, including a targeted focus on expanding organ donation activity within Broward County and within the larger SPA 4.

This condition will be met whether just this adult kidney transplant is approved or whether both this adult project and the companion pediatric project are approved.

The intent of this condition and this funding opportunity is twofold. First, to ensure that all local residents are aware of available kidney transplant resources, including ensuring access to the pre-transplant evaluation process whereby a patient would potentially gain access to an ultimate transplant. Second, this funding is intended to expand organ donor awareness and the dramatic need for increased organ donation within the community. The ultimate goal of this funding is to enhance access to transplant care and to expand the pool of available organs to increase eventual transplant volumes.

Need:

Need is not published by the Agency for adult 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 #10388) contends that project approval is warranted based on the following reasons:

- The number of adult kidney transplants performed at centers in TSA 4 increased sharply between 2012 and 2014.
- The number of adult kidney transplants received by residents of TSA 4 has also steadily increased from 274 in the 12 months ending September 2012 to 346 in the 12 months ending September 2014—a jump of 26 percent.

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- A significant number of adult kidney transplant recipients who reside in TSA 4 currently travel outside the service area for transplantation services – 141 in the past three years.
- A new transplant program at MRH would significantly shorten the travel distance of residents in TSA 4 who now travel to other service areas for their transplant and would also shorten the travel distance of residents of Palm Beach County who now receive their transplants at Jackson Memorial.
- There is a growing waiting list for adult 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 adult kidney transplants performed in Florida. MRH notes about 250 adult kidney recovery cases were realized each year in TSA 4 from 2012 to 2014.
- There is a growing number of ESRD patients on dialysis in Florida and a much higher number of ESRD patients per transplant program in TSA 4 than in other service areas.
- There has been a steady increase from 2012 -2104 in adult kidney transplant rates in TSA 4.
- The ESRD conversion rate is lower in Broward and Palm Beach Counties than in Miami-Dade County.
- The adult population (ages 15+) in TSA 4 is projected to grow almost seven percent by 2020 – from 5.1 million to 5.5 million adult 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.

North Broward Hospital District d/b/a Broward Health Medical Center (CON application #10389) contends that project approval is warranted based on the following reasons:

- From CY 2012 to CY 2014, the two operational adult kidney transplantation providers in TSA 4 realized a volume growth rate of 31 percent (an additional 90 cases).
- In CY 2014, Jackson Memorial Hospital provided more adult kidney transplants than any other single provider statewide and significantly more than the second highest volume provider of this service – Tampa General Hospital.
- Using 2013 data and assuming no additional adult kidney transplantation volume in the area, demand is more than adequate to support the two existing TSA 4 providers and the proposed project.

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- Using 2013 data, adult kidney transplant outmigration (to a non-TSA 4 provider by a TSA 4 resident) totaled 57 cases, which is larger than the year four case volume forecast of 50 cases.
- Year one and year two volume estimates are comparable to those of Cleveland Clinic Hospital's adult kidney transplantation program during its start-up phase

Quality of Care:

Both co-batched applicants described their ability to provide quality care.

South Broward Hospital District d/b/a Memorial Regional Hospital (CON application #10388) 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 #10389) 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 #10388)** and **North Broward Hospital District d/b/a Broward Health Medical Center (CON application #10389)** 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.

CON Action Numbers: 10388 and 10389

Medicaid/Indigent Care:

South Broward Hospital District d/b/a Memorial Regional Hospital (CON application #10388): 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.

According to Schedule 7A, MRH intends to provide incrementally with the proposed project, 0.00 percent of its proposed adult 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).

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 adult kidney transplant patients from TSA 4 regardless of their ability to pay.

North Broward Hospital District d/b/a Broward Health Medical Center (CON application #10389): 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, 6.0 percent of total annual patient days will 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 #10388 to establish an adult kidney transplantation program in Broward County, District 10, Organ Transplantation Service Area 4. The total project cost is \$229,240. There is no construction or renovation associated with this project.

CONDITIONS:

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

- (1) The MRH adult kidney transplant program will comply at all times with Medicare conditions of participation, including the requirement of providing a minimum average annual volume to 10 kidney transplants in a one year period 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 adult kidney transplant patients from Organ Transplant Service Area 4 (Monroe Miami-Dade, Broward, Palm Beach, and Collier Counties) regardless of their ability to pay.

Deny CON #10389.

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