

STATE OF FLORIDA  
DIVISION OF ADMINISTRATIVE HEARINGS

NORTH BROWARD HOSPITAL DISTRICT,  
d/b/a BROWARD HEALTH MEDICAL  
CENTER,

Petitioner,

vs.

Case Nos. 15-5549CON  
15-5550CON

SOUTH BROWARD HOSPITAL DISTRICT,  
d/b/a MEMORIAL REGIONAL HOSPITAL  
AND AGENCY FOR HEALTH CARE  
ADMINISTRATION,

Respondents.

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RECOMMENDED ORDER

Pursuant to notice, the Division of Administrative Hearings, by its designated Administrative Law Judge, W. David Watkins, held a final hearing in the above-styled case on February 15-19, 22 and 23, 2016, in Tallahassee, Florida.

APPEARANCES

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STATEMENT OF THE ISSUES

Whether Certificate of Need (CON) applications 10386 and 10388 filed by South Broward Hospital District, d/b/a Memorial Regional Hospital (Memorial), to establish a pediatric kidney transplantation program at Joe DiMaggio Children's Hospital and an adult kidney transplantation program at Memorial Regional Hospital in Broward County, both of which are proposed for organ transplantation service area (OTSA) 4, should be approved.

Alternatively, do competing CON applications 10387 and 10389 filed by North Broward Hospital District, d/b/a Broward Health Medical Center (Broward Health), to establish a pediatric kidney transplantation program at Chris Evert Children's Hospital and Broward Health Medical Center, on balance, better satisfy the applicable statutory and rule review criteria for award of a CON

to establish a pediatric or adult kidney transplantation program in OTSA 4?

PRELIMINARY STATEMENT

This case involves the comparative review of applications filed by Broward Health and Memorial for CONs to establish pediatric and adult kidney transplantation programs at their respective facilities: Broward Health Medical Center (BHMC) and Chris Evert Children's Hospital (CECH); Memorial Regional Hospital (MRH) and Joe DiMaggio Children's Hospital (JDCH). All of these facilities are located in Broward County, AHCA District 10, OTSA 4.

On April 20, 2015, Memorial filed letters of intent to establish pediatric and adult kidney transplantation programs, CON Nos. 10386 and 10388. On May 5, 2014, Broward Health filed grace period letters of intent to establish similar programs, CON Nos. 10387 and 10389.

On August 21, 2015, AHCA issued its State Agency Action Reports (SAARs) preliminarily approving Memorial's applications and denying Broward Health's.

On September 11, 2015, Broward Health filed Petitions challenging the Agency's decisions. The Agency referred the petitions to the Division of Administrative Hearings (DOAH) on September 30, 2015. The undersigned was assigned to conduct a formal administrative hearing and issue a recommended order.

The cases were consolidated on October 16, 2015. The final hearing began as scheduled on Monday, February 15, 2016, and concluded on Tuesday, February 23, 2016.

At the final hearing, Broward Health presented the testimony of: Robyn Farrington, chief nursing officer at BHMC; Barbara Sverdlik, Ph.D., Director of Nursing for Adult Care and Transplant Administrator at BHMC; Audra Hutton-Lopez, Nurse Practitioner with the Adult Liver Transplant Program at BHMC; Thomas Allen Davidson, a health planner with experience in health finance; and Mark Richardson, an expert in health planning.

Broward Health offered the video deposition and exhibits of Andreas Tzakis, M.D., as Broward Health Exhibit 11.

Broward Health's Exhibits 1, 10, 14, 18, 25, 26, 31, 34 and 41 were admitted into evidence. The following Broward Health Exhibits were received into evidence over objection: 2, 3, 11, 19, and 42.

Memorial presented the testimony of: Ioana Dumitru, M.D., an expert in organ transplantation; Alexandru Constantinescu, M.D., an expert in pediatric nephrology and pediatric transplant nephrology; Sherry Alvarado, Transplant Administrator for MRH's cardiac and vascular institute and an expert in transplant administration and the establishment of transplant programs; Chantal Leconte, CEO of JDCH and an expert in healthcare

administration; Zeff Ross, CEO of MRH and an expert in healthcare administration; and Michael Carroll, an expert in healthcare planning and finance.

Memorial offered the deposition transcript of Andreas Tzakis, M.D., with its objections noted, as Memorial Exhibit 144.

Memorial's Exhibits 1-7, 9, 12, 13, 18, 34, 37, 39, 49, 51, 93, 123, 129, 133-135, 137, and 156 were admitted into evidence. The following Memorial Exhibits were received into evidence over objection: 14-17, 22, 23, 26, 53 and 75.

AHCA presented the testimony of: Marisol Fitch, an expert in healthcare planning and CON. AHCA Exhibits 1-3 were admitted into evidence.

Subject to hearsay objections, the parties' Joint Exhibits 1-27 were admitted into evidence.

The Transcript (Volumes 1 through 11) of the final hearing was filed with DOAH on March 8, 2016. The parties were directed to file their proposed recommended orders on or before April 7, 2016.

On April 7, 2016, the parties filed their Proposed Recommended Orders. On the same date, the parties filed a Joint Stipulation of Facts. To the extent relevant, those factual stipulations have been incorporated herein.

All citations are to the 2015 versions of the Florida Statutes, or Florida Administrative Code, unless otherwise noted.

## FINDINGS OF FACT

### I. Background

1. AHCA is the state health planning agency charged with administering the CON program pursuant to the Health Facility and Services Development Act, sections 408.031-408.0455, Florida Statutes.

2. Pursuant to Florida Administrative Code Rule 59C-1.044, AHCA requires applicants to obtain separate CONs for the establishment of each adult or pediatric organ transplantation program, including heart, kidney, liver, bone marrow, lung, lung and heart, pancreas and islet cells, and intestines transplantations. For purposes of determining the need for organ transplantation services, the State of Florida is divided, by rule, into four service planning areas, corresponding generally with the northern, western central, eastern central, and southern regions of the state.

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

4. "Kidney transplantation" is defined by rule 59C-1.002(41) as a "tertiary health service, "a health service which, due to its high level of intensity, complexity, specialized or limited applicability, and cost, should be limited to, and concentrated in, a limited number of hospitals to ensure the quality, availability, and cost effectiveness of such service."

5. For purposes of kidney transplantation, a "pediatric patient" is "a patient under the age of 15 years." Fla. Admin. Code R. 59C-1.044(2)(c).

A. The Applicants

6. The North Broward Hospital District and South Broward Hospital District are special, independent taxing districts established by the Legislature to ensure access to needed medical services to the residents of Broward County. Both districts are governed by respective boards appointed by the Governor.

7. BHMC has a strong and diverse medical staff, including a broad mix of pediatric and adult specialists and subspecialists who provide high quality care to all segments of the community. More than 350 physicians are on BHMC's active medical staff, with the comprehensive medical staff totaling more than 900 professionals. BHMC is a statutory teaching

hospital and the flagship hospital of the North Broward Hospital District.

8. CECH is located within BHMC and offers pediatric specialists and subspecialists, including physicians in the areas of pediatric cardiology, pediatric critical care medicine, pediatric emergency medicine, pediatric endocrinology, pediatric gastroenterology, pediatric genetics, pediatric hematology-oncology, pediatric infectious disease, pediatric intensivist, pediatric nephrology, pediatric ophthalmology, pediatric pulmonary, pediatric rheumatology, pediatric surgery, and pediatric urology.

9. The South Broward Hospital District operates MRH, Memorial Regional Hospital South, JDCH, Memorial Hospital West, Memorial Hospital Miramar, and Memorial Hospital Pembroke.

10. MRH is a 777-bed acute care tertiary hospital. It is the flagship facility of the South Broward Hospital District and is one of the largest hospitals in Florida. MRH offers extensive and diverse health care services, including the Memorial Cardiac and Vascular Institute, which features renowned surgeons and an adult heart transplantation program. MRH also includes the Memorial Cancer Institute, which treats more inpatients than any other in AHCA District 10, and Memorial Neuroscience Center, which provides innovative technology and world-class physicians.



11. JDCH is a dedicated pediatric hospital physically connected to MRH.

12. The leadership of both the North Broward and South Broward Hospital Districts were in the midst of transition at the time of the final hearing. Although there was an attempt to suggest that such transitions should be a factor in this CON proceeding, both Districts are stable, well-established providers. Personnel changes, including the replacement of chief executive officers at both Districts, were not an influential factor in this proceeding.

B. The Applicants' Experience with Transplant Services

13. Broward Health has provided liver transplantation since 2004. Broward Health's liver transplantation program has had higher annual volumes in the past, but is currently offering approximately 12 liver transplantations per year. In total, Broward Health has performed more than 200 liver transplantations since beginning its program.

14. On or about June 23, 2010, Broward Health entered into a five-year contract with the University of Miami (UM) under which UM agreed to provide Broward Health with surgical coverage for Broward Health's liver transplantation program.

15. Throughout its history, Broward Health's liver transplantation program has offered high quality. During the two most recent surveys, in 2009 and 2012, inspectors with the

Centers for Medicare and Medicaid Services (CMS) found that Broward Health's liver transplant program had no deficiencies. Broward Health's liver program complies with all CMS and United Network for Organ Sharing (UNOS) standards.

16. Broward Health's liver transplant program exceeds national standards. As of June 2014, 63.3 percent of Broward Health's transplant patients received a liver transplant within six months of being placed on the waitlist. This is less than half of the national average of 15.3 months. Additionally, Broward Health's mortality rate for liver transplantation is far better than national standards.

17. Memorial established a pediatric heart transplant program in 2011 and an adult heart transplant program in 2014. Memorial's adult and pediatric heart transplant volumes have been relatively low. Memorial has performed a total of 14 pediatric heart transplants over the past five years.

18. In 2012, Cleveland Clinic Hospital (CCH) filed a letter of intent (LOI) and application to establish an adult kidney transplant program. Broward Health submitted a grace period LOI and competing application, No. 10152.

19. Both applications were initially approved and neither was challenged. Accordingly, both programs received final approval by AHCA.

20. After receiving the adult kidney transplant program approval, Broward Health attempted to amend or supplement its liver transplantation agreement with UM to include UM surgical and medical support for Broward Health's adult kidney transplantation program.

21. Broward Health also applied to UNOS for approval of the adult kidney transplantation program, and identified the UM physicians as those who would provide the necessary surgical support for the program.

22. However, Broward Health never reached an agreement with UM to use its kidney transplant surgeons and did not otherwise recruit the necessary physicians. Broward Health's CEO at that time, Mr. Frank Nask, found UM's proposal to support the kidney transplantation program to be cost prohibitive and decided not to execute the contract amendment with UM. He then instructed staff to dismantle the UNOS-approved kidney transplant program they had already created.

23. Despite the inability to negotiate kidney coverage with UM in 2012, Broward Health continued to offer its adult liver transplantation program using UM surgeons.

24. Had UNOS known that the UM doctors were not available to perform kidney transplants, it would not have approved Broward Health's adult kidney transplantation program.

25. In March 2014, Broward Health notified CMS, UNOS, and its patients that it was "inactivating" its adult kidney transplantation program. Inexplicably, Broward Health never notified AHCA of this decision.

26. On January 14, 2015, AHCA advised Broward Health that CON No. 10152 had expired and requested that Broward Health return the CON. There is no dispute that CON 10152 has been terminated.

27. Two batching cycles passed from the time Broward Health closed its adult kidney transplantation program until the cycle at issue in these proceedings.

28. In its application for CON No. 10152, Broward Health recognized that an applicant's prior failure to implement a CON is a proper consideration in the award of future CONs. The application touted Broward Health's "history of providing transplantation services compared to that of CCH. CCH had an adult kidney transplant program . . . but elected to abandon [it] . . . ." (Memorial Ex. 23, pp. MHS15031-32).

29. Memorial was awarded a CON to establish an adult heart transplantation program at the same time Broward Health was awarded CON No. 10152. Memorial successfully recruited the necessary physicians and staff and implemented that program.

30. The nature of the tertiary services and the two-year planning horizon in this proceeding underscore the importance of

applicants being positioned to successfully implement the programs with as little delay as possible.

C. The Applicants' Proposals

**Broward Health**

31. Broward Health's proposal relies on the experience it gained through its substantial implementation of its kidney transplantation program in 2012, as well as existing experience and resources related to their adult liver transplantation program. Broward Health acquired significant experience in establishing an adult kidney transplantation program by applying for, and receiving, UNOS approval in 2012.

32. Broward Health's application proposed to hire two abdominal transplant surgeons, Dr. El Gazzaz and Dr. Misawa. The offer to Dr. Misawa, however, has since been withdrawn. Broward Health expects to hire Dr. El Gazzaz. Since the filing of its CON application, Broward Health decided to supplement its surgical coverage by expanding its existing contract with the Cleveland Clinic for liver transplant surgical coverage to include kidney transplantation services should the kidney program receive approval.

33. Broward Health conditioned acceptance of a pediatric kidney transplantation CON on also receiving approval of the adult kidney transplantation CON. Broward Health prepared its financial schedules under the assumption that the adult and

pediatric programs were linked, and that both would receive approval.

34. Since livers and kidneys are both abdominal organs, there is substantial overlap in the type of care that is required for transplant patients for each organ. Sometimes both kidneys and livers are transplanted at the same time. Historically, Broward Health has referred out 10 to 15 percent of its liver transplant patients to other providers because it could not offer combined kidney/liver transplantation.

35. Broward Health has accumulated experienced personnel for abdominal transplants. Broward Health's existing nurses care for liver transplant patients and are therefore already prepared to care for kidney transplant patients. Broward Health's team also includes a transplant social worker, transplant psychologist, financial counselors, and quality coordinators.

36. Broward Health plans to hire an additional financial specialist and two Registered nurses (RNs), as well as additional full-time equivalents (FTEs) for a data analyst, pharmacist, and dietician.

37. Broward Health proposes to use the same clinical and ancillary staff for both adult and pediatric kidney transplantation.

38. Unlike Memorial, Broward Health does not intend to perform kidney transplants using live donor organs. Rather, cadaveric organs will be used exclusively.

39. Neither of Broward Health's applications includes the expense of hiring or contracting for the surgeons needed for its proposed programs. Indeed, there was no evidence that Broward Health's existing liver transplant surgeons would be willing to perform kidney transplants such that their presence at BHMC or CECH would give Broward Health an advantage in terms of the degree to which its existing services would support its proposed programs.

40. Broward Health has previously developed kidney transplantation policies and procedures related to its 2012 kidney program. These policies and procedures will only require minor updates relative to its later application.

#### **Memorial**

41. The Memorial adult program would be located at its flagship hospital, MRH. Memorial asserts that it has the requisite staff and resources currently in place to provide expert care to adult patients with chronic end-stage renal disease (ESRD). Memorial 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.

42. Memorial asserts a full range of appropriate inpatient and outpatient services for this patient population on a 24-hour basis including, but not limited to, continuous renal replacement therapy, hemodialysis, and cyclic peritoneal dialysis.

43. Memorial points out that it developed a program to educate staff regarding specific issues related to transplant care (as part of the development of its cardiac transplant program) and that much of this education is relevant to the kidney transplant population.

44. Memorial plans to recruit an experienced transplant surgical director, transplant surgeons, transplant nephrologists and surgical team, and all necessary staff as required.

45. As to Memorial's proposed pediatric program, the program would be located at JDCH, which is on the campus of, and physically connected to, MRH. JDCH has operated a pediatric nephrology and hypertension program, offering advanced care for children with acute or chronic kidney disorders since 2003. The program is headed by Dr. Alexandru Constantinescu, a board certified pediatric nephrologist. JDCH operates the only pediatric outpatient dialysis unit in Broward County. Dialysis is necessary to sustain the life of a patient with ESRD.

46. With the exception of the actual surgical procedure, JDCH currently provides all the medical care and ancillary



services required by pediatric kidney transplant patients, including pre-transplant care, transplant follow-up, and long-term post-transplant care.

47. The only additional personnel JDCH needs in order to implement a pediatric kidney transplantation program is a transplant surgeon and a transplant coordinator, and both are identified in JDCH's application.

48. JDCH currently refers children who need kidney transplants to other facilities to receive the actual transplant surgery. After transplantation, the patients return to JDCH for their ongoing follow-up care.

49. JDCH's program also includes a cutting-edge component to transition pediatric transplant patients into the adult clinical setting. Because a transplant patient never ceases to be followed by his or her medical providers, JDCH's program allows patients to stay within the same institution and to interact with the adult providers during the transition and adjustment period from child to adult. This existing program gives Memorial an advantage over Broward Health with respect to its pediatric and adult applications.

50. In 2006, JDCH became one of five centers that compose the Florida's Comprehensive Children's Kidney Failure Center ("CCKFC") program. JDCH is the only non-academic center approved to provide nephrology care for children with chronic

kidney disease who are enrolled in the Department of Health Children's Medical Services network.

51. In addition, JDCH and Memorial have provided pediatric and adult heart transplantation services since 2010 and 2014, respectively.

52. JDCH's pediatric heart transplantation program was certified by the CMS in 2011 and was recertified in 2015. CMS certified Memorial's adult heart transplantation program in November 2015.

53. Memorial has committed to the development and implementation of its pediatric kidney transplant program, regardless of whether its adult program is also approved.

## II. The Review Criteria

54. The statutory criterion for the evaluation of CON applications, including applications for organ transplantation programs, is set forth at section 408.035.

55. In addition, AHCA has promulgated a transplantation rule, rule 59C-1.044, which governs the approval of new programs. However, the rule does not contain a methodology that predicts the future need for transplant programs. Instead, the rule sets forth a minimum volume of annual transplants for existing programs that must be met before a new program will normally be approved.

56. The parties agree that the availability, quality of care, accessibility, and extent of utilization of existing health care facilities and health services in OTSA 4 under section 408.035(1)(a), immediate financial feasibility under section 408.035(1)(f), and costs and methods of construction under section 408.035(1)(i) are not at issue.

A. Section 408.035(1)(a) and Rule 59C-1.044(8)(d): The need for the health care facilities and health services being proposed

57. All parties are in agreement that there is a need for at least one new adult kidney transplant program and one new pediatric kidney transplant program in OTSA 4. However, Broward Health argues that two additional adult kidney transplantation programs could be supported in OTSA 4. Memorial disagrees with this contention.

58. Neither applicant's need or utilization projections, nor the Agency's SAARs, considered simultaneous approval of two new adult kidney transplant programs.

59. Broward Health's applications make no mention of a need for two adult kidney transplantation programs, and do not include any analysis of the impact of approving two programs. Broward Health's health planning expert, Mark Richardson, acknowledged that "the application basically was put forth to show there was a need for the Broward program. It was silent on whether there is a need for a second or not."

60. Nothing in Broward Health's applications address the impact Memorial and Broward Health's proposed adult kidney transplantation programs would have upon each other or upon existing providers if both were approved.

61. The notion of approving both adult applications would have impacted AHCA's analysis with respect to a number of review criteria, including utilization of existing programs, availability of resources such as health personnel, extent to which the proposed services will enhance access and competition, and the impact on existing providers. Stated differently, Broward Health's position at hearing that two adult kidney transplantation programs should be approved would have altered the nature and scope of Broward Health's adult application, as well as the Agency's review of both the Memorial and Broward Health adult applications.

62. Memorial's health care planning and financial expert, Michael Carroll, assessed the applicants' need projections as well as population growth, the incidence of ESRD in OTSA 4, volumes of existing kidney transplant providers in Florida, and availability of organs.

63. Memorial projects that its programs will perform 30 adult kidney transplants and five pediatric kidney transplants. Mr. Carroll found the projections reasonable based on the number of kidney transplants being performed in OTSA 4,

and the recent growth in procedures. No contrary evidence was presented.

64. Mr. Carroll's analysis confirms the need for one additional adult kidney transplantation program in OTSA 4. In part because kidney transplantation is constrained by the availability of organs, Mr. Carroll opined that only one adult program should be established at this time.

65. Broward Health's planning expert, Mark Richardson, also reviewed existing volumes, population and discharge data, and information gathered from meetings with Broward Health representatives. He opined at final hearing that OTSA 4 could sustain two additional adult kidney transplantation programs.

66. Mr. Richardson's opinion is based on the fact that each applicant forecasted 30 adult kidney transplants by the end of year two for what he interpreted as a total of 60 cases. Mr. Richardson argued that, even if two new programs were approved, these figures would satisfy the requirement in rule 59C-1.044(8)(d), that each applicant project a minimum of 15 adult kidney transplants per year by the end of year two.

67. Mr. Richardson's opinions assume that Broward Health will capture approximately 29 percent of Broward County kidney transplant patients, its current market share of patients discharged with certain renal failure diagnostic codes. In 2013, 97 Broward County residents received kidney transplants

somewhere in Florida. Mr. Richardson assumed that if Broward Health captured 29 percent of those patients, they would account for 80 percent of Broward Health's projected kidney transplant volume, with the other 20 percent resulting from in-migration, for a total of 35 kidney transplants. Mr. Richardson assumed that 30 of those patients would be adults, and five pediatric.

68. The 97 patients in Mr. Richardson's analysis received both cadaveric and living donor transplants. Broward Health will not use living donor organs at least for the first four years of its programs.

69. Living donor transplants account for 20 to as much as 40 percent of kidney transplants. Mr. Richardson's methodology therefore cannot be applied to a program like Broward Health's, which would be restricted to cadaveric donors.

70. The credible evidence of record established that there is a need for one additional pediatric kidney transplantation program and one, not two, additional adult kidney transplantation program in OTSA 4.

B. Section 408.035(1)(c): The ability of the applicant to provide quality of care and the applicant's record of providing quality of care; Section 408.035(1)(d): The availability of resources, including health personnel, management personnel, and funds for capital and operating expenditures, for project accomplishment and operation; and Rules 59C-1.044(3-4) and 59C-1.044(8)(a-c)

71. The parties' disagreement concerning which applications best satisfy the above criteria centered on:

(1) which applicant's existing programs provide a greater degree of support for the proposed programs; (2) the applicants' ability to recruit the necessary physicians to implement the programs, taking into consideration Broward Health's failure to implement the adult kidney transplantation program awarded by CON No. 10152; (3) the use of employed versus contracted physicians; (4) the use of living donor organs; (5) the "co-location" of the proposed adult and pediatric programs; and (6) the results of a May 2015 CMS survey of Memorial's pediatric heart transplantation program.

(1) Which applicant's existing programs provide a greater potential degree of support

72. Broward Health relies heavily on its existing adult liver transplantation program, and the prior approval by UNOS of its now-terminated adult kidney transplantation program, to argue that it is best-suited to operate the adult and pediatric kidney transplantations programs at issue in this proceeding.

73. However, there was no evidence that Broward Health's existing liver transplant surgeons will perform kidney transplants such that their presence at BHMC or CECH could give Broward Health an advantage in terms of the degree to which its existing services would support its proposed programs. Moreover, liver transplant volume at Broward Health has steadily

declined since 2007. The program has never been profitable, and Broward Health has considered discontinuing it.

74. Broward Health also asserts that its experience transplanting livers, which, like kidneys, is an abdominal organ, should be weighed more heavily than Memorial's experience with heart transplants. According to Broward Health, many staff members from Broward's liver transplant program can simultaneously work with the kidney transplant program, because the two abdominal transplant programs require a similar skill set that is transferrable from one to the other. However, again, given the uncertainty as to the identity of the surgeons who will be performing the kidney transplants for Broward Health, this argument is unpersuasive.

75. Given the history, size, and resources of both hospital systems, the undersigned concludes that the proposed adult kidney transplantation programs are on equal footing as to the support offered by their existing programs.

76. However, given Memorial's experience with pediatric heart transplant patients, Memorial has an advantage over Broward Health with respect to the pediatric kidney program. As noted by several witnesses at hearing, children are not "little adults," and therefore a track record of working with children is crucial.



(2) The applicants' ability to recruit the necessary physicians to implement the programs; and

(3) The use of employed versus contracted physicians

77. Rule 59C-1.044(4) requires that applicants meet certain staffing requirements, including: "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."

78. Absent evidence that either applicant had secured the necessary physicians to support its programs, AHCA properly reviewed each applicant's history of recruitment and establishing transplant programs.

79. Memorial has already successfully recruited physicians and other health care professionals needed to care for ESRD and kidney transplant patients. Its existing transplant programs are operated under the direction of physicians who are employed by MRH.

80. In contrast, for whatever reason, Broward Health was not able to reach an agreement with UM to provide the required surgical and medical support for its previously approved kidney transplantation program, resulting in the abandonment of the program.

81. Memorial's record of recruiting for, and implementing organ transplantation programs, compared to Broward Health's

record, gives Memorial an advantage in terms of the applicants' history of providing, and ability to provide, quality of care in organ transplantation.

82. Employed, as opposed to contracted physicians, are more invested in their transplant programs, and provide the hospital with more control in ensuring that the service is implemented and operational. Employing physicians also improves patient safety and outcomes. Unlike Memorial, Broward Health's existing transplantation program is directed by contracted physicians.

83. Broward Health's applications state that "two kidney transplant surgeons [are] currently committed to support the proposed new adult and pediatric programs and a third surgeon [is] currently being recruited."

84. The "two kidney transplant surgeons" are identified in letters of intent, accepted into evidence over a hearsay objection. Neither of the physicians who purportedly signed the letters testified at the hearing.

85. The letters of intent are not binding. Indeed, one of the letters was revoked at the instruction of Dr. Tzakis, the Cleveland Clinic surgeon who serves as medical director for Broward Health's liver program. The second physician was being recruited for Broward Health's liver transplantation program; his letter of intent did not address kidney transplantation.

86. It became apparent at hearing that Broward Health's "plan A" has now become to contract with the Cleveland Clinic to provide professional services, including surgical coverage for the proposed kidney transplantation programs.

87. Memorial's plan to employ physicians, rather than contract for their services, gives Memorial and JDCH an additional advantage over BHMC and CECH.

(4) The use of living donor organs

88. Unlike Broward Health, Memorial will use living donor organs, as well as deceased or "cadaveric" donor organs, in its proposed programs, and its applications include the related costs associated with establishing a live donor program.

89. There are significant benefits to use of living donor organs, including reduction or elimination of a patient's time on the waiting list, improved recovery times, better patient outcomes, increased organ life, and the possibility of avoiding dialysis, which carries an increased risk of mortality for children.

90. As acknowledged by Broward Health in its application for CON No. 10152, living donor kidney transplantation also has the following "distinct advantages:"

instead of occurring on an emergency schedule based upon the availability of a suitable organ, the procedure can be scheduled so as to best accommodate the needs of both recipient and donor, and to

minimize organ preservation time. In many instances, the total time from removal of the organ to restoration of blood flow in the recipient can be less than one hour. For these and other reasons, live donor transplants typically result in better quality of life and longer survival rates for recipients. (Memorial Ex. 23, p. MHS15056).

91. Memorial's plan to use living donor organs gives it an advantage over Broward Health in terms of its ability to provide quality of care in pediatric and adult kidney transplantation.

(5) The "co-location" of the proposed adult and pediatric programs

92. Especially for pediatric patients nearing the transition to adult care, there are significant benefits in "co-locating" adult and pediatric transplant programs, i.e., one provider operating both programs. For example, co-location allows pediatric patients to transition into the adult setting with providers they trust, reduces the patient and family's stress, and improves quality of care.

93. In addition, some resources from adult and pediatric kidney transplantation programs can be shared if they are co-located, which improves the programs' financial feasibility.

94. These factors weigh in favor of granting both pediatric and adult programs to one provider, if appropriate.

(6) The May 2015 CMS survey of Memorial's pediatric heart transplantation program

95. Broward Health's primary attack against Memorial with respect to sections 408.035(1)(c) and (d), centered on the results of a May 2015 CMS survey of Memorial's pediatric heart transplantation program. The survey found numerous deficiencies, including deficiencies related to patient safety. CMS notified Memorial that the deficiencies were substantial enough to warrant terminating the program if not immediately corrected. CMS notified Memorial that the program would be terminated unless the deficiencies were cured within 45 days.

96. In response to the survey, Memorial hired an outside consultant, Transplant Solutions. Transplant Solutions conducted its own survey and identified the same deficiencies noted in the CMS survey.

97. Even after Memorial implemented its corrective action plan, CMS found additional deficiencies, though the new deficiencies were not sufficient to warrant termination of the program.

98. Barbara Sverdlik, Director of Nursing and Transplant Administrator at BHMC, compared the lack of deficiencies in the 2012 survey of Broward Health's adult liver transplantation program with the results of the May 2015 survey of JDCH's pediatric heart transplantation program.

99. As Ms. Sverdlik acknowledged, JDCH ultimately passed its 2015 survey and, in spite of the results of the initial survey, “[JDCH] could offer a good quality [pediatric kidney transplantation] program.”

100. Although concerning, it is not entirely surprising that numerous deficiencies were found in Memorial’s relatively new pediatric heart transplant program. However, it is more significant to the undersigned that Memorial took immediate action to correct those deficiencies in order to ensure that the program continued without interruption.

101. JDCH’s May 2015 Survey therefore does not give Broward Health any advantage or Memorial any disadvantage under the review criteria.

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

102. Three primary considerations were identified at final hearing relevant to which applicant’s proposed programs are more likely to enhance access: the commitment of each applicant to the proposed programs; the availability of donor organs at each facility; and the availability of services at each facility.

103. Access is significantly enhanced by the use of living donor organs, not only for the living donor recipient, but also for other potential transplant recipients on the wait list.

104. The 20 to 40 percent of kidney transplant patients who could receive a living donor transplant would not have access to kidney transplantation at Broward Health for at least the first four years of its programs, whereas those same patients would have immediate access to the needed services at Memorial.

105. In this regard, and as acknowledged by witnesses for the Agency and Broward Health, Memorial's programs would enhance access to needed kidney transplantation services to a significantly greater extent than Broward Health's.

106. In its applications and at final hearing, Broward Health touted its existing adult liver program as providing a foundation for its proposed kidney transplantation programs. However, just five percent of liver transplant recipients require a simultaneous liver and kidney transplant. Any access advantage Broward Health might claim to patients requiring dual transplantations is outweighed by Memorial's use of living donor organs which impacts a much larger percentage of transplant patients.

107. It is uncontroverted that Broward Health abandoned its prior adult kidney transplantation program, thereby exacerbating the access challenges that exist in OTSA 4 with regard to kidney transplant services.

108. Also, despite a recognized need for a pediatric program, Broward Health's pediatric application was conditioned on the award of the adult program; it "will not be developed as a stand-alone pediatric kidney transplant program." (JE 12, p. BH83). The adult program is really Broward Health's focus, and this is evident even in Broward Health's financial and staffing projections.

109. As established through the final hearing testimony of their CEOs, MRH and JDCH are steadfastly committed to establishing pediatric and adult kidney transplantation programs.

110. It is also noteworthy that JDCH operates the only pediatric outpatient dialysis program in Broward County, again highlighting its commitment to the pediatric population suffering from kidney disease. In contrast, the proposed Broward Health program would rely on a third party, DaVita, to provide pediatric outpatient dialysis.

111. As the applicant which is more committed to provide the needed services to both the pediatric and adult populations, and which has an unblemished track record of implementing programs, Memorial would enhance access to pediatric and adult kidney transplantation services in OTSA 4 to a greater extent than Broward Health.



112. At hearing, Marisol Fitch, the Agency representative, explained why AHCA concluded that as between the two applicants, Memorial would be most likely to enhance access to this needed service:

Q So as between these two applicants, one telling you that if you don't give them a CON for an adult program, they are not going to implement a CON for the children's program, versus the other one, which of these two applicants would best ensure and enhance access for residents of this area of the state?

A If you are talking about all residents, including the pediatric population, then it would be the applicant that was going to do both.

Q That's Memorial; isn't that right?

A They did not condition their application on - they would do the pediatric without the adult.

Q Now I will ask you the same question regarding the issue of the live donor program. One applicant is indicating they will not establish and operate a live donor program, the other one will.

Of the two applicants, which would enhance access to the residents of the district that we are dealing with here?

A The applicant that used live donor since a large chunk of donors for kidneys are live donors.

Q That would mean Memorial; isn't that right?

A That is correct.

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

113. The parties have stipulated that short-term financial feasibility, the ability to fund and open the projects, is not at issue. However, the parties contested the long-term financial feasibility of each proposal.

114. The Agency's application review concluded that the proposed programs were financially feasible in the long-term. That conclusion presumed that the assumptions underlying the applicants' financial figures were appropriate.

115. In Schedule 8A of its pediatric application, Memorial projected a net loss of \$1,129,885 in its second year, while Broward Health projected a net excess of revenue over expenses of \$200,717 at the end of year two.

116. In Schedule 8A of its adult application, Memorial projected a net loss of \$589,691 in its second year, and Broward Health projected a net excess of revenue over expenses of \$560,709 at the end of year two.

117. According to Broward Health's financial consultant, Tom Davidson, the primary reason Broward Health's financial projections appear more favorable than Memorial's is because Memorial's applications include the costs of required transplant physicians, while Broward Health's do not. As Mr. Davidson testified at hearing:

Q How can you explain that difference? Have you analyzed the two pro formas to figure out why Broward Health projects it can make money at a lower volume than what you think Memorial Health would do to break even?

A Yes, I mean it's entirely - not only in the pro formas, but actually in the real world, it is a function of the physician expense. This is kind of an interesting case from a financial feasibility point of view because there is really only one issue that needs to be analyzed. You have two applicants in the same county, both tax-supported programs that provide a lot of charity care. They both want the same service, they are both projecting the same volume.

Every line item in the real world, forget about what's in the pro formas, but when the real world comes around, whatever goes on in terms of payer mix, gross charges, and in particular net revenues with Medicare and Medicaid and commercial insurers, all those numbers are just going to be what they are. They are going to have to spend the same money to take care of the transplant patient. There is nothing really that a sensible human being could bring up that would distinguish the two in terms of financial feasibility except for this one issue.

Does one hospital have to hire a bunch of new doctors to get into business or do both? Broward Health represented to me and I represented in the financial projections that I prepared that they would not. Memorial represented in their forecasts that they would.

And that's the entire difference. And it's really the only difference that there can be between these two applications. Because otherwise, if you just think about it

logically - you don't have to be a finance person - there's no - you can't slip a piece of paper between these two programs in terms of revenues, expenses, and other expenses, because you've got to take care of patients. You have to give them lab tests and things cost what they cost.

So without getting into some really kind of bazaar attempts to distinguish these two, that's the question. And I think as a health planner it is my firm opinion that that is the only thing on the financial side that Your Honor has to consider, whether or not Broward Health has to hire doctors.

118. Originally, Mr. Davidson included approximately \$900,000 in his expense projections for the cost of adding two physicians. He later eliminated those expenses by assuming that the surgeons currently performing adult liver transplants would also perform Broward Health's adult and pediatric kidney transplants at no additional cost.

119. Broward Health's applications do not include any costs associated with employing or contracting for physicians needed to operate its programs and Broward Health does not know what the financial terms of either arrangement might be.

120. As acknowledged by Robyn Farrington, Chief Nursing Officer at BHMC, Broward Health will need additional physicians beyond those who are already either employed or contracted by Broward Health in order to operate adult and pediatric kidney transplant programs.

121. As Michael Carroll credibly testified, even assuming the surgeons performing liver transplants at BHMC also performed kidney transplants at no additional cost, it is improper to exclude the costs for those physicians from a financial assessment of the kidney program: "whatever time that liver transplant surgeon spends [performing kidney transplants] should be allocated to the kidney transplant program."

122. Broward Health's pediatric application also failed to include any additional staff for the proposed project. This is because, unlike Memorial, the financial and staffing projections in Broward Health's applications are interdependent: the staffing and expenses in Broward Health's pediatric application assume that Broward Health is awarded the CON for an adult program and that, in large part, the adult program would support the pediatric program without the need for additional resources. Accordingly, no expenses associated with adding staff is reflected on Schedule 8A of Broward Health's pediatric application. However, since children are not simply small adults, additional staff would, in fact, be required for Broward Health's pediatric program.

123. If its pediatric application is approved, Broward Health will then evaluate what additional staffing it might need for its program. However, as of now there is no way to determine from its applications what staff Broward Health will

need for its pediatric program or what the additional cost of that staff will be.

124. In short, there is no way to forecast the cost of either of Broward Health's proposed programs.

125. The uncertainty regarding the ultimate cost of the Broward Health programs contrasts with Memorial's applications, which were presented as "stand-alone" projects with regard to projected costs. All resources necessary to operate the adult and pediatric kidney transplantation programs are included in each application. Notwithstanding the stand alone financial presentations, it is reasonable to assume that some resources will be shared if Memorial receives final approvals for both programs.

126. As pointed out by Broward Health, Memorial's applications contained four mathematical errors that impacted its financial projections. Specifically, Memorial included an incorrect number of adult transplants to be performed prior to CMS certification, improperly calculated Medicare reimbursements, overstated organ procurement costs, and included too many post-transplant follow up appointments.

127. Memorial prepared corrected financial schedules to account for these errors. Revised Schedule 8A for Memorial's adult application showed a net excess of revenue over expenses of \$745,434 at the end of year two. Revised Schedule 8A for

Memorial's proposed pediatric program showed a net loss of \$1,026,422 at the end of year two. The combined net loss at the end of year two for both programs totals \$280,988.

128. The errors did not affect Memorial's volume projections, the programs' scope, orientation, philosophy, accessibility, or need assessment.

129. Memorial has the financial ability to absorb the losses for its proposed pediatric program, even if operated as a stand-alone program.

130. If Memorial's adult and pediatric programs are co-located, some resources will be shared, and the combined programs will approach break even by the end of year two.

131. In this case, long-term financial feasibility is not accorded as much weight as it might be in other CON determinations, because there is an established need for these tertiary services, and both applicant organizations have the ability, if they so choose, to subsidize operational losses in order to maintain the programs. Stated differently, the projected long-term financial feasibility of both applicants' proposals is not a basis for distinguishing between them. Rather, the commitment of the applicants to their proposals, as addressed above, is the more critical consideration.

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

132. The Cleveland Clinic is an existing provider of adult kidney transplantation services in OTSA 4. If Broward Health's "plan A" is implemented, a contract with the Cleveland Clinic for surgeons to operate an adult kidney transplantation program in the same county and OTSA is less likely to foster competition that promotes quality and cost-effectiveness than approval of Memorial's independent programs.

133. Broward Health's proposals will not foster competition for pediatric or adult living donor transplants.

134. These considerations weigh in favor of Memorial with respect to the ability of both its proposed adult and pediatric kidney transplantation programs to foster competition pursuant to section 408.035(1)(g).

F. Section 408.035(1)(i): The applicants' past and proposed provision of health care services to Medicaid patients and the medically indigent

135. Consistent with their missions, both applicants provide substantial services to Medicaid patients and the medically indigent.

136. Mr. Richardson was critical of Memorial's applications because they do not include Medicaid in their projected payor mix. However, Mr. Richardson's data showed a miniscule percentage of Broward County residents who received a



kidney transplant and are Medicaid-eligible. And although Medicare makes up a far larger portion of the payor mix, Broward Health's pediatric application included no Medicare in its payor mix assumptions.

137. As Mr. Davidson testified, it is improper to draw any conclusions from an applicant excluding Medicaid as a payor source or from the fact that Broward Health did not include any bad debt or charity care in its applications.

138. As Mr. Richardson agreed, Memorial provides a large volume of Medicaid care and the pediatric applications are on equal footing on this criterion. Mr. Richardson also correctly agreed that the applicants are the same in terms of their history of serving Medicaid and medically-indigent adult patients.

139. There is no evidence that either applicant has a greater commitment to providing kidney transplantation services to Medicaid patients and the medically indigent than the other. Accordingly, neither applicant is entitled to preference under this criterion.

#### CONCLUSIONS OF LAW

##### I. Jurisdiction

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

## II. Burden of Proof and Balancing

141. Each of the applicants has the burden of proving that its applications should be approved. Mem'l Healthcare Group, Inc., d/b/a Mem'l Hosp. Jacksonville v. AHCA and St. Vincent's Med. Ctr., Inc., et al., Case No. 02-0447CON, RO at ¶ 442 (Fla. DOAH Feb. 5, 2003 at ¶422) (Fla. AHCA Apr. 8, 2003) (citing Boca Raton Artificial Kidney Ctr. v. Dep't of HRS, 475 So. 2d 260 (Fla. 1st DCA 1985)).

142. The award of a CON must be based on a balanced consideration of all applicable statutory and rule criteria. Balsam v. Dep't of HRS, 486 So. 2d 1341 (Fla. 1st DCA 1986). “[T]he appropriate weight to be given to each individual criterion is not fixed, but rather must vary on a case-by-case basis, depending upon the facts of each case.” Collier Med. Ctr., Inc. v. Dep't of HRS, 462 So. 2d 83, 84 (Fla. 1st DCA 1985).

## III. Review Criteria

143. Need for kidney transplantation programs is established by demonstrating compliance with section 408.035(1)(a) and rule 59C-1.044(8)(d). See Methodist Med. Ctr., Inc. v. St. Luke's Hosp. Assoc. and AHCA, Case No. 99-0724, RO at ¶ 15 (Fla. DOAH Feb. 17, 2000; Fla. AHCA Apr. 13, 2000).

144. Rule 59C-1.044(8) (d) does not establish a numeric need methodology. It states that a new program shall not normally be approved unless existing providers meet certain utilization thresholds and the applicant reasonably projects certain minimum procedure volumes within two years of operation.

145. Broward Health's attempt to establish a need for two adult kidney transplant programs is a departure from its applications and would require a very different review by the Agency than was conducted. The dual-approvals theory is so material a change from Broward Health's applications that it constitutes an impermissible amendment. Cnty. Hospice of N.E. Fla. v. AHCA, United Hosp. of Fla., Inc., et al., Case Nos. 10-1865CON, RO at ¶ 148-149 (Fla. DOAH Mar. 22, 2011; Fla. AHCA May 2, 2011) (finding that when a CON application proposed approval of one program, the applicant could not argue for approval of two at final hearing).

146. On balance, Memorial's applications better satisfy the established need for one pediatric and one adult kidney transplantation program in OTSA 4 than Broward Health's.

147. AHCA properly considered Memorial's recent success and Broward Health's recent failure in implementing CONs for organ transplantation programs in assessing the applicants' ability to provide quality of care and record of providing quality of care under section 408.035(1) (c), and the

availability of resources including health and management personnel for project accomplishment under section 408.035(1) (d) .

148. Memorial's plans to use employed physicians and living donors also give its adult and pediatric programs significant advantages over Broward Health in terms of the applicants' ability to provide quality of care.

149. A preponderance of the evidence weighed in favor of Memorial with respect to providing quality of care under section 408.035(1) (c), and the availability of resources including health personnel required by section 408.035(1) (d), and staffing and services required by rules 59C-1.044(3-4) and 59C-1.044(8) (a-c) .

150. Memorial's proposed programs also will enhance access to both adult and pediatric kidney transplantation services in OTSA 4 to a greater extent than Broward Health's proposed programs, and therefore will better satisfy section 408.035(2) (e) .

151. Memorial's commitment to these programs is demonstrated by its thoughtfully-developed, comprehensive pediatric nephrology program, its program for transitioning pediatric transplant patients to the adult clinical setting, and its willingness, unlike Broward Health, to proceed with either program on a stand-alone basis.

152. Unlike Broward Health, Memorial's proposed pediatric and adult kidney transplantation programs also will provide access to these needed services to the substantial number of transplant patients who receive living donor organs. This fact weighs heavily in favor of Memorial, and places Memorial's applications well-ahead of Broward Health's in terms of section 408.035(2)(e).

153. Pursuant to section 408.035(1)(f), the applicants were required to demonstrate the long-term financial feasibility of their proposals. While Memorial's applications revealed net losses at the conclusion of year two, corrections to mathematical errors significantly reduced those losses. If co-located, Memorial's programs would be financially feasible.

154. Memorial's proposed kidney transplantation programs will foster competition that promotes quality and cost-effectiveness (section 408.035(12)(g)), to a greater extent than Broward Health's.

155. The applicants are significant providers of Medicare, Medicaid, and medically-indigent care. They are on equal footing in terms of the related review criterion, section 408.035(1)(i).

156. Evaluating Broward Health's and Memorial's adult and pediatric applications under the applicable statutory and rule criteria compels the conclusion that both the adult and

pediatric kidney transplant program applications submitted by Memorial are superior to the competing applications submitted by Broward Health. The facts mitigating most heavily in favor of Memorial are its unequivocal commitment to the pediatric population, its history of implementing CON-approved programs, and the offering of living-donor transplants. Broward Health's failure to successfully implement its previously-approved adult kidney transplant program weighs heavily against approval of a second CON, especially at the expense of Memorial.

#### IV. Ruling on Broward Health's Motion in Limine

157. In its "Motion in Limine to Exclude Prohibited Application Amendment," Broward Health argued that Memorial's revised financial projections should be excluded from evidence as substantial amendments to the applications.

158. Impermissible amendments have been found where they alter the purpose, nature, or scope of an application. See e.g. Manor Care, Inc., and Health Quest Corp. v. Dep't. of HRS, 558 So. 2d 26 (Fla. 1st DCA 1989) (finding an impermissible, substantial change when an applicant for community nursing home beds "updated" its application to present a different facility design, sought to increase the facility's square footage, and altered its Medicaid commitment, seemingly to overcome criticism from the Agency); Hillsborough Cnty. Hosp. Auth. d/b/a Tampa Gen. Hosp. v. Dep't. of HRS, et al., Case No. 89-1286, RO at

¶¶ 58-59 (Fla. DOAH Dec. 7, 1989; Fla. HRS Jan. 23, 1990) (rejecting Hillsborough's revised financial schedules which included changes to staffing and equipment plans, as well as the plan for whether the provider would hire certain personnel or use personnel from another facility).

159. Calculation corrections like those reflected in Memorial's revised financial schedules, however, are permissible and even encouraged. HCA Health Servs. of Fla., Inc., d/b/a Oak Hill Hosp. v. Hernando HMA Inc., d/b/a Brooksville Reg'l Hosp., Case No. 02-0454 RO at ¶ 79 (Fla. DOAH Feb. 19, 2003; Fla. AHCA Feb. 19, 2003) (concluding that corrections to schedules 7A and 8A which resulted in additional revenues of approximately \$5.6 million were "not an impermissible amendment to the CON"); Vitas Healthcare Corp. of Fla. v. Heartland Servs. of Fla., et al., Case No. 04-3856CON RO at ¶ 215 (Fla. DOAH Dec, 13, 2006; Fla. AHCA Dec. 15, 2006) ("[i]f information in an application is incorrect, it must be corrected even if the correction is made after the application is deemed complete. The correction will be allowed so long as the information does not change the nature and scope of the application."); Community Hospice, Case No. 10-1865CON (DOAH Mar. 22, 2011; Fla. AHCA May 2, 2011) (finding that an expert's "break even analysis" prepared in response to an attack on the applicant's financial feasibility was not an impermissible amendment since the

applicant did not change its utilization projections or assumptions).

160. Memorial's revisions do not alter the purpose, nature, or scope of its applications and therefore do not constitute prohibited substantial amendments to Memorial's applications under rule 59C-1.010(3)(b). Accordingly, Broward Health's Motion in Limine is denied.<sup>1/</sup>

RECOMMENDATION

Based on the foregoing Findings of Fact and Conclusions of Law, it is RECOMMENDED that a final order be entered approving CON Application Nos. 10386 and 10388 filed by the South Broward Hospital District, d/b/a Memorial Regional Hospital, subject to the conditions contained in the applications, and denying CON Application Nos. 10387 and 10389 filed by the North Broward Hospital District, d/b/a Broward Health Medical Center.

DONE AND ENTERED this 4th day of May, 2016, in Tallahassee, Leon County, Florida.



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Filed with the Clerk of the  
Division of Administrative Hearings  
this 4th day of May, 2016.

ENDNOTE

<sup>1/</sup> Even if the revisions to the Memorial financial projections were determined to be impermissible, the evidence at final hearing established that both the Broward Health and Memorial applications are financially feasible in the long-term.

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NOTICE OF RIGHT TO SUBMIT EXCEPTIONS

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