

STATE AGENCY ACTION REPORT

CON APPLICATION FOR CERTIFICATE OF NEED

A. PROJECT IDENTIFICATION

1. Applicant/CON Action Number:

Wolfson Children's Hospital of Jacksonville, Inc./CON #10445

841 Prudential Drive, Suite 1802
Jacksonville, Florida 32207

Authorized Representative: Michael D. Aubin
Senior Vice President
(904) 202-5066

2. Service District

Organ Transplant Service Area (OTSA) 1: District 1 (Escambia, Okaloosa, Santa Rosa and Walton Counties), District 2 (Bay, Calhoun, Franklin, Gadsden, Gulf, Holmes, Jackson, Jefferson, Leon, Liberty, Madison, Taylor, Wakulla and Washington Counties), District 3 (Alachua, Bradford, Citrus, Columbia, Dixie, Gilchrist, Hamilton, Hernando, Lafayette, Levy, Marion, Putnam, Sumter, Suwannee and Union Counties – excluding Lake County) and District 4 (Baker, Clay, Duval, Flagler, Nassau and St. Johns Counties – excluding Volusia County).

B. PUBLIC HEARING

A public hearing was not held or requested regarding the establishment of a pediatric bone marrow transplantation program within approved CON #10426, in OTSA 1, District 4, Duval County, Florida.

Letters of Support

The applicant includes 29 unduplicated letters of support in CON application #10445 (Appendix-Letters of Support). Of these 29 letters, 28 are of OTSA 1 origin and one is from the State of New York authored by a trustee of the Baptist Health Foundation. All 29 letters indicate an affiliation with the applicant and are all individually composed. All these letters are complimentary of the services provided to children at Wolfson Children's Hospital. All these letters indicate need and support of the applicant to acquire its own Class 2 specialty hospital license. However, the reviewer notes that none of the 29 letters are specific to the application as proposed - to establish a pediatric inpatient bone marrow transplantation program. The letters are generically supportive of the applicant acquiring its own Class 2

specialty hospital license. The reviewer also notes that these 29 support letters are duplicates of the 29 support letters for co-batched, companion CON applications #10442 and #10443.

The 29 letters can be categorized as follows: physicians (16 letters), parents of children who are current or former recipients of services at Wolfson Children's Hospital (six letters), Wolfson Children's Hospital board members (three letters), one letter each from a hospital trustee (Baptist Health Foundation), a hospice provider (Northeast Florida Community Hospice®), a Wolfson Children's Hospital volunteer and a supportive area resident.

Some noted themes among the physician letters include:

- Wolfson Children's Hospital has progressed through developmental periods and has functioned well in its current status but for future stages of development as a tertiary and quaternary regional children's hospital, it needs to become a Class 2 institution.
- A separate Class 2 hospital license would allow the hospital to operate without the unnecessary interference of the operations of the adult hospital and without being subservient to the adult hospital's needs.
- In the current situation, there is duplication of effort in regards to Joint Commission compliance.
- The proposal would allow practitioners to be better able to use pediatric processes, operations, administrative support, policies/bylaws and other support services that are more attuned to the unique needs of children.
- While in the current situation Wolfson Children's Hospital provides outstanding care to children, there are barriers because of:
 - The existing combined children and adult hospital operations
 - Substantial burden in providing effective and efficient care for children under these circumstances
- Being administratively combined with adult colleagues via a common Class 1 license has led to many "speed bumps" and barriers to a smooth partnership.
- The world of pediatric medicine is vastly different than the world of Adult Medicine, not just in terms of size of equipment but in disease processes and the very specific requirements that accompany those needs – the proposed project would allow for improved efficiency and elevated quality.
- Wolfson Children's Hospital provides a continuum of care from the prenatal period through transition into adulthood—serving in a lead role in developing national public policy to develop and implement new systems approaches. Becoming a Class 2 institution will be instrumental in the development of the proposed project.
- "Independent" children's hospitals are viewed substantively differently by communities than adult hospitals.
- The essence of children's hospitals is their uniqueness which is always overshadowed by the needs and politics of the adult hospital where a children's hospital is not operating independently.

- Proposed project board structure will allow for decisions in the best interest of the child and their families—not influenced by the needs and priorities of an adult hospital system.
- Budgets, programs, services, professional staff structures, community relationships, etc. will all be improved, facilitated and advanced with the proposed project.
- Limitation in the current structure as:
 - Bylaws are set for adult services with limited knowledge of unique differences in providing services to pediatric patients
 - Unnecessary efforts regarding credentialing
 - Combined medical staffs and medical boards resulting in inefficiencies
- A more nimble structure is needed to address the complexity of navigating operations for a pediatric hospital system.
- Future plans for the applicant to move toward comprehensive pediatric trauma care possibly enabling the hospital to compete for federal funding from a more advantageous position – leading to enhanced quality care for children and their health needs.

C. PROJECT SUMMARY

Wolfson Children’s Hospital of Jacksonville, Inc. (CON application #10445), also referenced as WCHJ or the applicant, a development stage corporation and affiliate of not-for-profit hospital provider Baptist Health, is applying to establish an inpatient autologous and allogeneic pediatric bone marrow transplantation (PBMT) program within approved CON #10426, in OTSA 1. Wolfson Children’s Hospital (WCH) and Baptist Medical Center Jacksonville (BMCJ) are both located at the same physical location and currently operate under a common license for Southern Baptist Hospital of Florida, Inc. (SBHF). WCH/BMCJ is the sole PBMT provider in District 4 and one of two such providers in OTSA 1. The applicant is proposing to establish and operate a specialty hospital for children (patients 17 and under) at its current site under a new, separate license, to better serve children and their health needs. CON application #10445 is specific to a pediatric bone marrow transplantation program at its current site, under a new separate license. The applicant is proposing to establish and operate the PBMT program under a new, separate license, to better serve children and their health care needs. WCHJ maintains that the change in structure reflects an internal reorganization and will have no impact on the quality of care provided to children on existing providers.

The applicant states that patient care and hospital operations will be seamless during the proposed transition from the SBHF license to the WCHJ license.

Other existing SBHF-licensed services at Wolfson’s for which the applicant is seeking co-batched/companion CON approval in this batching cycle include:

- Pediatric cardiac catheterization services (CON application #10442)

- Pediatric open heart surgery services (CON application #10443)

Provided that the proposed co-batched/companion projects are approved the applicant plans to transition all these projects from their current licensed operations at WCH/BMCJ to approved CON #10426 (WCHJ).

According to the applicant, the projects are clearly connected to fully establish the proposed children's specialty hospital. The applicant expects that if approved, the proposed project will not increase the total number of PBMT programs in OTSA 1.

BMCJ is a Class 1 not-for-profit general hospital with 691 licensed beds and is located at the same physical location as the proposed project. This bed count includes: 582 acute care beds, 24 Level II neonatal intensive care unit (NICU) beds, 32 Level III NICU beds, 39 adult psychiatric beds and 14 child/adolescent psychiatric beds. The affiliate also provides Level II adult cardiovascular services and is a comprehensive stroke center. BMCJ operates a pediatric bone marrow transplantation program and shares a pediatric cardiac catheterization program and a pediatric open heart surgery program with UFHJ.

The Agency notes that WCHJ have CONs issued to establish a new 132-bed Class 2 specialty children's hospital (CON #10426), establish a new 24-bed Level II NICU (CON #10427) and establish a new 32-bed Level III NICU (CON #10428) through the delicensure of these same beds from BMCJ.

As a part of the proposed project, if approved and upon licensure, BMCJ will voluntarily delicense the existing PBMT program, the existing pediatric cardiac catheterization program and the existing pediatric open heart surgery program and will simultaneously license those same programs at their existing location, pursuant to the approved CON #10426. CON application #10445 includes a letter to this effect, dated June 6, 2016, signed by A. Hugh Greene, FACHE, President and CEO of Baptist Health, SBHF and Wolfson, Inc.

The proposed PBMT program, if approved, is expected to have initiation of service on October 1, 2016. Project costs total \$10,000. The project involves zero gross square feet (GSF) of renovated space and zero GSF of new construction, with no renovation and no construction costs. Total project costs include only the project development cost.

In Schedule C of CON application #10445, the applicant conditions the proposed project as follows:

- C.1. Specific site within the subdistrict. The parcel or address is as follows: 800 Prudential Drive, Jacksonville, Florida 32207, Duval County, District 4, Organ Transplant Service Area 1; the present site; this condition has been included in all related applications

- C.2. Percent of a particular population subgroup to be served. The population subgroup, along with the percent to be served, is as follows: *
- C.3. Special programs listed as: Wolfson, Inc., will operate the beds and services listed below in the children's specialty (Class 2) hospital (ages 17 and under) along with the pediatric bone marrow transplantation program in this application:
 - Acute Care – 132 beds
 - NICU Level II – 24 beds
 - NICU Level III – 32 beds
 - Child and Adolescent Psychiatric – 14 beds via CON exemption request
 - Pediatric Cardiac Catheterization
 - Pediatric Open Heart Surgery
 - Pediatric Bone Marrow Transplantation (this application)This condition will be included in all related applications.
- C.4. Other, specified as: Simultaneously voluntarily delicense the pediatric bone marrow transplantation program currently licensed under SBHF with the licensure the pediatric bone marrow transplantation at Wolfson, Inc.; this delicensure condition has been included in all associated applications

NOTE: * The reviewer notes that the applicant provides no text response to C.2. in its Schedule C.

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

D. REVIEW PROCEDURE

The evaluation process is structured by the certificate of need review criteria found in Section 408.035, Florida Statutes and rules of the State of Florida, Chapters 59C-1 and 59C-2, Florida Administrative Code. 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 evaluating the responses and data provided in the application and independent information gathered by the reviewer.

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

Rule 59C-1.010(3)(b), Florida Administrative Code, prohibits any amendments once an application has been 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 application with consultation from the financial analyst Eric West, Bureau of Central Services, who reviewed the financial data and Gregory Register, of the Office of Plans and Construction, who reviewed the application for conformance with the architectural criteria.

E. CONFORMITY OF PROJECT WITH REVIEW CRITERIA

The following indicate the level of conformity of the proposed project with the review criteria and application content requirements found in Sections 408.035 and 408.037; applicable rules of the State of Florida, Chapters 59C-1 and 59C-2, Florida Administrative Code. The reviewer provides the following analysis and review of CON application #10445 with regard to statutory and rule criteria.

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? Ch. 59C-1.008(2), Florida Administrative Code.

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

There are presently two operational and no CON approved pediatric BMT programs in OTSA 1—UF Health Shands Hospital (Alachua County) and BMCJ (Duval County). If approved, the proposed project will not change the inventory of pediatric bone marrow transplantation programs in the service area as the proposed project will delicense the pediatric BMT program at BMCJ and simultaneously reestablish that same program at WCHJ.

For the 12-month period ending December 31, 2015, a total of 17 inpatient PBMT procedures were performed at Service Area 1 hospitals. Data reported to the Agency for the most recent reporting period of January 1, 2015 through December 31, 2015 show the following pediatric BMT utilization data statewide:

**Florida Pediatric BMT Program Utilization
12 Months Ending December 31, 2015**

Hospital	OTSA	District	Total Procedures
UF Health Shands Hospital	1	3	9
BMCJ	1	4	8
All Children's Hospital	2	5	49
Florida Hospital	3	7	0
Jackson Memorial Hospital	4	11	36
Nicklaus Children's Hospital	4	11	18
		Total	120

Source: Agency for Health Care Administration Utilization Data for Pediatric Organ Transplantation Programs published April 1, 2016

Below is a five-year chart to account for inpatient PBMT transplants.

**Pediatric BMT Procedures
CY 2011 – CY 2015**

Facility/Transplant Service Area (TSA)	2011	2012	2013	2014	2015	Total
UF Health Shands Hospital	11	8	17	17	9	62
BMCJ	6	5	10	6	8	35
All Children's Hospital	26	37	35	43	49	190
Florida Hospital	7	14	8	0	0	29
Jackson Memorial Hospital	26	20	19	31	36	132
Nicklaus Children's Hospital	19	10	18	18	18	83
Total	95	94	107	115	120	531

Source: Agency for Health Care Administration Utilization Data for Pediatric Organ Transplantation Programs published for the referenced years

During the five-year period, statewide, inpatient PBMTs tended to trend upward. Specific to BMCJ for the same five-year period, this facility realized its highest number of procedures (10) in CY 2013 and its fewest number of procedures (five) in CY 2012.

The table below represents the occurrence of OTSA 1 inpatient PBMT resident discharges for CY 2015, demonstrating that 14 of 15 (93.33 percent) of these OTSA 1 residents received this procedure at an OTSA 1 hospital with 6.67 percent (one) patient out-migrated to a non-OTSA 1 facility to obtain the needed procedure. The Agency utilized MSDRGs 014, 016 and 017 in its CY 2015 discharge data run, to attain these totals. See the table below.

**Hospital of Treatment for OTSA 1 Residents
CY 2015 Inpatient Pediatric BMT Discharges**

Facility	TSA	TSA 1 Patients	Out-Migration Cases
University of Florida Shands Hospital	1	8	
BMCJ	1	6	
Johns Hopkins/All Children's Hospital	2	1	
Total		15	1

Source: Florida Center for Health Information and Transparency, MSDRGs 014, 016 and 017*
*Note: Some difference between the Agency hospital discharge database and the Agency Utilization Data for Pediatric Organ Transplantation Programs publication, for the same 12-month period (ending December 31, 2015) for pediatric BMT is to be expected.

WCHJ indicates utilizing the Agency inpatient database for the 12-month periods ending September 2013, September 2014 and September 2015 using MSDRGs 014, 016 and 017, to account for PBMT procedures, by hospital, for OTSA 1 pediatric residents age 0-17. The reviewer notes that Rule 59C-1.044(2)(c), Florida Administrative Code, defines a pediatric patient as a patient under the age of 15. See the table below.

**Recent Utilization – Pediatric Bone Marrow Transplant
Service Area 1 by MSDRG and Hospital
Pediatric Patient Age 0 to 17
FY12-FY15**

Time Frame	BMT Type	Johns Hopkins/All Children's Hospital	Wolfson under SBHF, Inc.	UF Health Shands Hospital	Total Patients
OCT 14-SEP 15	Allogeneic BMT MSDRG 14		8	2	10
	Autologous BMT MSDRGs 16 and 17	2	1	8	11
	Total BMT	2	9	10	21
OCT 13-SEP 14	Allogeneic BMT MSDRG 14	1	5	4	10
	Autologous BMT MSDRGs 16 and 17	1	3	4	8
	Total BMT	2	8	8	18
OCT 12-SEP 13	Allogeneic BMT MSDRG 14	1	6	2	9
	Autologous BMT MSDRGs 16 and 17		3	8	11
	Total BMT	1	9	10	20
Three Year Total	Allogeneic BMT MSDRG 14	2	19	8	29
	Autologous BMT MSDRGs 16 and 17	3	7	20	30
	Total BMT	5	26	28	59

Source: CON application #10445, page 14, Table 1-1

WCHJ concludes that based on the table above, OTSA 1 averages 20 pediatric BMT (ages 0-17) patients per year with 91.5 percent of these patients (54 patients) receiving care at an existing OTSA 1 provider. WCHJ asserts and the Agency has previously confirmed that recent utilization indicates that OTSA 1 residents generally have not out-migrated for this service, predominantly electing to remain in OTSA 1 for this procedure.

WCHJ offers discussion that PBMT is evenly split between allogenic and autologous in OTSA 1, based on the above table, but that these differences in PBMT types separate the two OTSA 1 PBMT service providers, with more allogenic procedures performed at the SBHF facility and more autologous procedures performed at UF Health Shands Hospital.

WCHJ contends that the next step is to use current utilization and population for the target 0 to 17 population in OTSA 1 to calculate the use rate, defined by WCHJ as PBMTs per 100,000 population. WCHJ indicates

utilizing the Agency inpatient database records and Nielsen population estimates/projections to reach a use rate of 2.35. See the table below.

**Pediatric (0 to 17) BMT Use Rate
OTSA 1**

2015 Pediatric BMT Discharges	21
2015 Pediatric Population OTSA 1	891,913
Use Rate (PBMT/100,000 population)	2.35

Source: CON application #10445, page 15, Table 1-2

WCHJ states that according to Nielsen, the OTSA 1 population for age 0 to 17 residents is expected to grow from 902,985 residents (2016) to 930,192 residents (2021) and that this is a change of 27,207 residents (or a 3.0 percent change). See the table below.

**OTSA 1
2016 and 2021 Population for 0 to 17**

2016 Population	2021 Population	Change	Percent Change
902,985	930,192	27,207	3.0%

Source: CON application #10445, page 15, Table 1-3

WCHJ states that using Nielsen population estimates and the 2.35 use rate, the applicant projects 21 PBMT patients (age 0-17) in 2016 and 22 PBMT patients (age 0-17) by 2021. See the table below.

**Projected PBMT Patients
OTSA 1 / 2016-2021**

Year	Population 0-17	Use Rate	Projected PBMT Patients
2016	902,985	2.35	21
2017	908,426		21
2018	913,868		22
2019	919,309		22
2020	924,751		22
2021	930,192		22

Source: CON application #10445, page 16, Table 1-4

The reviewer notes that as shown previously in this section, according to Florida Center for Health Information and Transparency data, for CY 2015, OTSA 1 facilities realized a total of 14 OTSA 1 PBMT (under age 15) discharges (CY 2015) and WCHJ is estimating 21 PBMT (age 0 – 17) patients for CY 2016.

The applicant states that using the Agency inpatient database, for the three-year period ending September 2015, Wolfson realized an average of 44.1 percent market share of OTSA 1 PBMT patients, age 0 to 17. See the table below.

**Wolfson Market Share for PBMT
OTSA 1 Patients 0 to 17
2013-2015**

Time Frame	Patients OTSA 1	Patients at Wolfson under SBHF, Inc.	Wolfson Share
OCT 14 – SEP 15	21	9	42.9%
OCT 13 – SEP 14	18	8	44.4%
OCT 12 – SEP 13	20	9	45.0%
Three-Year Total	59	26	44.1%

Source: CON application #10445, page 17, Table 1-5

The applicant discusses out-of-area utilization to indicate Wolfson had an average of 9.2. percent of its PBMT patients from out-of-area. See the table below.

**All Pediatric BMT at Wolfson (under SBH, Inc.)
FY 2013 – FY 2015**

Time Frame	TSA 1 Patients at Wolfson (under SBHF, Inc.)	All Patients at Wolfson (under SBHF, Inc.)	Percent Out-of-Area
OCT 14 – SEP 15	9	10	10.0%
OCT 13 – SEP 14	8	8	0.0%
OCT 12 – SEP 13	9	10	10.0%
Three-Year Total	26	28	9.2%

Source: CON application #10445, page 17, Table 1-5

WCHJ maintains that based on its prior patient OTSA 1 estimates, a 10 percent out-of-area patient estimate and an anticipated 44.1 percent market share—WCHJ expects 10 PBMT patients in both year one and year two with 11 PBMT patients in each of the following three years (2019-2021). See the table below.

**Projected PBMT Patients
Wolfson, Inc. Proposed Specialty Hospital for Children**

	2016	2017 Year 1	2018 Year 2	2019	2020	2021
Service Area (OTSA 1) Patients	21	21	22	22	22	22
Wolfson Share Percent	41.1%	41.1%	41.1%	41.1%	41.1%	41.1%
Wolfson Patients From OTSA 1	9	9	9	10	10	10
Out-of-Area Percent	10%	10%	10%	10%	10%	10%
Wolfson Out-of-Area Patients	1	1	1	1	1	1
Wolfson Total PBMT Patients	10	10	10	11	11	11

Source: CON application #10445, page18, Table 1-7

WCJH emphasizes that its estimates will not adversely impact any other existing PBMT programs in Florida. The applicant contends that the need for the proposed project extends beyond the reasons shown above. The applicant maintains that there are many benefits to licensing Wolfson separately from SBHF summarized below:

- Increased focus and efficiency:
 - Under the current combined hospital model, policies and procedures generally must apply to both pediatric and adult patients. With WCHJ separately licensed, the facility can focus all of its efforts exclusively on pediatrics and care for children.
- Increased grant funding and philanthropy:
 - Combined financial results disguise Wolfson's need for grant funding for patient care initiatives, teaching and research efforts. Separate licensure will allow Wolfson to accurately provide the hospital's true costs and provide separate financial statements.
- Enhanced access to care:
 - As a separate entity, WCHJ will have more flexibility to participate as a pediatric health care provider for health plans and allow for the development of pediatric direct contracts with insurers or employers. The expansion will increase the region's access to pediatric specialties and specialists at Wolfson.
- Attracting more pediatric specialists:
 - Separate licensure will provide possible access to federal Children's Hospital Graduate Medical Education (CHGME) funds for the training of future pediatric medical professionals. Physicians often choose to live and work in the community where they trained.

The applicant discusses these four topics in greater detail (pages 19 to 28 of the application). WCHJ contends that if approved, the proposed project will eliminate requirements and distractions to adult care, allowing a singular focus on the care of children.

2. Applications for the establishment of new pediatric allogeneic and pediatric autologous bone marrow transplantation program shall not normally be approved in a service planning area unless the following additional criteria are met:

The reviewer also notes that the applicant is a development stage corporation and has no operating history. However, the referenced current/existing program is that of Wolfson, within the existing BMCJ, and is currently licensed and authorized to provide an inpatient PBMT program in OTSA 1.

- (a) Requirements for Pediatric Allogeneic and Autologous Bone Marrow Transplantation Programs: Pediatric allogeneic and autologous bone marrow transplantation programs shall be limited to teaching and research hospitals with training programs**

relevant to pediatric bone marrow transplantation. (Rule 59C-1.044(9)(a) Florida Administrative Code).

WCHJ is a development stage corporation and has no operating history. However, WCH currently operates under the license held by BMCJ/SBHF for the current provision of pediatric inpatient BMT services. BMCJ is not a statutory teaching hospital.

The applicant indicates that as of March 17, 2016, WCH had 236 total residents (232 medical residents and four physical therapy residents), spread among 14 medical specialties as well as physical therapy residents. Additionally, WCHJ states that as of March 17, 2016, WCH had 13 MD fellow programs and seven PhD fellow programs, with a total of 50 fellows spread among these programs. The applicant notes that these physicians in training are primarily affiliated with UFHJ. The applicant further discusses other research and related affiliations maintaining that these practices and activities clearly provide a level of teaching and research that meets requirements and states that these practices will continue in the proposed program.

- (1) Applicants shall be able to project that at least 10 pediatric transplants will be performed each year. If both allogeneic and autologous pediatric transplants are performed, at least 10 of each shall be projected. New units shall be able to project the minimum volume for the third year of operation.**

The applicant states that its projections do not meet the threshold of 20 by the third year of operation but contends that the proposed program is a replacement of the existing Wolfson program licensed under SBHF and not an additional or new program. WCHJ contends that the proposed program should be approved under “not normal” circumstances.

The applicant notes that it has a shared services agreement with the Mayo Clinic Jacksonville and Nemours Children’s Specialty Care Jacksonville for a shared services program known as the Blood and Marrow Transplantation Program of Mayo Clinic, Nemours Children’s Specialty Care and Wolfson Children’s Hospital. According to WCHJ, the joint program has met and is a FACT-accredited (Foundation for the Accreditation of Cellular Therapy) cellular program. The reviewer notes that the applicant offers no documentation of this stated shared services agreement. The reviewer notes that according to the following website: <http://newsnetwork.mayoclinic.org/discussion/blood-and-marrow-transplant-program-of-mayo-clinic-nemours-childrens-clinic-and-wolfson-childrens-ho/>, a Mayo Clinic news

release on November 14, 2013 states that this shared program was awarded a three-year accreditation renewal by FACT.

WCHJ discusses differences between allogenic and autologous BMT procedures, that autologous BMT procedures have limited use in children, that the University of Florida Proton Center in Jacksonville has been highly successful for patients for whom an autologous BMT procedure is the course of action.

WCHJ states that the program at Wolfson is located in the largest metropolitan area in OTSA 1 and that this reduces travel burdens for the majority of the population. The reviewer notes that according to the Florida Center for Health Information and Transparency, of the six OTSA 1 pediatric (under 15 years age) patients that were discharged from WCH/BMCJ for an inpatient PBMT service in CY 2015, three had a District 4 patient origin, and three had a District 1 patient origin.

- (2) A program director who is a board-certified hematologist or oncologist with experience in the treatment and management of pediatric acute oncological cases involving high dose chemotherapy or high dose radiation therapy. The program director must have formal training in bone marrow transplantation.**

WCHJ states that Michael J. Joyce, MD, PhD, is the medical director of the existing PBMT program and will continue to be the medical director for the proposed program. WCHJ also states that Dr. Joyce is board-certified in pediatrics and pediatric hematology/oncology. The applicant indicates that Dr. Joyce has specific BMT training from Fred Hutchinson Cancer Center (Seattle, Washington) and the University of South Carolina. WCHJ includes Dr. Joyce's CV which states that Dr. Joyce is board-certified, with BMT training and is licensed to practice in Florida. The CV further indicates that Dr. Joyce's most recent appointment was the BMT program director at the Blood and Marrow Transplantation Program of Mayo Clinic, Nemours Children's Clinic and Wolfson Children's Hospital from September 2004 to 2007 and from November 2010 to 2013. The CV additionally states that Dr. Joyce is medical director at WCH's pediatric BMT program from January 1994 to present.

- (3) Clinical nurses with experience in the care of critically ill immuno-suppressed patients. Nursing staff shall be dedicated full time to the program.**

The applicant indicates that for the clinical care of inpatients, the applicant currently has a total of 44 inpatient registered nurses in the hematology/oncology unit, all of whom are trained to care for BMT patients—with 93 percent holding a bachelor’s degree, 11 percent are certified pediatric nurses, 11 percent are certified pediatric hematology and oncology nurses, and that 73 percent hold the Association of Pediatric Hematology/Oncology Nurses (APHO) biotherapy provider certificate. WCHJ maintains that these nurses will continue in their roles with the proposed program.

- (4) An interdisciplinary transplantation team with expertise in hematology, oncology, immunologic diseases, neoplastic diseases, including hematopoietic and lymphopoietic malignancies, and non-neoplastic disorders. The team shall direct permanent follow-up care of the bone marrow transplantation patients, including the maintenance of immunosuppressive therapy and treatment of complications.**

WCHJ states that the following six physicians are employed by Nemours Children’s Specialty Care Jacksonville and will transition to the proposed Wolfson, Inc., program.

Active Pediatric Hematologists/Oncologists at Wolfson

Pediatric Hematologist/ Oncologist	Florida License	Board Certification(s)
Michael J. Joyce, MD (Program Director)	ME58206	Pediatric Hematology/Oncology and Pediatrics
Manisha M. Bansal, MD	ME96890	Pediatric Hematology/Oncology and Pediatrics
Scott M. Bradfield, MD	ME88124	Pediatric Hematology/Oncology and Pediatrics
Cynthia A. Gauger, MD	ME79558	Pediatric Hematology/Oncology
Paul A. Pitel, MD	ME45892	Pediatric Hematology/Oncology and Pediatrics
Eric S. Sandler, MD	ME54007	Pediatric Hematology/Oncology and Pediatrics

Source: CON application #10445, page 32, Table 2-1

The applicant states and the reviewer confirms that these physician’s CVs are included in CON application #10445. On page 32, WCHJ names 16 specialty physicians as part of the

PBMT interdisciplinary team. Each of these 16 physicians is listed with a separate medical specialty.

- (5) **Age appropriate inpatient transplantation units for post-transplant hospitalization. Post-transplantation care must be provided in a laminar air flow room; or in a private room with positive pressure, reverse isolation procedures, and terminal high efficiency particulate aerosol filtration on air blowers. The designated transplant unit shall have a minimum of two beds. This unit can be part of a facility that also manages patients with leukemia or similar disorders.**

WCHJ contends that as a proposed children's specialty Class 2 hospital, all units are age-appropriate for children. The applicant states that it has two rooms that meet the criteria for prolonged reverse isolation and that these rooms are positive pressure isolation rooms with an ante room to separate the room from the corridor. The proposed project rooms are also stated to use HEPA filtration to filter air.

- (6) **A radiation therapy division on-site which is capable of sub-lethal x-irradiation, bone marrow ablation, and total lymphoid irradiation. The division shall be under the direction of a board-certified radiation oncologist.**

WCHJ indicates that radiation therapy is currently provided by Baptist MD Anderson Cancer Center, also licensed under SBHF, on the shared campus where Wolfson is located. WCHJ further indicates that Baptist MD Anderson will continue to provide radiation therapy on-site that meets the requirements for the proposed program, via a contractual agreement. The reviewer notes that WCHJ does not provide a sample or draft contract for Agency review.

WCHJ maintains that Michael R. Olson, MD is a board-certified radiation oncologist who is the program liaison for the PBMT program and will continue his work with the proposed program. The reviewer notes that per the Department of Health/Division of Medical Quality Assurance/Health Licensee Search website at <https://apps.mqa.doh.state.fl.us/MQASearchServices/Home>, Dr. Olson has a clear/active Florida medical license. According to the same source, the license information/practitioner profile/specialty certification page indicates that Dr. Olson is board certified in radiation oncology as well as hospice and palliative medicine.

- (7) **An ongoing research program that is integrated either within the hospital or by written agreement with a bone marrow transplantation center operated by a teaching hospital. The program must include outcome monitoring and long-term patient follow-up.**

The applicant states that WCH and Nemours Children's Specialty Care in Jacksonville have worked together for many years in the care of children with cancer and blood disorders. The applicant indicates that the shared program is certified as an American College of Surgeons Cancer Center, one of only 11 pediatric centers in the country. The reviewer notes that the applicant does not provide documentation to this attestation. A review of American College of Surgeons accredited pediatric cancer programs within 100 miles of ZIP Code 32207 (the applicant's ZIP Code), at website <https://www.facs.org/search/cancerprograms?zip=32207&distance=any&cat=PCP>, indicates that the sole accreditation holder is Nemours Children's Clinic at 807 Children's Way, Jacksonville, Florida 32207.

WCHJ also indicates that the shared program also participates in the Nemours NIH National Cancer Institute Community Oncology Research Program (NCORP), stated to be one of two pediatric programs in NCORP – The Children's Oncology Group, The Sunshine Project collaborative and several other research consortiums. A review of the NIH NCORP sites, at website <https://ncorp.cancer.gov/findasite/sites.php?state=Florida#research-bases>, indicates that Florida currently has two NCORP sites: Nemours NCORP and Florida Pediatric NCORP.

The applicant maintains that the shared program is actively engaged in the development of clinical trials and publishing results of those trials with over 60 open research trials. The applicant indicates a goal of improving outcomes for all children with cancer and blood disorders.

- (8) **An established research-oriented oncology program.**

See item E.2.(a)(7) of this report for a review of this provision.

(b) **Additional Requirements for Pediatric Allogeneic Transplantation Programs:**

- (1) **A laboratory equipped to handle studies including the use of monoclonal antibodies, if this procedure is employed by the hospital, or T-cell depletion, separation of lymphocyte and**

hematological cell subpopulations and their removal for prevention of graft versus host disease. This requirement may be met through contractual arrangements.

The applicant states the use of monoclonal antibodies and indicates meeting the requirement through a contractual arrangement with Pharmaceutical Management Branch (PMB). According to WCHJ, the relationship with PMB will continue to serve the needs of the proposed program. The reviewer notes that the applicant does not provide documentation of the stated contractual arrangement.

(2) An on-site laboratory equipped for the evaluation and cryopreservation of bone marrow.

The applicant states that it has an agreement with Mayo Clinic Jacksonville for the evaluation and preservation of bone marrow at the clinic's facility in Jacksonville along with policies and practices for transporting cells. The reviewer notes that the applicant does not provide documentation of the stated agreement or of policies and practices, as indicated. WCHJ reiterates the stated shared services program known as the Blood and Marrow Transplantation Program of Mayo Clinic, Nemours Children's Specialty Care and Wolfson Children's Hospital, with defined roles for each participant. According to WCHJ, the current arrangement meets the most comprehensive standards in the field, verified by rigorous on-site, peer reviewed inspections and that the proposed program will continue to meet and provide the highest standards of care in the most efficient manner possible.

(3) An age appropriate patient convalescent facility to provide a temporary residence setting for transplant patients during the prolonged convalescence.

WCHJ states that Wolfson and Nemours are located within a block of the Jacksonville Ronald McDonald House where a patient undergoing PBMT and his/her family may stay, including the post-transplantation period when they may be discharged from the hospital but engaged in outpatient clinic care that requires frequent monitoring. WCHJ maintains that the current Jacksonville Ronald McDonald House opened on the Southbank in 2001 with 30 rooms and initiated a 24-room expansion in 2015. WCHJ asserts that the house has provided a "home away from home" for over 33,000 families since 1988. The reviewer notes that according to the website <https://rmhcjacksonville.org/what-we-do/our-house/>, the

Jacksonville Ronald McDonald House is located at 824 Children's Way, Jacksonville, Florida 32207.

(4) An age appropriate outpatient unit for close supervision of discharged patients.

Per WCHJ, outpatient care is provided by the Nemours Children's Specialty Care Jacksonville, the stated practice of the program's hematologists/oncologists. WCHJ asserts that as a pediatrics-only practice, the facility and its practices are age appropriate for the close supervision of PBMT patients post-transplantation. According to WCHJ, Nemours will remain the outpatient setting in the proposed program and therefore meets this requirement.

2. Agency Rule Criteria

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

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

WCHJ asserts that the applicant, along with the physicians and services of the Nemours Children's Specialty Care Jacksonville, have the staff and necessary resources to care for PBMT patients prior to, during and post transplantation. WCHJ maintains that these resources are available 24/7 now and will continue to be available in the proposed program. See the table below.

Wolfson Children’s Hospital of Jacksonville, Inc. (CON application #10445) Staffing Patterns Year One and Year Two of Operations		
	Year One Ending 2017	Years Two Ending 2018
Administration		
Physicians		
Nursing		
R.N.s	5.6	5.6
Nurses’ Aides	1.2	1.2
Other	0.1	0.1
Ancillary		
Dietary		
Social Services		
Housekeeping		
Laundry		
Plant Maintenance		
GRAND TOTAL	6.9	6.9

Source: CON application #10445, Schedule 6

The reviewer notes that though WCHJ states in other parts of the application that other licensed staff will provide services pursuant to the proposed project, the above table is the totality of FTEs for the planned PBMT program.

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

The reviewer notes that this is not applicable to bone marrow transplantation programs.

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

WCHJ contends that as a proposed children’s specialty Class 2 hospital, all units are age-appropriate for children. The applicant states that it has two rooms that meet the criteria for prolonged reverse isolation and that these rooms are positive pressure isolation rooms with an ante room to separate the room from the corridor. The proposed project rooms are also stated to use HEPA filtration to filter air.

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

WCHJ states that the PBMT program currently has three established weekly meetings to present and review hematopoietic progenitor cell transplant candidates. The applicant provides a brief narrative description of the following weekly meeting headings:

- Weekly BMT patient/donor selection videoconference with Mayo Clinic Adult BMT transplant program
- Weekly PBMT RN meeting
- Monthly Multi-Institutional BMT Tumor Board Conference

WCHJ contends that these clinical review meetings will continue in the proposed program. The reviewer notes that the applicant offers no existing or planned formalized policies and procedures to account for protocols performed by the committee.

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.

The applicant maintains that it has written protocols for allogenic and autologous PBMT that include patient selection and patient management and evaluation during the pre-hospital, in-hospital and immediate post-hospital phases of transplantation. WCHJ indicates that these protocols, while subject to revision based on current evidence-based best practice, will continue to be used in the proposed program. The reviewer notes that that applicant does not offer these written protocols for Agency review.

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.

WCHJ maintains having written care guidelines that detail the therapeutic and evaluative procedures for acute and long-term management of both allogenic and autologous PBMT patients that includes commonly encountered complications. WCHJ further maintains that these care guidelines, while subject to revision based on current evidence-based best practice, will continue to be used by the applicant. The reviewer notes that that applicant does not offer these written care guidelines for Agency review.

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.**

This is not applicable to bone marrow transplantation programs.

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.**

The applicant notes that the PBMT transplantation program works through the BMCJ blood bank and has agreements with two outside labs – Mayo Clinic Jacksonville and the American Red Cross Blood Services Penn Jersey Region in Philadelphia, PA. According to WCHJ, these agreements include Human Leukocyte Antigen (HLA) testing on transplant candidates, family members and donors, including initial HLA typing and patent-donor verification. WCHJ states that these agreements will continue under the proposed program. The reviewer notes that the applicant does not offer these agreements for Agency review. The reviewer also notes that there were no support letters from Mayo Clinic Jacksonville or from the American Red Cross Blood Services Penn Jersey Region in Philadelphia, PA.

9. **Pathology services with the capability of studying and promptly reporting the patient's response to the organ transplantation surgery, and analyzing appropriate biopsy material.**

WCHJ points out that organ transplant surgery is not required for PBMT, but WCJH states having the ability to analyze biopsy material through laboratory services that will be provided contractually through BMCJ's on-site lab. WCHJ asserts that the pathologists who cover the lab currently have active privileges in the children's hospital and will continue to have privileges. The reviewer also notes that WCHJ offers no current, proposed or sample policies and procedures related to planned laboratory services at or for the proposed project.

10. **Blood banking facilities.**

The applicant states that the proposed program's blood bank is provided on-site through BCMJ and these services will continue to be provided on-site through a contractual arrangement. The

reviewer notes that the applicant offers no current, proposed or sample contractual agreement for the delivery of blood banking. Further, the reviewer notes that the applicant does not offer for Agency review any sample policies and procedures related to blood collection, blood administration and obtaining/dispensing blood products.

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

WCHJ indicates that as an existing program, current team members have experience in the treatment of PBMT patients. The applicant states that it has a competency guide and checklist, *Providing Care for the Pediatric Hematopoietic Stem Cell Transplant Patient*, for all new nurses who begin work in the hematology/oncology unit and provide care for transplant patients. The reviewer notes that the applicant offers no competency guide and checklist for Agency review.

The applicant maintains that as a member of Baptist Health, the unit is provided continuing education through the health system's education group based on needs assessment to ensure that team members have the latest information and training for their patients. Per WCHJ, the policies and practices will continue with the proposed program. The reviewer notes that the applicant offers no continuing education policies and procedures or other related publications or materials for Agency review.

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

The applicant states that a programmatic PBMT educational binder is provided to each patient and their family. The reviewer notes that the binder is not included for Agency review.

According to WCHJ, the materials are tailored based on the type of transplant and primarily contains the following content:

- a. Continuing regimen treatment schema, transplant and/or harvest calendar
- b. Medications used during transplant
- c. Pediatric Stem Cell Transplant, A Family Guidebook
- d. FDA: Food Safety for Transplant Recipients
- e. Inpatient routine and FAQs
- f. Consents: Transplant, data reporting, harvest, donors (matched related donor, matched unrelated, cord blood)

The applicant states that it provides other information and books as shown below:

- a. Autologous Stem Cell Transplant: A Handbook for Patients from BMTinfonet.org
- b. Bone Marrow and Blood Stem Cell Transplants: A Guide for Patients and Their Loved Ones from BMTinfonet.org (for allogenic transplant)
- c. Caregiver's Guide for Bone Marrow/Stem Cell Transplant: Practical Perspective from National Bone Marrow Transplant Link
- d. Helpful Hints from Caregivers from BMTinfonet.org
- e. Resource Directory for Patients from BMTinfonet.org
- f. Survivorship Guide for Bone Marrow/Stem Cell Transplant: Coping with Late Effects from National Bone Marrow Transplant Link
- g. Voices of Hope and Healing for Bone Marrow/Stem Cell Transplant: Offering Inspiration, Support and Hope to Patients, Survivors and Their Caregivers from National Bone Marrow Transplant Link

WCHJ indicates that it provides the HCT Quick Reference Guidelines: Transplant Consultation and Post- Transplant Care package from the National Marrow Donor Program. WCHJ indicates that the same information is available via bethematchclinical.org.

- 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.**

WCHJ lists the six physicians currently on staff that meet this requirement. Additionally, the applicant indicates that Samri Midani is board certified in pediatric infectious diseases and pediatrics and serves as a member of the transplant team, is a member of Nemours Children's Specialty Care Jacksonville as

the Chief, Division of Pediatric Infectious Disease since 2000. WCHJ includes Dr. Midani's CV in CON application #10445.

- 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.**

WCHJ previously described that Michael J. Joyce, MD, PhD meets this provision.

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

WCHJ states that the team members at Wolfson and Nemours provide care for PBMT patients work only with children and have the training and experience for the special needs of children. Per WCHJ, these pediatric trained and experienced team members will continue to work with PBMT patients in the proposed program.

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

WCHJ responses to this provision with the same information provided in item E.2.(a)(3) of this report, with the exception that WCHJ states that one-third of the nurses are chemotherapy certified. The reviewer notes that no CVs for these nurses are included in the application.

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

See item E.2.a.10 for the applicant's response to this provision.

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

WCHJ states that the inpatient nutritionist is a registered dietician nutritionist who is licensed and certified with 13 years of experience with hematology/oncology. WCHJ also states that the outpatient nutritionist is a master's prepared registered dietician and licensed dietician nutritionist who has worked at Nemours for 13 years. The applicant indicates that these nutritionists will continue to serve the proposed program. The reviewer notes that the nutritionists are not named and no CV is

provided for either practitioner to account for their credentials, experience or state licensure.

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

The applicant states that Wolfson has 50 respiratory therapists, all of whom are trained to treat PBMT patients that will be available to provide respiratory care to patients in the proposed program. The reviewer notes that the practitioners are not named and no CV is provided for any of these practitioners to account for their credentials, experience or state licensure.

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

WCHJ indicates having licensed social workers, one inpatient and one outpatient, and one certified child life specialist. WCHJ also indicates a PhD clinical psychologist who is board certified in child and adolescent psychology with 15 years of experience and a chaplain with a Master of Divinity are available to assist patients and their families and that these team members will continue to be available for the proposed program. The reviewer notes that none of the team members are named and no CV is provided for any of these practitioners to account for their credentials, experience or state licensure.

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

The applicant states the Wolfson, Inc., will comply with this requirement.

3. Statutory Review Criteria

a. Is need for the project evidenced by the availability, quality of care, accessibility and extent of utilization of existing health care facilities

**and health services in the applicant's service area?
ss. 408.035(1), (a) and (b), Florida Statutes.**

The applicant states that BMCJ will voluntarily delicense the existing pediatric inpatient BMT program, the existing pediatric cardiac catheterization program and the existing pediatric open heart surgery program and will simultaneously license those same programs at their existing location, pursuant to the approved CON #10426.

The reviewer notes that there are presently two operational and no CON approved pediatric BMT programs in OTSA 1. The OTSA 1 operational program in District 3 is at UF Health Shands Hospital and the operational program in District 4 is at BMCJ.

The table below illustrates the most recent reporting period of January 1, 2015 through December 31, 2015 show the following PBMT utilization data statewide:

**Florida PBMT Program Utilization
12 Months Ending December 31, 2015**

Hospital	OTSA	District	Total Procedures
UF Health Shands Hospital	1	3	9
BMCJ	1	4	8
All Children's Hospital	2	5	49
Florida Hospital	3	7	0
Jackson Memorial Hospital	4	11	36
Nicklaus Children's Hospital	4	11	18
		Total	120

Source: Agency for Health Care Administration Utilization Data for Pediatric Organ Transplantation Programs published April 1, 2016

For the 12-month period ending December 31, 2015, a total of 17 inpatient PBMT procedures were performed at OTSA 1 hospitals. Florida Center for Health Information and Transparency records indicate that for the 12-month period ending December 31, 2015, of the 15 OTSA 1 residents (0-14 years of age) that were discharged with a blood and bone marrow transplant procedure (ICD9-41.00 to 41.09), 14 patients (93.33 percent) received the procedure at a OTSA 1 provider programs and the remaining one patient (6.67 percent) received the procedure at a non-OTSA 1 provider. Below is a table to account for these totals and percentages.

**OTSA 1 Pediatric Residents (Under 15 Years of Age)
With a Blood or Bone Marrow Transplant Discharge (ICD9-41.00 to 41.09)
12 Months Ending December 31, 2015**

Hospital	Total Procedures	Percentage
UF Health Shands Hospital	8	53.33%
BMCJ	6	40.00%
All Children's Hospital	1	6.67%
Total	15	100.00%

Source: Florida Center for Health Information and Policy Analysis database run date of June 23, 2016

The applicant has previously documented that upon proposed project approval and licensure, BMCJ will voluntarily delicense its existing inpatient PBMT program and simultaneously reestablish the program at WCHJ, at its current physical location. Therefore, the total number of inpatient PBMT programs in OTSA 1 will remain constant. WCHJ reiterates that the proposed project is part of a series of CON applications to operate a children's specialty hospital under a separate hospital license, with the same beds and services that are currently operated under the SBHF license.

WCHJ discusses that three of Wolfson's five Children's Specialty Centers – Clay County, Volusia County and Columbia County located in OTSA 1 and that these centers further enhance access to pediatric care and to Wolfson services. The applicant notes that hospitals under the SBHF license have opened freestanding emergency rooms and that these provide access to pediatric emergency medicine specialists and nurses near where patients live, including emergency transportation for direct admits to Wolfson when the patient's condition requires an inpatient admission.

The reviewer notes that on page 49 of the application, WCHJ states that "This application will not increase the number of pediatric open heart surgery programs in PHSA 2 or Florida". The applicant's pediatric OHS proposal is submitted under co-batched/companion CON application #10443.

Consistent with the Agency's records, WCHJ states that OTSA 1 facilities realized inpatient PBMT procedures totaling 27, 23 and 17, in CY 2013, CY 2014 and CY 2015, respectively.

WCHJ previously forecasted 10 inpatient PBMT procedures for year one (ending 2017) and for year two (ending 2018). The reviewer notes that according to Agency records (see item E.1.a of this report) WCH/BMCJ completed 10 such procedures in CY 2013 and eight in CY 2015.

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.

WCHJ is a development stage corporation and has no operating history. However, WCH currently operates under the license held by BMCJ/SBHF and the applicant included the Agency License and The Joint Commission Accreditation Summary. The applicant points out that The Joint Commission recognizes SBHF as a Top Performer on Key Quality Measures for children's asthma for 2014.

The applicant discusses the specific awards noted below and eight additional awards on pages 51 through 52 of the application. WCHJ indicates that the

following recognitions/award are held by Baptist Health (the parent) facilities, including Wolfson’s current operations:

- Magnet Designation
- *US News* Best Children’s Hospitals
- Beacon Award for Excellence – Gold

Baptist Health operates four hospitals in Florida, three hospitals in Duval County and one hospital in Nassau County, with a cumulative total of 1,022 licensed beds. Agency records indicate that Baptist Health affiliated hospitals had four substantiated complaints during the three-year period ending June 7, 2016 with BMCJ having three substantiated complaints. A single complaint can encompass multiple complaint categories. The tables below account for these Baptist Health and BMCJ substantiated complaints by complaint categories.

**Baptist Health Substantiated Complaint Categories
Three Years Ending June 7, 2016**

Complaint Category	Number Substantiated
Quality of Care/Treatment	3
Admission/Transfer/Discharge Rights	1
Nursing Services	1

Source: Agency for Health Care Administration complaint records

**Baptist Medical Center Jacksonville
Substantiated Complaint Categories
Three Years Ending June 7, 2016**

Complaint Category	Number Substantiated
Quality of Care/Treatment	2
Admission/Transfer/Discharge Rights	1
Nursing Services	1

Source: Agency for Health Care Administration 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 bench marks established from financial ratios collected from Florida acute care hospitals. While not always a perfect match to a particular CON project it is a reasonable proxy for health care related entities. Below is an analysis of the audited financial statements of Baptist Health System, Inc. and Subsidiaries (Parent) where the short term and long term measures fall on the scale (highlighted in gray) for the most recent year. All numbers except for ratios are in thousands.

Baptist Health System, Inc. and Subsidiaries (in thousands)		
	Sep-15	Sep-14
Current Assets	\$361,527	\$352,243
Total Assets	\$2,789,741	\$2,445,858
Current Liabilities	\$197,040	\$186,901
Total Liabilities	\$1,132,303	\$893,545
Net Assets	\$1,657,438	\$1,552,313
Total Revenues	\$1,511,271	\$1,349,954
Excess of Revenues Over Expenses	\$119,072	\$191,439
Cash Flow from Operations	\$144,799	\$173,494
Short-Term Analysis		
Current Ratio (CA/CL)	1.8	1.9
Cash Flow to Current Liabilities (CFO/CL)	73.49%	92.83%
Long-Term Analysis		
Long-Term Debt to Net Assets (TL-CL/NA)	56.4%	45.5%
Total Margin (ER/TR)	7.88%	14.18%
Measure of Available Funding		
Working Capital	\$164,487	\$165,342

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

Capital Requirements and Funding:

The applicant indicates on Schedule 2 capital projects totaling \$16,034,386 which includes equipment, renovations, acute care beds, NICU III Beds, NICU II Beds, Ped Cardiac Catheterization, Ped Open Heart Surgery, and Ped Bone Marrow Transplant (the CON currently under review). Funding for this

project will be provided by the parent. The parent provided a copy of its September 30, 2015 and 2014 audited financial statements. These statements were analyzed for the purpose of evaluating the parent’s ability to provide the capital and operational funding necessary to implement the project. Based on our analysis above, the parent has an adequate financial position.

Staffing:

The applicant provides a Schedule 6 for new inpatient health care facilities. Schedule 6 indicates that the proposed project will consist of a constant 6.9 FTEs each for year one (ending 2017) and year two (ending 2018). The reviewer notes that according to Schedule 10 of the application, initiation of service is set for October 1, 2016. See the table below.

Wolfson Children’s Hospital of Jacksonville, Inc. (CON application #10445) Staffing Patterns Year One and Year Two of Operations		
	Year One Ending 2017	Years Two Ending 2018
Administration		
Physicians		
Nursing		
R.N.s	5.6	5.6
Nurses’ Aides	1.2	1.2
Other	0.1	0.1
Ancillary		
Dietary		
Social Services		
Housekeeping		
Laundry		
Plant Maintenance		
GRAND TOTAL	6.9	6.9

Source: CON application #10445, Schedule 6

Notes to Schedule 6 indicate that staffing levels were determined by comparing the current staffing levels by job code for the functions included specifically for bone marrow transplant patients at Wolfson, ended September 2015.

Conclusion:

Funding for this project and the entire capital budget should be available as needed.

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

A comparison of the applicant’s estimates to the control group values provides for an objective evaluation of financial feasibility, (the likelihood that the services can be provided under the parameters and conditions contained in schedules seven and eight), and efficiency, (the degree of

economies achievable through the management skills of the applicant). In general, projections that approximate the median are the most desirable, and balance the opposing forces of feasibility and efficiency. In other words, as estimates approach the highest in the group, it is more likely that the project is feasible, because fewer economies must be realized to achieve the desired outcome. Conversely, as estimates approach the lowest in the group, it is less likely that the project is feasible, because a much higher level of economies must be realized to achieve the desired outcome. These relationships hold true for a constant intensity of service through the relevant range of outcomes. As these relationships go beyond the relevant range of outcomes, revenues and expenses may go either beyond what the market will tolerate, or may decrease to levels where activities are no longer sustainable.

Because the proposed Pediatric Bone Marrow Transplant Unit cannot operate without the support of the hospital, we have evaluated the reasonableness of the projections of the entire hospital including the project. The applicant was compared to other pediatric hospitals. This hospital does not have historical operations to determine the average length of stay to calculate the case mix. However, this hospital was formerly part of an established hospital. Because of this, the Agency used the case mix for the former parent facility. This methodology is used to adjust the group values to reflect the intensity of the patient as measured by length of stay. Inflation adjustments were based on the new CMS Market Basket, 1st Quarter, 2016.

	PROJECTIONS PER APPLICANT		COMPARATIVE GROUP VALUES PPD		
	Total	PPD	Highest	Median	Lowest
Net Revenues	251,243,757	4,178	4,447	3,691	2,972
Total Expenses	231,567,741	3,850	6,028	3,757	2,887
Operating Income	19,676,016	327	481	311	-2,340
Operating Margin	7.83%		Comparative Group Values		
	Days	Percent	Highest	Median	Lowest
Occupancy	60,141	81.57%	72.52%	57.22%	27.25%
Medicaid/MDCD HMO	33,251	55.29%	70.73%	68.52%	66.40%
Medicare	173	0.29%	0.42%	0.38%	0.25%

NRPD, CPD, and profitability or operating margin that fall within the group range are considered reasonable projections.

The projected net revenue, total expenses and profit per patient day fall within the group range and are considered reasonable. Profitability appears achievable.

Conclusion:

This project appears to be financially feasible.

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

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

Conclusion:

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

- 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; Ch 59A-3, Florida Administrative Code.**

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

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

- 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 applicant is a development stage corporation and has no Medicaid history. However, the parent, not-for-profit hospital provider Baptist Health, operates a total of four hospitals in Florida, all in District 4, with BMCJ the current provider of the licensed inpatient PBMT program slated for delicensure at BMCJ to be simultaneously licensed at WCHJ.

The Agency maintains payer source data for PBMT cases and patient days. MS-DRG data obtained from the Florida Center for Health Information and Transparency indicates that Florida hospitals reported 105 pediatric PBMT procedures in CY 2015. See the table below.

**Florida Pediatric Open Heart Surgery Discharges
MS-DRGs 014, 016 and 017
CY 2015**

Facility	Total Procedures	Total Medicaid/Medicaid Managed Care and Charity Care Procedures	Percent Medicaid/Medicaid Managed Care and Charity Care Procedures	Total Patient Days	Medicaid/Medicaid Managed Care and Charity Care Days	Percent Medicaid/Medicaid Managed Care and Charity Care
Florida Hospital	4	4	100.00%	28	28	100.00%
Baptist Medical Center Jacksonville	8	7	87.50%	355	327	92.11%
Nicklaus Children's Hospital	21	16	76.19%	862	670	77.73%
UF Health Shands Hospital	10	5	50.0%0	807	560	69.39%
Jackson Memorial Hospital	22	14	63.64%	1,151	629	54.65%
Johns Hopkins/All Children's Hosp	40	21	52.50%	1,285	685	53.31%
Total	105	67	63.81%	4,488	2,899	64.59%

Source: Florida Center for Health Information and Transparency

As shown above, 63.81 percent of the state's total inpatient PBMT procedures and 64.59 percent of the total inpatient PBMT patient days were provided to Medicaid/Medicaid Managed Care and charity care, in CY 2015. It is noted that Florida Hospital was the sole provider to report charity care procedures/days for this procedure, in CY 2015.

The table below illustrates BMCJ state fiscal year (SFY) 2015-2016 low-income pool (LIP) program participation, as of June 6, 2016. BMCJ is currently not a disproportionate share hospital (DSH) provider. The reviewer notes that BMCJ has fully exhausted its SFY 2015-2016 LIP allocation.

Baptist Health Medical Center Jacksonville LIP and DSH Program Participation SFY 2015-2016		
Program	Annual Total Allocation	Year-to-Date Total Allocation as of June 6, 2016
LIP	\$264,548	\$264,548

Source: Agency Division of Medicaid, Office of Program Finance

WCHJ points out that Wolfson's operations are governed and will continue to be directed by Baptist Health's ongoing policy and practice of providing health care services in a non-discriminatory manner to all patients,

including Medicaid and the medically indigent. The applicant indicates that Baptist Health’s services to those who lack financial resources to obtain health care is directed by system-wide financial policies.

The applicant includes the signed, five-page Baptist Health Policy and Procedure Manual (Hospital Financial Assistance Policy effective September 1, 2015). In this policy, the reviewer notes that for patients with family income equal to or less than 200 percent of the Federal Poverty Level (FPL), the amount eligible for financial assistance equals the patient responsible balance. Eligibility for financial assistance for patients with family income in excess of 200 percent FPL is also described in this policy.

The applicant additionally includes the signed, one-page Baptist Health Policy and Procedure Manual (Self-Pay Discounts Policy effective October 2013). In this policy, the reviewer notes that for fully uninsured patients (except for CT, MRI, and childbirth services) patients verified to have no form of third party healthcare services will be provided discounts necessary to reduce their self-pay obligation to 35 percent of billed charges. Eligibility for discount assistance for third party coverage for patients that have exhausted their benefit or for non-covered services is also described in this policy.

WCHJ indicates that its commitment to Medicaid patients and the medically indigent is evident when the analysis is restricted to those patients who were treated in units with services that are part of WCH. The applicant contends that using Wolfson’s internal financial statements, 52.8 percent of WCH’s gross revenue was from Medicaid and self-pay in FY 2015. See the table below.

**Wolfson Children’s Hospital
Revenue Analysis by Payer / FY 2015**

Payer	Percent Gross Revenue
Medicaid	51.9%
Self-Pay	0.9%
Managed Care	37.8%
Tricare and Other	8.5%
Medicare	1.0%
TOTAL	100.0%

Source: CON application #10445, page 69, Table 3-5

The applicant’s Schedule 7A includes estimates of utilization for the proposed program by payer mix, for year one and year two. See the table below.

**Wolfson Children’s Hospital of Jacksonville, Inc. (CON application #10445)
 Estimated Patient Days and Percentage by Payer Mix
 for the Proposed Pediatric Bone Marrow Transplantation Program
 Year One and Year Two**

Payer	Year One (Ending 2017)		Year Two (Ending 2018)	
	Total Patient Days	Percent of Patient Days	Total Patient Days	Percent of Patient Days
Medicaid	0	0.0%	0	0.0%
Medicaid HMO	6	60.0%	6	60.0%
Other Managed Care	3	30.0%	3	30.0%
Other Payers	1	10.0%	1	10.0%
Self-Pay	0	0.0%	0	0.0%
Total	10	100.0%	10	100.0%

Source: CON application #10445, Schedule 7A

The applicant indicates that it did not condition project approval to any percent of pediatric inpatient PBMT cases or patient days due to the relatively small projected utilization for the proposed project. WCHJ contends that PBMT patients will receive care in WCHJ’s acute care beds, with 33 percent of those beds conditioned to Medicaid patient days, pursuant to CON #10426. The reviewer notes that there are no conditions on the existing pediatric inpatient bone marrow transplantation program at WCH/BMCJ.

F. SUMMARY

Wolfson Children’s Hospital of Jacksonville, Inc. (CON application #10445), a development stage corporation and an affiliate of not-for-profit hospital provider Baptist Health, is applying to establish a pediatric inpatient bone marrow transplantation program within approved CON #10426, in OTSA 1, Duval County, Florida. The applicant submitted additional companion applications in this batching cycle (CON applications #10442 and #10443). The proposed project would result in BMCJ delicensing its existing inpatient PBMT program and the applicant simultaneously acquiring the inpatient PBMT program under its own (WCHJ’s) license. The proposed project would not change the inventory count or the physical location of the existing BMCJ inpatient PBMT program.

Total project costs include only the project development cost of \$10,000. The project involves zero GSF of renovated space and zero GSF of new construction, with no renovation and no construction costs.

The applicant’s proposed conditions are included on pages four and five of this report.

Need:

There is no fixed need pool publication for PBMT programs. It is the applicant's responsibility to demonstrate the need for the project. The

Agency states that the applicant did demonstrate need for the proposed project.

There are currently two operational and no CON approved pediatric bone marrow transplantation programs in OTSA 1. Project approval would result in no change in the inventory count or the physical location of the existing PBMT programs in OTSA 1.

The applicant forecasts 10 inpatient PBMTs for each of year one and year two of operation (ending 2017 and ending 2018, respectively).

WCHJ summarizes that the need for the proposed project is based on “not normal” circumstances and is documented by the following factors:

- Recent utilization at WCH/BMCJ (over the five-year period ending December 31, 2015), is reasonably consistent with the expected year one and year two forecasts
- Increased focus and efficiency, as operating under a separate license will relieve WCHJ of the distractions and duplications that result from pairing with adult hospitals
- Increased grant funding and philanthropy
- Enhanced access to care
- Attracting more pediatric specialists

The reviewer notes that in most instances regarding required staffing (non-physician/allied health and other health care support staffing), stated contractual relationships, arrangements and service delivery procedures and policies, WCHJ does not include documentation to verify the stated linkages. However, the Agency notes that SBHF is already licensed for and is providing the inpatient PBMT and that the proposal would essentially replace the existing program under a different license.

Quality of Care:

As a development stage corporation, the applicant has no operating history. However, the pediatric inpatient BMT program slated for licensure to the applicant at approved Class 2 hospital CON #10426 is already licensed by the Agency and is operational under the Class 1 hospital license for BMCJ which is accredited by The Joint Commission.

Agency data indicates that Baptist Health affiliated hospitals had four substantiated complaints during the three-year period ending June 7, 2016 with BMCJ having three substantiated complaints during this same three-year period.

The applicant’s parent demonstrates the ability to provide quality care.

Financial Feasibility/Availability of Funds

- Funding for this project and the entire capital budget should be available as needed
- This project appears to be financially feasible
- This project is not likely to have a material impact on competition to promote quality and cost-effectiveness

Architectural Analysis

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

Medicaid/Charity Care:

The applicant does not condition any Medicaid/Medicaid Manage Care or charity care cases or patient days to the proposed project. However, WCHJ indicates that the pediatric BMT patients will receive the care in WCHJ's acute care beds, with 33 percent of those beds conditioned to Medicaid patient days, pursuant to CON #10426.

There are no conditions on the existing pediatric inpatient bone marrow transplantation program at WCH/BMCJ.

Schedule 7A of the application indicates that in year one (ending 2017) and in year two (ending 2018), each, the applicant estimates Medicaid/Medicaid HMO at 60.0 percent and self-pay at 0.0 percent, total annual patient days.

BCMJ had an annual allocation of \$264,548 for SFY 2015-2016 for the LIP, has fully exhausted that allocation and is not a DSH provider.

G. RECOMMENDATION

Approve CON #10445 to establish a new inpatient autologous and allogeneic pediatric bone marrow transplantation program within approved CON #10426, in OTSA 1, District 4, Duval County. The total project cost is \$10,000. The project involves zero GSF of renovated space and zero GSF of new construction, with no renovation and no construction costs.

CONDITIONS:

- C.1. Specific site within the subdistrict. The parcel or address is as follows: 800 Prudential Drive, Jacksonville, Florida 32207, Duval County,

District 4, Organ Transplant Service Area 1; the present site; this condition has been included in all related applications

- C.2. Percent of a particular population subgroup to be served. The population subgroup, along with the percent to be served, is as follows:
- C.3. Special programs listed as: Wolfson, Inc., will operate the beds and services listed below in the children's specialty (Class 2) hospital (ages 17 and under) along with the pediatric bone marrow transplantation program in this application:
 - Acute Care – 132 beds
 - NICU Level II – 24 beds
 - NICU Level III – 32 beds
 - Child and Adolescent Psychiatric – 14 beds via CON exemption request
 - Pediatric Cardiac Catheterization
 - Pediatric Open Heart Surgery
 - Pediatric Bone Marrow Transplantation (this application)

This condition will be included in all related applications.

- C.4. Other, specified as: Simultaneously voluntarily delicense the pediatric bone marrow transplantation program currently licensed under SBHF with the licensure the pediatric bone marrow transplantation at Wolfson, Inc.; this delicensure condition has been included in all associated application.

AUTHORIZATION FOR AGENCY ACTION

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

DATE: _____

Marisol Fitch
Health Administration Services Manager
Certificate of Need