

STATE AGENCY ACTION REPORT

ON APPLICATION FOR CERTIFICATE OF NEED

A. PROJECT IDENTIFICATION

1. Applicant/CON Action Number

Baptist Hospital of Miami, Inc.
d/b/a Baptist Hospital of Miami/CON #10420
8900 North Kendall Drive
Miami, Florida 33176

Authorized Representative: Mr. S. Chris Ciocco
(786) 662-7761

2. Service District/Subdistrict

Organ Transplant Service Area (OTSA) 4: District 10 (Broward County), District 11 (Miami-Dade and Monroe Counties); Collier County only (in District 8) and Palm Beach County only (in District 9).

B. PUBLIC HEARING

A public hearing was not held or requested for the proposed project.

Letters of Support

Baptist Hospital of Miami, Inc., d/b/a Baptist Hospital of Miami (CON application #10420) submitted a large number of letters of support and the Agency received a few independently. The majority of these letters were of OTSA 4/local area origin, many were of a form letter variety but some were individually composed. Of these letters, most of the physicians indicate affiliation with Baptist Hospital and in turn the parent organization (Baptist Health South Florida), in some cases the parent's Miami Cancer Institute, Miami Cardiac & Vascular Institute or the Baptist Health Medical Group. A few letters indicate being past or likely adult bone marrow transplantation patients of the applicant. Some major recurring themes expressed to support the proposed project include:

- Last year, more than 40 percent of bone marrow transplant inpatients chose to leave South Florida to seek treatment
- Over the next five years, a 13 percent increase is expected in cases due to the region's aging and growing population

- The patient population's proximity to their medical team and ease of care are essential elements of treating their disease
- South Florida patients and their families are often forced to uproot their lives to travel for life-saving care--compounding the emotional, physical and financial burden of treatment
- Baptist Hospital is a nationally recognized provider of quality care, having been named the best regional hospital in south Florida by U. S. News & World Report in its 2015 Best Hospitals list
- Baptist Health provided \$317 million last year in charity care and community benefit
- Baptist Health provided about 167,000 services to Medicaid recipients--the cost of which exceeded reimbursement
- The neediest of patients would receive the care regardless of their financial standing
- The \$430 million Miami Cancer Institute on the Baptist Hospital campus reinforces Baptist's position to lead cancer care in the region today and into the future

Some support letters are noted below:

- Gwen Margolis (35th District), Oscar Braynon II (36th District), Anitere Flores (37th District), Rene Garcia (38th District) and Dwight Bullard (39th District), Miguel Diaz de la Portilla (District 40), State Senators, The Florida Senate
- Joseph "Joe" Geller (District 100), Manny Diaz Jr. (District 103), Barbara Watson (District 107), Erik Fresen (District 114), Michael Bileca (District 115), Joe Felix Diaz (District 116), Kionne L. McGhee (District 117), Frank Artiles (District 118), Jeanett M. Nunez (District 119) and Holly Raschein (District 120), State Representatives, The Florida House of Representatives
- Board of County Commissioners/Miami-Dade County Commission
 - Vice Chairman and District 13 Commissioner
 - District 3, 4, 7, 8, 10 and 11 Commissioners
- Mayor of:
 - City of Doral
 - City of Homestead
 - City of Sweetwater
 - City of West Miami
 - Town of Cutler Bay
 - Town of Miami Lakes
 - Village of Palmetto Bay
 - Village of Pinecrest
- President/CEO of Affiliated Baptist Health
 - Homestead Hospital
 - South Miami Hospital
 - Baptist Hospital of Miami

- President/CEO of
 - Bethesda Health, Inc.
- Senior Vice President for Health Affairs
 - Florida International University (FIU), Herbert Wertheim College of Medicine
- Dean, College of Nursing
 - Nova Southeastern University
 - Barry University

C. PROJECT SUMMARY

Baptist Hospital of Miami, Inc., d/b/a Baptist Hospital of Miami (CON application #10420), (also referenced as Baptist Hospital, BHM or the applicant), a not-for-profit Class 1 hospital, affiliated with Baptist Health South Florida (also referenced as Baptist Health, BHSF or parent), proposes to establish an adult inpatient autologous and allogeneic bone marrow transplantation program at Baptist Hospital of Miami, to primarily serve the local residents of OTSA 4 and will provide needed care to other Florida and US residents, as well as international patients who rely on BHSF's resources for their health care needs. Non-CON regulated outpatient bone marrow transplantation services are also planned, to be provide at the Miami Cancer Institute (MCI), a BHSF affiliate currently in development.

BHM indicates that the vast majority of clinical and non-clinical infrastructure to support the proposed project is already in place. The applicant states that the inpatient adult bone marrow transplant care will be provided in a renovated six private bed bone marrow transplant (BMT) unit, located on the 4 Main East Nursing Unit within BHM.

BHSF, the parent, operates BHM, Doctors Hospital, Homestead Hospital, Mariners Hospital, South Miami Hospital and West Kendall Baptist Hospital, all Class 1 acute care hospitals within District 11 (Miami-Dade and Monroe Counties). BHM's 728 licensed bed compliment includes 669 acute care beds, 22 Level II neonatal intensive care unit (NICU) beds, 14 Level III NICU beds and 23 comprehensive medical rehabilitation (CMR) beds. BHM is a Level II adult cardiovascular services center and a comprehensive stroke center.

BHSF indicates that it is the largest not-for-profit health care system in South Florida and one of the largest within the southeastern United States.

The adult inpatient autologous and allogeneic bone marrow transplant program, if approved, is expected to have issuance of license in September 2017 and initiation of service in October 2018.

Project costs total \$8,303,255. The project involves 14,750 gross square feet (GSF) of renovated space (no new construction) with total renovation costs of \$6,337,500. Total project costs include building, equipment, project development and start-up costs.

In Schedule C, the applicant conditions the proposed project as follows:

- The proposed adult BMT program will be located at Baptist Hospital of Miami, located at 8900 North Kendall Drive, Miami, Florida.
- A fully qualified adult allogeneic and autologous bone marrow transplant Medical Director, meeting all allogeneic and autologous criteria requirements will be in place and active in the BMT program prior to program initiation.
- Baptist Hospital will delicense 12 acute care beds upon the completion of the 4 Main East renovation and the establishment of the new bone marrow treatment program.
- Baptist Hospital will provide at least 10 percent of transplant case volume on an annual basis to Medicaid/Medicaid Managed Care/Charity/Self-Pay patients.

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

D. REVIEW PROCEDURE

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

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

Section 59C-1.010(2) (b), Florida Administrative Code, allows no application amendment information subsequent to the application being deemed complete. The burden of proof to entitlement of a certificate rests with the applicant. As such, the applicant is responsible for the representations in the application. This is attested to as part of the application in the Certification of the Applicant.

As part of the fact-finding, the consultant, Steve Love, analyzed the application with consultation from Financial Analyst Everett (Butch) Broussard of the Bureau of Central Services, who evaluated 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 criteria and application content requirements found in Florida Statutes, sections 408.035, and 408.037; applicable rules of the State of Florida, Chapter 59C-1 and 59C-2, Florida Administrative Code.

1. Fixed Need Pool

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

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

There are presently three operational adult inpatient bone marrow transplant programs in Service Area 4, with no CON approved adult inpatient bone marrow transplantation programs pending licensure in OTSA 4. The operational programs are at Memorial Hospital West (Broward County), Good Samaritan Medical Center (Palm Beach County) and the University of Miami Hospital & Clinics (Miami-Dade County).

Data reported to the Agency for the most recent reporting period, July 1, 2014 through June 30, 2015 show the following adult bone marrow transplant utilization data:

Florida Adult Bone Marrow Transplantation Program Utilization July 2014 – June 2015			
Hospital	OTSA	District	Total Procedures
UF Health Shands Hospital	1	3	149
Mayo Clinic	1	4	87
H. Lee Moffitt Cancer Center	2	6	453
Florida Hospital-Orlando	3	7	148
Good Samaritan Medical Center	4	9	148
Memorial Hospital West	4	10	22
Univ. of Miami Hosp. & Clinics	4	11	133
		TOTAL	1,140

Source: Agency for Health Care Administration Utilization Data for Adult Organ Transplantation Programs, published October 2, 2015

As shown above, for the 12-month period ending June 30, 2015, within OTSA 4, the highest number of adult inpatient bone marrow transplantation procedures (148) was performed at Good Samaritan Medical Center, the next highest number (133) at the University of Miami Hospital & Clinics and the fewest (22) at Memorial Hospital West.

Below is a five-year chart to account for adult inpatient bone marrow transplants ending June 30, 2015.

**Adult Inpatient Bone Marrow Transplantation Procedures
June 30, 2011 through June 30, 2015**

Facility/OTSA	7/2010- 6/2011	7/2011- 6/2012	7/2012- 6/2013	7/2013- 6/2014	7/2014- 6/2015	Total
UF Health Shands Hospital (OTSA 1)	127	130	117	93	149	616
Mayo Clinic (OTSA 1)	78	65	87	89	87	406
H. Lee Moffitt Cancer Center (OTSA 2)	391	402	424	421	453	2,091
Florida Hospital-Orlando (OTSA 3)	74	72	133	141	148	568
Good Samaritan Medical Center (OTSA 4)	2	0	0	0	148	150
Memorial Hospital West* (OTSA 4)	3	10	12	16	22	63
Jackson Memorial Hospital** (OTSA 4)	55	37	0	0		92
Univ. of Miami Hospital & Clinics (OTSA 4)	0	60	122	141	133	458
Total	730	776	895	901	1,140	4,442

Source: Agency for Health Care Administration Utilization Data for Adult Organ Transplantation Programs, published October 2010 – October 2015

Note: * Memorial Hospital West became operational effective 5/3/2011

** Jackson Memorial Hospital terminated its program effective 9/27/2013

Historic data indicates that, for the five years ending June 30, 2015, H. Lee Moffitt Cancer Center & Research Institute Hospital maintained the highest volume of adult bone marrow transplantations (2,091 procedures), followed by UF Health Shands Hospital (616 procedures) and Florida Hospital-Orlando (568 procedures). During the five-year period, adult inpatient bone marrow transplantations trended upward each year (from 730 procedures as of June 30, 2011 to 1,140 procedures

as of June 30, 2015), with H. Lee Moffitt Cancer Center & Research Institute Hospital being the single highest volume provider for each of the five years.

Of the three current providers in Service Area 4, for the 12 months ending June 30, 2015, the University of Miami Hospital & Clinics is the single highest volume provider (458 procedures), followed by Good Samaritan Medical Center (150 procedures) and then Memorial Hospital West (63 procedures). Within the five-year period, Service Area 4 providers, collectively, have realized steady volume increases in procedures for each year, with a substantial increase in the 12 months ending June 30, 2015. The lowest volume procedures, collectively for the five-year period, was 60 procedures (for the 12-months ending June 30, 2011) and the highest volume procedures, collectively for the same period, was 303 procedures (for the 12 months ending June 30, 2015).

Rule 59C-1.044(9)(b), Florida Administrative Code, states that adult allogeneic bone marrow transplantation programs shall be limited to teaching and research hospitals. According to the Agency's Hospital Beds and Services List publication (issued July 17, 2015) Baptist Hospital of Miami is not a statutory teaching hospital. However, the applicant contends that it meets all criteria being a research hospital (CON application #10420, page 20) and also that BHM materially meets the threshold to be considered a teaching hospital within the context of its CON application #10420. Further, BHM indicates that BHM's MCI (expected to initiate service by late 2016/early 2017) will:

- Consolidate system-wide Baptist Health's network of outpatient services and specialties
- Greatly expand cancer treatment technology and resources
- Add a dedicated cancer research initiative
- Establish tumor-specific initiatives and programs

Additionally, the applicant states that it is the intent of BHM's MCI to establish a clinical and research linkage with a national/international cancer institution to ensure that the residents of south Florida, and beyond, have integrated access to any services/programs/research initiatives that are available only at the nation's top cancer programs.

The reviewer notes that the applicant does not include a written agreement, non-financial memorandum of understanding or other signed document to indicate a clinical and research linkage between BHM's MCI and a national/international cancer institution to jointly conduct research. However, the reviewer notes that according to BHM:

- In 2014, Baptist Health cancer patients had access to 65 clinical trials
- A 20-page itemization of study projects with a date of closure or date of next review in 2016
- a four-page summary of the BHM's Center for Research and Grants indicating that a research cycle consists of:
 - identifying a research area
 - designing a research study
 - carrying out the research
 - analyzing the research results
 - publishing the results

The reviewer indicates that February 10, 2016 it was announced the MCI will become a member of Memorial Sloan Kettering Cancer Center's "cancer alliance" which include access to Sloan-Kettering's physicians, treatment protocols and educational resources.

The reviewer notes that community support letters and the applicant consistently state that "last year, more than 40 percent of bone marrow transplant inpatients chose to leave South Florida to seek treatment". BHM states that the proposed project is being developed to resolve the access problem in the planning area, as evidenced by the documented high outmigration levels.

During the 12-month period ending June 30, 2015, a total of 78 OTSA 4 adult residents (15 years of age or older) were discharged with a blood and bone marrow transplant procedure (MS-DRGs 14, 16 and 17), 58 (69.23 percent) received the procedure in OTSA 4¹ and the remaining 20 patients (25.64 percent) received the procedure at a non-OTSA 4 provider. H. Lee Moffitt Cancer Center was the highest volume non-Service Area 4 provider of adult Service Area 4 residents that received the procedure (24.36 percent). Below is a table to account for these totals and percentages.

¹ The Agency notes that providers listed may be providing outpatient adult blood/bone marrow transplantation services.

**Transplant Service Area 4 Adult Residents (Age 15 or Older)
With a Blood or Bone Marrow Transplant Discharge (MS-DRGs 14, 16 and 17)
12 Months Ending June 30, 2015**

Hospital	Total Procedures	Percentage
Broward Health Medical Center	1	1.28%
Delray Medical Center	1	1.28%
Good Samaritan Medical Center	2	2.56%
H. Lee Moffitt Cancer Center	19	24.36%
Jackson Memorial Hospital	1	1.28%
Mayo Clinic	1	1.28%
Memorial Hospital West	11	14.10%
Miami Children's Hospital	1	1.28%
University of Miami Hospital and Clinics	41	52.56%
Total Procedures	78	100.00%

Source: Florida Center for Health Information and Policy Analysis database run date of January 6, 2016

The Agency reviewed the ICD 9 Procedure Codes 41.00 to 41.09 that apply to bone marrow transplantation and stem cell transplantation. During the 12-month period ending June 30, 2015, a total of 148 Service Area 4 adult residents (15 years of age or older) were discharged with a bone marrow or stem cell transplant procedure, 96 (64.86 percent) received the procedure at a OTSA 4 provider and the remaining 52 patients (35.14 percent) received the procedure at a non-OTSA 4 provider. H. Lee Moffitt Cancer Center was the highest volume non-OTSA 4 provider (49 of 148 procedures or 33.11 percent). Outmigration occurred in 52 of 148 (35.14 percent) of cases. Below is a table to account for these totals and percentages.

**Transplant Service Area 4 Adult Residents (Age 15 or Older)
With a Bone Marrow or Stem Cell Transplant Discharge (ICD 9/41.00 – 40.09)
12 Months Ending June 30, 2015**

Hospital	Total Procedures	Percentage
All Children's Hospital	1	0.68%
Broward Health Medical Center	2	1.35%
Delray Medical Center	2	1.35%
Good Samaritan Medical Center	2	1.35%
H. Lee Moffitt Cancer Center	49	33.11%
Holy Cross Hospital	2	1.35%
Jackson Memorial Hospital	6	4.05%
Mayo Clinic	2	1.35%
Memorial Hospital West	14	9.46%
Miami Children's Hospital	4	2.70%
South Miami Hospital	1	0.68%
University of Miami Hospital and Clinics	63	42.57%
Total Procedures	148	100.00%

Source: Florida Center for Health Information and Policy Analysis database run date of January 6, 2016

Therefore, in summary, based on the above tables, for the 12-month period ending June 30, 2015, the majority of area residents did not migrate outside of Service Area 4 for these procedures.

BHM proposes a 21-page need argument (CON #10420, pages 22-43), with 17 tables. The applicant’s need justification is briefly discussed below.

Service Area Population Profile

Using the Agency’s Florida Population Estimates and Projections by AHCA District 2010 to 2030 publication, issued February 2015, BHM provides four population tables by age cohorts for 2015 and 2020. The first two population tables indicate an OTSA 4 total population of 6,246,180 in 2015, rising to 6,571,262 population in the same service area by 2020. The applicant states and the Agency agrees that for OTSA 4, Miami-Dade County has the largest population base with 2,642,231 total residents (July 1, 2015) to 2,795,753 total residents (July 1, 2020).

Using the same source as indicated above, BHM provides the following two tables to account for the 2015-2020 population growth rate for the total service area population as well as for the age 15+ population, the age group targeted for the proposed project. BHM expects the age 15+ population in Service Area 4 to grow by 294,415 residents (5.7 percent) from 2015 to 2020 and that this accounts for more than 90 percent of the total population growth. See the two tables below.

OTSA 4 2015-2020 Population Growth Total and Percent

County	Pop 0-14	Pop 15-64	Pop 65+	Total
Miami-Dade	14,377 / 3.1%	82,241 / 4.6%	56,904 / 14.3%	153,522 / 5.8%
Monroe	-209 / -2.3%	-2,818 / -5.7%	2,498 / 16.5%	-529 / -0.7%
Broward	2,867 / .09%	4,073 / 0.3%	46,127 / 16.0%	53,067 / 2.9%
Palm Beach	10,671 / 4.7%	32,054 / 3.8%	42,382 / 13.7%	85,107 / 6.2%
Collier	2,964 / 5.4%	14,560 / 7.4 %	16,391 / 17.3%	33,915 / 9.8%
Service Area Total	30,670 / 2.8%	130,110 / 3.2%	164,302 / 14.9%	325,082 / 5.2%

Source: CON application #10420, page 24

OTSA 4 2015 and 2020 Population Age 15+ Total and Percent

County	2015 Pop 15+	2020 Pop 15+	2015-2020 Pop 15+ Growth
Miami-Dade	2,174,378	2,313,523	139,145 / 6.4%
Monroe	64,271	63,951	-320 / -0.5%
Broward	1,485,234	1,535,434	50,200 / 3.4%
Palm Beach	1,151,683	1,226,119	74,436 / 6.5%
Collier	291,887	322,838	30,951 / 10.6%
Service Area Total	5,167,453	5,461,865	294,415 / 5.7%

Source: CON application #10420, page 24

Bone Marrow Transplant Providers and Provider Volume

BHM reiterates the Agency’s published statewide adult inpatient bone marrow transplantation procedures July 2014 through June 2015 of 1,140 procedures as well as these total procedures for each of the last

three years ending June 30, 2015. However, the applicant states that the Agency’s publication data reflects inpatient and outpatient procedures as well as both autologous and allogeneic adult bone marrow transplants. The Agency notes that only inpatient bone marrow transplantation procedures are CON-regulated, not outpatient procedures, with outpatient procedures not being included in the Agency’s publication.

Current Bone Marrow Transplant Planning Area Resident Volume

Using Agency inpatient hospital discharge data for calendar year (CY) 2014, BHM states a total volume of 776 (allogeneic and autologous) age 15+ bone marrow transplant cases in Florida. The applicant emphasizes that these 776 cases are inpatient only. The reviewer notes that the applicant states that this accounts for DRGs 014/allogeneic, DRG 015/autologous with complications or major complications) and DRG 016/autologous without complications (CON application #10420, page 26). However, the reviewer notes in the table below and the Florida Center for Health Information and Policy Analysis confirms that the correct bone marrow transplant MS-DRGs are 14, 16 and 17.

**Total Florida Bone Marrow Transplant Volume
Patients Age 15+, CY 2014**

	Discharges Age 15+
DRG 014 Allogenic	374
DRG 016 Autologous W CC/MCC	355
DRG 017 Autologous W/O CC/MCC	47
Total Autologous	402
Total	776

Source: CON application #10420, page 27

The reviewer notes that per the Florida Center for Health Information and Policy Analysis inpatient hospital database, a total of 770 ICD 9 Procedure Codes 41.00 to 41.09 discharges occurred for Florida residents age 15+ for the 12 months ending June 30, 2015.

BHM stresses that resident-specific data must be modified to reflect the fact that outpatient BMT volume is not included in the source data. BHM further stresses that in order to estimate total BMT cases from a given area, the inpatient BMT must be inflated to factor in the important outpatient volume (CON application #10420, page 27). BHM projects that outpatient BMT volumes are double those of inpatient BMT volumes. Again using Agency inpatient hospital discharge data for CY 2014, BHM states a total volume of 152 (allogeneic and autologous) age 15+ bone marrow transplant cases in OTSA 4. The applicant emphasizes that these 152 cases are inpatient only. See the table below.

**OTSA 4 Inpatient Bone Marrow Transplant Volume
Patients Age 15+, CY 2014**

	Discharges Age 15+
DRG 014 Allogenic	74
DRG 016 Autologous W CC/MCC	72
DRG 017 Autologous W/O CC/MCC	6
Total Autologous	78
Total	152

Source: CON application #10420, page 27

The reviewer notes that per the Florida Center for Health Information and Policy Analysis inpatient hospital database, a total of 148 ICD 9/41.00-41.09 discharges occurred for OTSA 4 residents age 15+ for the 12 months ending June 30, 2015.

BHM contends that converting this inpatient-only adult OTSA 4 resident discharge BMT volume to an estimate of total (inpatient and outpatient) BMT volume results in an estimate of 308 total adult BMT cases performed in OTSA 4 during 2014. See the table below.

**OTSA 4 Total (IP and OP) Bone Marrow Transplant Volume
Patient Age 15+, CY 2014**

	Discharges Age 15+
Allogenic – 100% IP	74
IP Autologous	78
OP Autologous – estimated at 2X IP Autologous volume	156
Total IP + OP Autologous	234
Total	308

Source: CON application #10420, page 28

BHM states that as presented above, the three OTSA 4 adult BMT providers performed 303 cases during the 12 months ending June 30, 2015 - this total for the time frame referenced is confirmed by the Agency. The applicant maintains that comparing this 303 case level to the 308 case forecast used in this approach shows the reasonableness of this total case estimate (within two percent of actual facility total case volume). The reviewer confirms that this estimate is within two percent. The applicant further states that when adding 64 outmigration and five in-migration cases in CY 2014, this results in a final 362 adult BMT case estimate.

BHM asserts that a second variable assessment of the Baptist market sizing approach (estimating the total in- and out-patient adult BMT cases from OTSA 4) was performed and that the Baptist market sizing model was proven to be reasonable and realistic. The applicant generates a use rate of 69.5 adult BMT cases per 100,000 persons age 15+. Based on this, the applicant forecasts 359 cases in 2015. See the table below.

**OTSA 4 Forecast Adult Total (IP and OP) Bone Marrow Transplant Volume
Based on the Application of Florida Adult BMT Use Rates
to Planning Area Population**

Adult BMT Cases in Florida Facilities 12 Months Ending 06/2015	1,140
Total Florida Population Age 15+	16,404,322
Florida Adult BMT Cases per 100,000 Population Age 15+	69.5 per 100,000
Transplant Services Planning Area 4 2015 Pop Age 15+	5,167,453
Transplant Services Planning Area 4 2015 Forecast Adult BMT Cases	359

Source: CON application #10420, page 29

Bone Marrow Transplant Planning Area Resident Patient Flows

The applicant asserts that based on Agency inpatient hospital discharge data for CY 2014, at least 42 percent of OTSA 4 residents left the South Florida Area to receive care in either Tampa (Moffitt) or Jacksonville (Mayo). See the table below.

**OTSA 4 Residents
Adult (Age 15+) Inpatient BMT Patient Destination Data / CY 2014**

Program	Discharges	Percent of Total Discharges
H. Lee Moffitt	62	41%
Univ. of Miami Hospital	58	38%
Memorial Hospital West	12	8%
Mayo Clinic	2	1%
All Other	18	12%
Total	152	

Source: CON application #10420, page 30

More recent Agency inpatient hospital discharge data for the 12 months ending June 30, 2015 previously showed that outmigration occurred in 25 of 78 (or 25.64 percent) of cases for MS-DRG 14, 16 and 17, indicating some migration but at a more moderate rate (25.64 percent compared to 42 percent as contended by BHM).

Forecast Bone Marrow Transplant Planning Area Resident Volume

BHM forecasts 348 discharges by 2018 (year one) and 373 discharges by (year three). According to BHM, this estimate is based on the discharge data referenced above, plus the assumption that total planning area adult resident BMT volume will increase by 13 percent for 2014 to 2018 and an additional seven percent from 2018 to 2020. BHM contends that this growth rate is based upon planning area market forecasts by “the

Advisory Board’s Oncology Forecaster”, which factors population growth, population age mix changes, cancer incidence shifts and changes in expected cancer treatment approaches into its forecast methodology. See the table below.

**OTSA 4 Total (IP and OP) Bone Marrow Transplant Volume
Residents Age 15+, CY 2014 / 2018 / 2020**

	Discharges Age 15+
2014 Baseline	308
2018 Forecast	348
2020 Forecast	373

Source: CON application #10420, page 31

In 2018 (year one), the applicant forecasts 31 adult BMT cases (a nine percent market share) and in 2020 (year three), the applicant forecasts 52 cases (a 14 percent market share, from within the planning area). See the table below.

**Baptist Hospital of Miami
Forecast 2018/2020 Adult BMT Cases from the Planning Area**

	Total Planning Area Resident Adult BMT Cases	Forecast Market Share	Forecast Baptist Hospital of Miami Planning Area BMT Cases
2018	348	9%	31
2020	373	14%	52

Source: CON application #10420, page 32

BHM states that due to its and BHSF’s geographic patient draw internationally and from beyond South Florida, the applicant anticipates a 10 percent in-migration factor which increases total anticipated cases to 34 in 2018 (year one) and 58 in 2020 (year three). See the table below.

**Baptist Hospital of Miami
Forecast 2018/2020 Total Adult BMT Cases**

	Forecast Baptist Hospital of Miami Planning BMT Cases	Forecast In-Migration from Beyond the Planning Area	Forecast Total Baptist Hospital of Miami BMT Cases
2018	31	10%	34
2020	52	10%	58

Source: CON application #10420, page 32

The applicant discusses that Baptist oncologists have recently referred an adequate volume of adult BMT area patients to validate the anticipated case estimates shown above.

No Material Adverse Impact on Existing Adult BMT Providers

BHM anticipates no material adverse impact due to case shifts among the two largest (by volume) allogeneic and autologous bone marrow transplantation providers who serve TSA 4 residents – H. Lee Moffitt Cancer Center and University of Miami Hospital and Clinics. In both year one and year three of the proposed project, BHM expects that H. Lee Moffitt Cancer Center will still realize over 400 cases and that the University of Miami Hospital and Clinics will still realize over 100 cases, stating that these are strong volumes. See the table below.

**OTSA 4 Shift of Resident Adult BMT Patients to Baptist
No Market Growth Offset**

	2018	2020
Proposed Baptist BMT Cases from Planning Area	31	52
Moffitt Percent of Planning Area Adult BMT Cases	41%	41%
University of Miami Percent of Planning Area BMT Cases	38%	38%
Cases Shifted from Moffitt	13	21
Cases Shifted from University of Miami	12	20
Cases Shifted from All Other Providers Combined	6	11
Current Moffitt Adult BMT Cases	453	453
Current University of Miami Adult BMT Cases	133	133
Moffitt Adult BMT Cases After Shift	440	435
University of Miami Adult BMT Cases After Shift	121	113

Source: CON application #10420, page 34

The applicant also provides a table below to account for expected market growth offsets following the shift of OTSA 4 resident adult BMT patients to Baptist Hospital of Miami.

**OTSA 4 Market Growth Offsets Following the Shift of
Resident Adult BMT Patients to Baptist**

	2018	2020
Forecast Baptist Adult BMT Cases for Planning Area	31	52
Forecast Planning Area Adult BMT Cases Growth from 2014 Base	40	65
Net Growth in Adult BMT Cases Beyond Baptist Cases	9	13

Source: CON application #10420, page 34

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

- (a) **Adult Allogeneic Bone Marrow Transplantation Programs: Adult allogeneic bone marrow transplantation programs shall be limited to teaching and research hospitals. Applicants shall meet the following requirements. (Rule 59C-1.044(9)(b) Florida Administrative Code).**

BHM is not a statutory teaching hospital. However, the applicant discusses its medical education and the Graduate Medical Education (GME) program (CON application #10420, pages 65 – 68) and its clinical research activity and capabilities (CON application #10420, pages 68 – 71). Each is discussed briefly below.

The applicant states that BHSF hospitals have teaching activity officially affiliated with FIU's Herbert Wertheim College of Medicine, as well as Fellowship teaching activity associated with the Doctors Hospital-UHZ Sports Medicine Institute Fellowship Program. Research activities are also discussed through the supervision of BHSF physicians. Graduate health care, pharmacy and nursing education (including an RN residency program) are also discussed.

The applicant states that BHM and BHSF together have a large number of active research studies currently underway, and have established and proven research support and infrastructure systems currently in place to support current and future clinical research activity. BHSF maintains that cancer research is a major portion of its research activity, with 90+ current cancer studies underway, accounting for more than 40 percent of all active studies.

- (b) **Applicants shall be able to project that at least 10 adult allogeneic transplants will be performed each year. New units shall be able to project the minimum volume for the third year of operation.**

The applicant estimates 34, 46 and 58 adult inpatient BMT cases in total for the first three years of planned operation.

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

BHM states that a program medical director, consistent with the above defined credentials, is currently being recruited and the position will be filled prior to the initiation of the proposed BMT program.

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

BHM states being an “ANCC-accredited Magnet Hospital” and indicates currently having a large and qualified staff of credentialed nurses with experience in providing quality care to critically ill immune-suppressed patients and support to the patients’ families. According to BHM, the hospital’s existing oncology services – a 48-bed oncology unit “5 Clarke” – is contained within the hospital, with 12 of those beds considered acuity adaptable and dedicated to stepdown level care. BHM asserts that oncology patients admitted to this unit are either acutely ill or chronically ill with cancer, with a large portion of these patients also immuno-suppressed. Per BHM, the unit reports to Nursing Director Dr. Linda Brewer and Jan Roy, a Masters-prepared Patient Care Manager who is certified in oncology nursing and has more than 20 years of oncology nursing experience.

The reviewer notes that the applicant does not include a curriculum vitae of these practitioners (Dr. Linda Brewer or Jan Roy). However, the reviewer notes that the Florida Department of Health (DOH) FLHealthSource.gov website at <https://appsmqa.doh.state.fl.us/MQASearchServices/HealthCareProviders/LicenseVerification?LicInd=18781&ProCde=1701&org=%20>, indicates that Linda J. Brewer is a licensed registered nurse (RN), with this license originally issued on September 8, 1980.

BHM states that it employs more than 130 critical care clinical nurses with experience and competencies in the care of critically-ill immuno-suppressed patients within the Critical Care Unit (CCU). BHM also asserts that all proficient, advanced and expert nurses in the CCU are educated and competent to care for critically-ill, immuno-suppressed patients and have the opportunity to do so with the current patient population. According to the applicant, the hospital’s CCU is nationally recognized as a Gold-status Beacon Unit, 68 percent of all CCU nurses are nationally

certified in critical care and 79 percent hold a Bachelor of Science in Nursing degree or higher. The reviewer notes that the applicant does not include documentation to verify the Gold-status Beacon Unit recognition.

According to BHM, upon initiation of the BMT program, selected nurses from the Oncology Unit and from the existing Critical Care services will be shifted to support the needs of the BMT patients and their families.

- (e) 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.**

The applicant states meeting this criterion having a strong and experienced medical team to support patients in need of bone marrow transplantation, with 19 hematologists and oncologists currently on staff at BHM. BHM states that the hospital's hematologists/oncologists and the CVs of selected members of this staff are included in Appendix 4 (CON application #10420). A review of the applicant's Appendix 4 indicates a list of 18 BHM MCI physicians and a CV for each of four of these 18 physicians. Other board certifications were included in Appendix 4 for these physicians.

The applicant also discusses an experienced team of other medical specialists active at BHM, capable of providing specialty support services to the BMT patients as may be needed (CON application #10420, page 73). The applicant does not name any of these practitioners or offer an appendix for a CV review.

- (f) **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.**

BHM indicates a new, all private room, 8,800 square feet, six bed adult BMT unit on the hospital's Four Main/East patient floor, as part of the proposed project. The applicant indicates that each room will include headwall electrical, data and medical gases to supported the intended patient acuity levels and will be maintained under a positive pressure relative to the adjacent corridor and have a minimum air exchange rate of 12 per hour. The applicant indicates that the proposed project will require a new air handling unit, approximately 18,000 cfm and additionally, this new air handling unit will have MERV 17 (HEPA) final filters and MERV 8 (30 percent) pre-filters, equipped with variable speed drives and UV lights.

The reviewer notes that the applicant does not affirmatively state post-transplant care will include a laminar air flow room, or if and whether the private rooms with positive pressure will have reverse isolation procedures.

- (g) **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.**

BHM states that the hospital currently has an established radiation therapy service, onsite, capable of providing all needed support for the proposed project. BHM assures that sub-lethal x-irradiation, bone marrow ablation and total lymphoid irradiation is currently available within this existing service, with the current radiation therapy team trained and experienced in the delivery of these BMT support therapies.

The applicant indicates that Minesh Mehta, MD, FASTRO, a world renowned board certified radiation oncologist is the Chief of Radiation Therapy at BHM. Dr. Mehta's CV indicates that he is board certified in radiation oncology, has board certification with the United Council for Neurologic Subspecialties, Neuro-Oncology and that he has the following address. The reviewer notes that according to DOH FLHealthSource.gov website at <https://appsmqa.doh.state.fl.us/MQASearchServices/HealthCareProviders/LicenseVerification?LicInd=126372&ProCde=1501&org=%20>, Dr. Minesh P. Mehta is a licensed medical doctor with this license originally issued on November 11, 2015. This licensee's primary practice address is stated to be 22 S Green Street, Baltimore, Maryland 21201. FLHealthSource.gov also indicates that Dr. Mehta is certified by the American Board of Radiology-Radiation Oncology. The reviewer perused the parent's (BHSF's) "Find a Doctor" portion of its website at <https://baptisthealth.net/en/layouts/find-doctor/default.aspx#/tab/default>. This website includes physicians within the BHSF family of hospitals (including BHM). Dr. Mehta does not appear under the radiation oncology specialty tab of this website. The reviewer notes that a January 21, 2016 press release named Dr. Minesh Mehta as Deputy Director and Chief of Radiation Oncology at MCI.

BHM contends that upon completion of the MCI radiation therapy facilities, forecast to be completed by Winter 2017, the following equipment/technologies will be available to support the proposed project:

- Elektra Gamma Knife Perfexion Plus (new)
- Accuray Cyberknife M-6 (new)
- Accuray Tomotherapy HDA (relocated from South Miami Hospital)
- Varian Truebeam STX (relocated from BHM)
- Varian Truebeam (new)

(h) 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.

BHM states that cellular processing services will be provided by OneBlood or other external specialty providers with applicable accreditation and certification. The application includes a signed letter from Rita A. Reik, MD, FCAP, Chief Medical Officer, OneBlood, Inc., dated November 3, 2015. This letter offers OneBlood's services to BHM to support the proposed project. The reviewer notes that while the narrative states that OneBlood will provide services, the appendix does not include a signed or draft contractual arrangement between the parties.

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

BHM states that bone marrow evaluation and cryopreservation will be provided by OneBlood. However, there is no signed or draft contractual arrangement between the parties.

(j) 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.

BHM indicates 200+ current clinical research studies underway within BHSF, including outcome monitoring and long-term patient follow-up, with a strong research infrastructure established and operational within the Health System.

(k) An established research-oriented oncology program.

BHM indicates 90+ current oncology clinical research studies underway within BHSF, including outcome monitoring and long-term patient follow-up, with a strong research infrastructure established and operation within the Health System.

(l) A patient convalescent facility to provide a temporary residence setting for transplant patients during the prolonged convalescence.

BHM states that it works cooperatively with a number of local hotels to ensure that patients and their families have

accessible housing during extended hospital stays or extended recuperative stays. Specifically, the applicant asserts having linkages with various hotels in the Dadeland Mall area, approximately 1.5 miles from the BHM campus. According to the Mapquest.com website, BHM is 2.5 driving miles due east from the Dadeland Mall (at 7535 N. Kendall Drive, Miami, Florida 33156). The reviewer notes that prices indicated among the eight hotels listed by the applicant range in price from a low of \$85.28 (plus taxes and fees) to a high of \$125-\$229 (plus taxes and fees). BHM indicates that the hospital's social work staff currently provides a strong resource for providing assistance to all patients in accessing housing or resolving other non-medical needs.

BHM asserts being in the process of constructing a new hotel facility on the hospital's campus with approximately 180 rooms (with 25 percent to 30 percent being designed as extended stay suites). BHM states this facility will provide a superb setting for BMT patients and their families.

(m) An outpatient unit for close supervision of discharged patients.

BHM maintains that all outpatient support for BMT patients will be provided in the under-construction MCI facilities, located on the hospital's campus. The applicant discusses the function of MCI, with a portion as a cancer clinical facility and another portion as a cancer research facility. BHM points out that the MCI is to be completed prior to the proposed project's planned initiation of service. The applicant indicates that the "outpatient clinic" will be 5,950 square feet.

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.**

The applicant reports having the necessary staff and other resources needed to care for adult BMT patients' chronic illness prior to, during and after the BMT procedure. BHM asserts having or will have 24-hour availability of all required inpatient and outpatient services as well as the facilities necessary to support the proposed project. The applicant reiterates its on-staff hematology and oncology medical staff and that a program director being recruited.

The applicant states having on-staff 24/7 medical support staff including intensive care physicians, cardiologists (including invasive and electro-physiologists), pulmonary medicine physicians (including interventional pulmonologists), infectious disease specialists familiar with the care of severely immune-compromised patients, neurologist, neurosurgeons, gastroenterologists (including interventional gastroenterologists), ophthalmologists, dermatologists, ENT physicians, thoracic surgeons, vascular surgeons, interventional radiologists, psychologists and psychiatrists, including sub-specialty radiologists, orthopedists and urologists.

BHM states having the necessary radiation therapy or high-dose chemotherapy technologies, resources and staff available in-house to prepare patients for the BMT

procedure. The parent's website "Find a Doctor" website referenced earlier has numerous oncology radiation physicians listed as on-staff.

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.**

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.**

BHM states having 32 beds in its CCU with coverage 24 hours a day, seven days a week and is staffed with Critical Care Intensivists and other staff. BHM maintains that all patients in critical care are monitored in the Baptist Health eICU, a remote monitoring system by critical care intensivists and nurses.

The applicant does not specifically address prolonged reverse isolation when required.

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

BHM assures that a clinical review committee (CRR) will be established to evaluate all potential patients regarding the suitability of the patient to be served by the proposed project. According to BHM, the CRR members are at a minimum:

- BMT Medical Director and other BMT physician staff
- Medical support staff including-
 - BHM laboratory/pathology/blood bank staff
 - Infectious disease staff
 - Psychology/psychiatry staff

- Nursing/support staff including-
 - Program manager/coordinator
 - Program research/data manager
 - Social worker
 - Financial analyst
 - Pharmacist
 - Dietician

BHM maintains that the CCR will meet at least weekly and if a patient is initially identified as an appropriate candidate for BMT, the patient will undergo a comprehensive pre-transplantation evaluation. Steps regarding continued CCR activities is discussed (for continued patient eligibility or if a patient is found not appropriate for the proposed service).

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.

BHM states that written protocols for the proposed project will be established prior to the initiation of the service. BHM assures that these protocols and guidelines will be modeled after existing program protocols and guidelines utilized successfully at regional and national programs and will be consistent with the guidelines as defined by the Foundation for the Accreditation of Cellular Therapy (FACT), the National Marrow Donor Program and the American Society of Blood and Marrow Transplantation. The following protocols/guidelines are provided: Autologous BMT Roadmap, Allogeneic BMT Recipient and Donor Roadmap, Patient Selection, Evaluation, Treatment and Management and the Post-Transplant Plan of Care-Low Term-Follow-Up.

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.

The applicant states that written protocols defining therapeutic and evaluative procedures for the acute and long term management of each BMT patient will be established prior to the initiation of the proposed project. BHM assures that these protocols and guidelines will be modeled after

existing program protocols and guidelines utilized successfully at regional and national programs and will be consistent with the guidelines as defined by the FACT, the National Marrow Donor Program and the American Society of Blood and Marrow Transplantation.

BHM discusses infection and Graft Versus Host Disease (GVHD)--both acute GVHD and chronic GVHD. BHM asserts that its BMT medical and support team will be trained and prepared for infection issues/GVHD issues in the proposed program and will provide all necessary care to treat these conditions when they occur. The applicant also mentions side effects that staff will be prepared to address as well as post-transplant protocols.

- 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.**

BHM states plans to work with the OneBlood organization to provide all necessary tissue typing services.

- 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.**

BHM indicates that the Laboratory Department at BHM offers a full range of services in order to aid the organization's medical staff in determining cause and course of disease through the analysis of tissues, blood and other body fluids. BHM contends that its in-house expertise and infrastructure, combined with the OneBlood external resources, will ensure that all BMT patients will have the

required laboratory support to optimally meet their medical needs. BHM states the scope of services currently available within the Laboratory Department includes:

- Chemistry
- Coagulation
- Cytology
- Flow cytometry
- Hematology
- Histology
- Microbiology
- Phlebotomy
- Serology
- Transfusion service
- Urinalysis

BHM maintains that laboratory services are provided 24 hours a day, seven days a week and is led by Edwin Gould, MD. According to Dr. Gould's CV (CON application #10420, Appendix 7), his position is Medical Director, Laboratories, Baptist Hospital of Miami and he is certified in Anatomic and Clinical Pathology by the American Board of Pathology.

The reviewer notes that according to DOH FLHealthSource.gov website at <https://appsmqa.doh.state.fl.us/MQASearchServices/HealthCareProviders/Details?LicInd=27962&ProCde=1501>, Dr. Edwin Warren Gould is a licensed medical doctor with this license originally issued on December 18, 1979. This licensee's primary practice address is Baptist Hospital of Miami and this practitioner is certified by the American Board of Pathology.

BHM assures that the BHM Laboratory is accredited by the College of American Pathologists (CAP), adheres to all applicable standards, is licensed by the State of Florida and maintains a CLIA Laboratory Certificate of Accreditation. The reviewer notes that that BHM does not include a copy of its reported State of Florida laboratory license or its CLIA Laboratory Certificate of Accreditation.

10. Blood banking facilities.

BHM states that the existing blood banking and transfusion facilities and services currently in existence at BHM are appropriate for supporting the blood requirements of the proposed project and reiterates the services of OneBlood. The applicant lists its existing transfusion services on pages 52-53 of CON application #10420. The reviewer notes that the applicant makes no statement of whether the blood banking operation is part of or separate from the BHM Laboratory Department.

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

BHM indicates that its established and proven Clinical Learning Department will be used to establish a comprehensive education and training program for the staff dedicated to the proposed program. The applicant points out that clinical learning falls under the scope of the Corporate Chief Nursing Officer of BHSF. The applicant names 30 staff that are part of the Clinical Learning Department. The reviewer notes that many of these staff are RNs, with most have other advanced education and/or licensures. The applicant also lists seven additional departments/processes that support the Clinical Learning Department.

BHM broadly discuss in detail its hospital-wide training and education programs, particularly its nursing training program, asserting that all staff education, training infrastructure and expertise will be used to ensure that the staff of the new BMT program patients will be fully trained and supported to provide optimal levels of patient care.

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

BHM assures that a comprehensive education program for patients, their families and patient's primary care physicians will be established prior to the initiation of the proposed

project. Topics to be included include:

- Understanding bone marrow transplant
- The transplant process
- Post-transplant
- Discharge from the transplant program

BHM indicates that in addition to providing a focused BMT educational program, all patients/family members involved with the BMT program will also be directed to access the hospital's health information resources, including the "Baptist's Health Library". CON application #10420, Appendix 9, includes the patient information brochures *Transplant Basics*, *Understanding Transplant* and *How It Works*, distributed by the National Bone Marrow Donor Program.

- 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.**

BHM reiterates having 19 hematologists and oncologists currently on staff at BHM, having a strong and experienced medical team to support patients in need of bone marrow transplantation as well as a program medical director who is currently being recruited and the position will be filled prior to the initiation of the proposed BMT program.

Regarding the criterion for a physician with one-year experience in the management of infectious diseases shall be a member of the transplant team, the reviewer notes that none of the physician CVs included in CON application #10420, Appendix 4, include a physician that is board-certified in infectious disease. However, the reviewer

perused the parent's (BHSF's) "Find a Doctor" portion of its website at <https://baptisthealth.net/en/layouts/find-doctor/default.aspx#/tab/default>. This website includes numerous physicians within the BHSF family of hospitals (including BHM) with infectious disease specialties. The reviewer notes that the applicant does not state that any of these physicians, board certified in infectious disease, will be included in the proposed transplant team.

- 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.**

BHM reiterated that BHM states that a program medical director, consistent with the above defined credentials, is currently being recruited and the position will be filled prior to the initiation of the proposed BMT program.

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

This criterion is not applicable.

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

BHM contends having a large and qualified staff of credentialed nurses that meet this requirement that operates an existing 48-bed Oncology Unit with 12 of these beds considered acuity adaptable and dedicated to Stepdown level care. The applicant states that oncology patients admitted to this unit are either acutely ill or chronically ill with cancer.

The applicant reiterated Nursing Director Dr. Linda Brewer and Jay Roy, a Masters-prepared Patient Care Manager who is certified in oncology nursing and has more than 20 years of oncology nursing experience.

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.

BHM states having current expertise, staff and resources necessary to meet the blood banking needs of the proposed project. The applicant reiterates the resources of OneBlood and its existing transfusion services.

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

BHM states that specific to the proposed program, the hospital's existing oncology nutritional support resources will be used to provide care to BMT patients. The applicant asserts that its registered dietitians (RDs) are Florida licensed with certification in oncology and nutrition support. Below are the listed dietician/nutrition staff that the applicant indicates are actively working primarily with oncology patients:

- Karla Otero, RD, LD/N, CDE, CSO (registered and licensed dietitian, certified diabetes educator, certified specialist oncology)
- Alice Pereira, RD, LD/N, CDE, CSO (registered and licensed dietitian, certified diabetes educator, certified specialist oncology)
- Maria G. Townsend (Lupita), MS, RD, LD/N, SNSC, CSO, (Master's degree, registered and licensed dietitian, certified nutrition support clinician, certified specialist oncology)

Additional Nutrition Support Team Members are:

- Caitlin Coughlin, RD, LD/N, CNSC
- Ann Merrill, RN, CNSC
- Che Chan, RPh, SNSC

According to BHM, this experience core group of nutrition support professionals will be used as a starting point in establishing the nutrition support services for the proposed project. The reviewer notes that the applicant does not affirmatively state that any of the nutritionists listed in this section have expertise in the needs of transplant patients. The applicant does not offer the resume of any of these practitioners.

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

BHM states having 83 registered respiratory therapists (RRTs) within the Respiratory Department overseen by John Bayer, who is a Masters-prepared RRT with 20 years of experience eight additional RRTs in the Pulmonary Laboratory. BHM contends that its RRTs are specifically experienced in providing respiratory support to immunosuppressed patients, such as will occur among patients in the proposed program, and each has expertise and training in providing care to the hospital's oncology patients. The applicant asserts that prior to opening the proposed program, the RRTs who will provide respiratory care for the new patients will receive structured education about current standards of respiratory and pulmonary care for bone marrow patients by an expert in the field.

The reviewer notes that the applicant does not affirmatively state that any of its RRTs have expertise in the respiratory needs of transplant patients. The applicant does not offer the resume of any of these practitioners.

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.

BHM states currently having a full complement of psychologists, psychiatrists and social workers to work with its patients, including its oncology patients seen at the hospital. BHM maintains that its Social Work Department will ultimately have social workers specifically trained and assigned to support bone marrow transplant patients and families. BHM asserts that the BMT social workers will be knowledgeable in the spectrum of community services and assets available to support bone marrow transplant patients and their families throughout the full continuum of bone marrow care, including pre- and post-transplant care. The applicant also states that one of its financial counselors will be trained specifically for this patient population.

9. **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 that it fully cooperates with the Agency in providing all required data and information requested by the Agency. BHM assures that once the proposed project is operational, all required BMT data will likewise be submitted to the Agency. BHM asserts plans to also report BMT data to applicable national BMT data/information networks.

3. Statutory Review Criteria

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

The mileage chart below indicates the driving distances to the nearest seven Florida adult inpatient bone marrow transplant providers from the proposed location for CON application #10420.

Driving Distances in Miles – CON application #10420 Baptist Hospital of Miami, Inc., d/b/a Baptist Hospital of Miami and Florida Adult Inpatient Bone Marrow Transplantation Providers								
Facility	Baptist Hospital of Miami	Univ. of Miami Hospital & Clinics	Memorial Hospital West	Good Samaritan Medical Center	Florida Hospital -Orlando	H. Lee Moffitt Cancer Center	UF Health Shands Hospital	Mayo Clinic
Baptist Hospital of Miami		13.9	28.5	82.3	251.9	282.8	349.4	357.6
University of Miami Hospital & Clinics	13.9		21.0	69.7	235.2	282.2	332.7	341.7
Memorial Hospital West	28.5	21.0		63.8	229.7	263.3	327.2	336.2
Good Samaritan Medical Center	82.3	69.7	63.8		172.5	205.5	270.1	281.8
Florida Hospital-Orlando	251.9	235.2	229.7	172.5		87.0	114.4	137.4
H. Lee Moffitt Cancer Center	282.8	282.2	263.3	205.5	87.0		122.6	208.0
UF Health Shands Hospital	349.4	332.7	327.2	270.1	114.4	122.6		89.1
Mayo Clinic	357.6	341.7	336.2	281.8	137.4	208.0	89.1	

Source: www.Mapquest.com

The chart above illustrates that from the proposed **CON application #10420**, the nearest adult inpatient bone marrow transplant provider (University of Miami Hospital & Clinics) is 13.9 miles, the second nearest provider (Memorial Hospital West) is 28.5 miles and the final OTSA 4 provider (Good Samaritan Medical Center) is 82.3 miles. For the five-year period ending June 30, 2015, the highest volume provider in OTSA 4 was University of Miami Hospital & Clinics and the highest volume provider statewide was H. Lee Moffitt Cancer Center. OTSA 4 is the only service area with more than two operational adult inpatient bone marrow transplant providers and if the proposed project is approved, Service Area 4 would have four such providers.

Data reported to the Agency for the most recent reporting period, July 1, 2014 through June 30, 2015 show the following adult inpatient bone marrow transplant utilization data:

Florida Adult Bone Marrow Transplantation Program Utilization July 2014 – June 2015			
Hospital	OTSA	District	Total Procedures
UF Health Shands Hospital	1	3	149
Mayo Clinic	1	4	87
H. Lee Moffitt Cancer Center	2	6	453
Florida Hospital-Orlando	3	7	148
Good Samaritan Medical Center	4	9	148
Memorial Hospital West	4	10	22
Univ. of Miami Hosp. & Clinics	4	11	133
		TOTAL	1,140

Source: *Agency for Health Care Administration Utilization Data for Adult Organ Transplantation Programs*, published October 2, 2015

As previously stated, for the 12-month period ending June 30, 2015, the majority of OTSA 4 residents seeking adult inpatient bone marrow transplant (74.36 percent) have had this procedure performed at a OTSA 4 provider location, with 24.36 percent of patients receiving care at H. Lee Moffitt Cancer Center and one patient received the procedure at Mayo Clinic. For the period, outmigration occurred in a total of 20 of 78 cases (25.64 percent). See the table below.

**OTSA 4 Adult Residents (Age 15 or Older)
With a Blood or Bone Marrow Transplant Discharge (MS-DRGs 14, 16 and 17) 009
12 Months Ending June 30, 2015**

Hospital	Total Procedures	Percentage
Broward Health Medical Center	1	1.28%
Delray Medical Center	1	1.28%
Good Samaritan Medical Center	2	2.56%
H. Lee Moffitt Cancer Center	19	24.36%
Jackson Memorial Hospital	1	1.28%
Mayo Clinic	1	1.28%
Memorial Hospital West	11	14.10%
Miami Children's Hospital	1	1.28%
University of Miami Hospital and Clinics	41	52.56%
Total Procedures	78	100.00%

Source: Florida Center for Health Information and Policy Analysis database run date of January 6, 2016

In 2018 (year one), the applicant forecasts 31 adult BMT cases and in 2020 (year three), the applicant forecasts 52 cases, from within the planning area.

BHM contends that need for the proposed project is based on the overall health policy goal to ensure that local South Florida BMT patients have a quality, patient acceptable, local BMT service option which will support a larger portion of local residents staying within the South Florida area to obtain BMT cases. BHM contends that the existing adult BMT provider network (in OTSA 4) is not providing adequate service to meet local needs. The Agency notes that OTSA 4 has the largest number of adult BMT providers (three) of any service area statewide.

BHM asserts that the actual provider selection made by local residents and the actual patient decision to not use local programs, documents that a new service offering is needed to appropriately meet local needs. The Agency notes that the applicant has not shown a local area lack of availability or a lack of accessibility for the tertiary service being proposed but has shown some patient preference to receive the service outside OTSA 4. BHM concludes that outmigration (in the local area) is a significant local cancer treatment system limitation and a major driver in developing the proposed program. The applicant contends that the existing OTSA 4 adult BMT providers are mature, stable programs with varying focuses that can withstand the proposed project.

- 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.**

BHSF, the parent, states that its distinctive pineapple logo, an age-old symbol of hospitality, reflects a patient-centered focus of warmth and welcome. BHSF indicates that all its centers are fully accredited by The

Joint Commission and follow rigorous quality standards. BHM asserts having a long and illustrative history of providing patient care that is among the highest quality within the industry. The parent states that it maintains a Committee on Quality and Patient Safety and a Center for Performance Excellence (CPE).

BHM includes a 14-page Performance Improvement (PI) Plan in Appendix 15 of CON application #10420. The reviewer notes that page one of the PI Plan has six approval signature lines - none include a signature. The reviewer notes that the presented PI Plan cannot be verified as to being in effect based on the information provided. According to the applicant, the PI Plan describes the process for promoting awareness and providing guidance in the continuous improvement of clinical practice, support services, patient safety and leadership.

The applicant notes that BHSF and BHM have received many accolades including top honors for National Quality Measures from The Joint Commission and being ranked among the top hospitals nationwide by U. S. News & World Report. According to the applicant, The Joint Commission awarded BHSF *27 Top Performer* status designations, including awarding BHM eight *Top Performer* status designations. BHM asserts that U. S. News & World Report recognized BHSF with numerous “high performing” awards and that for the fourth year in a row, BHSF was the most decorated health care provider in the region (Miami Metro Area) by U. S. News & World Report. Other stated awards/recognitions for the parent and/or the applicant include:

- Outstanding Achievement-American College of Surgeons’ Commission on Cancer
- The Commonwealth Fund
- Press Ganey (issuing 18 awards for patient satisfaction)
- Leapfrog Group (Fall 2015) issuing “all eligible Baptist Health hospitals with “straight A’s” acknowledging these providers as among the safest providers in South Florida and the country
- Gold-Level Beacon Award for Excellence from the American Association of Critical Care Nurses
- 100 Best Companies to Work For: #19 in the nation and #1 in Florida – Fortune
- Most Diverse of Fortune 100 Best Companies to Work For – Fortune
- World’s Most Ethical Companies – Ethisphere Institute
- Best Employers for Healthy Lifestyles – Platinum Award – National Business Group on Health
- Most Wired Hospitals and Health Systems – Hospital & Health Networks

CON application #10420 does not include The Joint Commission accreditation or the Agency licensure for the applicant. The reviewer performed an Agency records search and found that Baptist Hospital of Miami, Inc.’s most recent Agency license was effective July 1, 2015 and expires June 30, 2017.

Baptist Health South Florida operates five Miami-Dade County hospitals and one Monroe County hospital (six hospitals in total within District 11), with a cumulative total of 1,151 licensed beds. Agency complaint records indicate, for the three-year period ending November 18, 2015, BHSF had seven substantiated complaints. Baptist Hospital of Miami had two substantiated complaints of the seven. The substantiated complaint categories for BHM were Nursing Services and Quality of Care/Treatment (one substantiated complaint each). A single complaint can encompass multiple compliant categories. Please see the chart below.

Baptist Health South Florida Substantiated Complaint Categories for the 36 Months Ending November 18, 2015	
Complaint Category	Number Substantiated
Nursing Services	3
Infection Control	2
Quality of Care/Treatment	2
Emergency Access	1
Resident/Patient/Client Assessment	1
Resident/Patient/Client Rights	1

Source: Agency Complaint Records

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

Analysis:

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 South Florida, Inc. and Affiliates (parent of the applicant) where the short term and long term measures fall on the scale (highlighted in gray) for the most recent year.

CON 10420, Baptist Health South Florida, Inc. and Affiliates		
	Sep-14	Sep-13
Current Assets	\$469,908,522	\$422,754,096
Total Assets	\$4,759,610,671	\$4,376,055,223
Current Liabilities	\$536,102,861	\$471,974,549
Total Liabilities	\$1,672,475,641	\$1,658,685,965
Net Assets	\$3,087,135,030	\$2,717,369,258
Total Revenues	\$2,281,002,309	\$2,170,068,871
Excess of Revenues Over Expenses	\$356,521,571	\$372,491,540
Cash Flow from Operations	\$338,548,199	\$355,951,976
Short-Term Analysis		
Current Ratio (CA/CL)	0.9	0.9
Cash Flow to Current Liabilities (CFO/CL)	63.15%	75.42%
Long-Term Analysis		
Long-Term Debt to Net Assets (TL-CL/NA)	36.8%	43.7%
Total Margin (ER/TR)	15.63%	17.16%
Measure of Available Funding		
Working Capital	(\$66,194,339)	(\$49,220,453)

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%	1 50%-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 \$147,576,138 which includes \$8,303,255 for this project. The applicant indicates on Schedule 3 of its application that funding for the project will be provided by the applicant from available cash on hand.

The applicant provided a copy of the December 31, 2014 audited financial statements for its parent. A letter of financial commitment from Baptist Health South Florida, Inc.’s executive vice president and chief financial officer was also included. 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 applicant has an adequate financial position.

Staffing:

The table below shows the Baptist Hospital of Miami’s projected staffing for the proposed project in years one and two, ending 2018 and 2019, respectively. The reviewer notes that the applicant’s Schedule 6A year one and year two ending dates differ from the applicant’s Schedule 7A year one and year two ending dates (September 2018 and September 2019, respectively, for Schedule 7A). The reviewer also notes that the applicant’s Schedule 10 shows initiation of service in October 2017, which would indicate year one ending in September 2018, which is consistent with Schedule 7A but not Schedule 6A. In both year one and year two, BHM expects the total FTE counts to remain constant, with no FTE change in either of the stated FTE categories. The table below accounts for FTEs to be added as a result of the proposed project, if approved.

Baptist Hospital of Miami, Inc., d/b/a Baptist Hospital of Miami CON application #10420 Adult Inpatient Autologous and Allogeneic Bone Marrow Transplantation Program Staffing Patterns		
	Year One Ending 2018	Year Two Ending 2019
ADMINISTRATION		
Administrator	0.5	0.5
NURSING		
R.N.s	9.42	9.42
Nurse’s Aides (Techs)	4.66	4.66
Other: Non-DPC Nurses	1.00	1.00
TOTAL	15.58	15.58

Source: CON application #10420, Schedule 6A

The applicant states that forecast staff requirements to support the proposed project are based upon an estimate of the incremental staff required to support the Baptist hospital/inpatient portion of the adult bone marrow transplantation program. The applicant also states that due to the low inpatient volume anticipated for the proposed program during the first few years of operation, only direct care incremental staff is anticipated.

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.

The immediate and long-term financial feasibility of the project is tied to expected profitability. The purpose of our analysis for this section is to evaluate the reasonableness of the applicant's profitability projections and, ultimately, whether profitability is achievable for this project. Typically, our analysis includes an evaluation of net revenue per patient day (NRPD), cost per patient day (CPD) and profitability, where we compare the NRPD, CPD and profitability to actual operating results from related hospitals as reported on Florida Hospital Uniform Reporting System reports and adjust for inflation.

In this instance, however, the applicant provided Schedule 7 projected revenue for the proposed transplant program only, and did not provide projected revenue for the combined operations. Because the grouping data of like-hospitals reflects revenues and expense data for combined operations and not specific programs, any comparison for program-specific revenues to total/combined revenues making up the group averages would be invalid. As a result, net revenues and overall profitability cannot be analyzed.

However, staff notes that the parent company had \$470 million in current assets and \$338.5 in cash flow from operations at September 30, 2014. With anticipated project costs of \$8.3 million and projected project operating expenses of \$1.6 million in year one and \$1.8 in year two, the applicant should be able to absorb all the costs of the project.

Conclusion:

This project appears to be financially feasible based on the low project cost and funding available to the applicant.

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

No. Due to the health care industry's existing barriers in consumer-based competition, this project will not likely foster the type competition generally expected to promote quality and cost-effectiveness.

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

Price-Based Competition is Limited - Medicare and Medicaid account for 41.2 percent of hospital charges in Florida, while HMO/PPOs account for approximately 45.9 percent of charges. While HMO/PPOs negotiate prices, fixed price government payers like Medicare and Medicaid do not. Therefore, price-based competition is limited to non-government payers. Price based competition is further restricted as Medicare reimbursement in many cases is seen as the starting point for price negotiation among non-government payers. In this case, 48.5 percent of patient days are expected to come from Medicare and Medicaid with 40.2 percent from HMO/PPOs.

The User and Purchaser of Health Care are Often Different – Roughly 87.1 percent of hospital charges in Florida are from Medicare, Medicaid, and HMO/PPOs. The individuals covered by these payers pay little to none of the costs for the services received. Since the user is not paying the full cost directly for service, there is no incentive to shop around for the best deal. This further makes price based competition irrelevant.

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

In addition to the above barriers to competition, a study presented in The Dartmouth Atlas of Health Care 2008 suggests that the primary cost driver in Medicare payments is availability of medical resources. The study found that excess supply of medical resources (beds, doctors, equipment, specialist, etc.) was highly correlated with higher cost per

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

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 and 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 and propose the provision of 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.**

Below is a chart to account for the applicant’s and the district’s Medicaid/Medicaid HMO and charity care percentages for fiscal year (FY) 2014 provided by the Agency’s Florida Hospital Uniform Reporting System (FHURS).

**Medicaid and Charity Care for
Baptist Hospital of Miami, Inc. (CON application #10420)
Compared to the District for FY 2014**

Applicant	Medicaid and Medicaid HMO Days	Charity Percentage Service	Combined Medicaid and Charity Care
Baptist Hospital of Miami*	19.58%	5.30%	24.88%
District 11 Average	22.78%	4.24%	27.02%

Source: Fiscal Year 2014 Agency for Health Care Administration Actual Hospital Budget Data
Note: * For this review, Baptist Hospital of Miami’s fiscal year ended 9/30/2014

The table below illustrates BHM’s FY 2015-2016 low-income pool (LIP) participation, as of December 10, 2015. The applicant did not participate in the disproportionate share hospital (DSH) program for FY 2015-2016.

Baptist Hospital of Miami, Inc. (CON application #10420) LIP Program Participation for FY 2015-2016		
Applicant/Program	Annual Total Allocation	Year-to-Date Total Allocation As of December 10, 2015
Baptist Hospital of Miami/LIP	\$1,220,091	\$0.00

Source: Florida Agency for Health Care Administration, Division of Medicaid, Office of Program Finance

BHSF state that it has a proven history of providing health services to Medicaid patients and the medically indigent. Further stated is that the proposed project will likewise provide adult marrow transplant services to all patients in need, including Medicaid and medically indigent patients who are medically appropriate to participate in the program.

The parent (BHSF) indicates providing \$301 million in total community benefit in FY 2015 – at cost. The parent notes that this is approximately 13 percent of the its net patient revenue after bad debt and is “well more” than the estimated value of Baptist’s not-for-profit exemptions – estimated to be \$101.8 million for 2015. The applicant breaks down into categories these community costs, including over \$2.9 million (at cost) in community education programs and over \$2.5 million in community clinic support. The applicant contends that other than Jackson

Memorial Hospital, BHM provides the largest amount of charity care within Miami-Dade County (excluding specialty providers). BHSF asserts providing free health care to people with household incomes up to three times (300 percent) the federal poverty level.

Using the Agency 2013 Hospital Financial Data Report, the applicant provides the following Miami-Dade County acute care hospital profile.

Miami-Dade County Acute Care Hospital Profile - 2013

	Baptist Hospital	Homestead Hospital	All Baptist Miami-Dade Hospitals	All Miami-Dade Acute Care Hospitals	Miami-Dade Hospitals w/o Jackson
Medicaid Days	33,247	13,068	77,664	352,947	248,400
Total Days	176,206	33,011	340,583	1,609,565	1,211,403
Percent Medicaid	18.9%	39.6%	22.8%	21.9%	20.5%
Charity \$\$ (000s)	\$184,463	\$101,443	\$409,858	\$1,148,345	\$802,385
Gross Revenue (000s)	\$3,426,964	\$846,359	\$7,278,334	\$26,854,374	\$22,817,524
Percent Charity	5.4%	12.0%	5.6%	4.3%	3.5%

Source: CON application #10420, page 98

The reviewer notes that statewide during the 12-month period ending June 30, 2015, there were 36 Medicaid/Medicaid Managed Care patients that received adult bone marrow transplantation based on the Agency’s Florida Center for Health Information and Policy Analysis hospital discharge data.

Baptist Hospital conditions that the applicant will provide at least 10 percent of transplant case volume on an annual basis to Medicaid/Medicaid Managed Care/charity/self-pay patients.

According to Schedule 7A, BHM intends to provide in the proposed adult allogeneic and autologous bone marrow transplantation program 21.3 percent Medicaid/Medicaid HMO and 0.00 percent Self-Pay in year one (ending September 2018) and 21.4 percent Medicaid/Medicaid HMO and 0.00 percent self-pay in year two (ending September 2019) total annual patient days. The reviewer notes that Schedule 7A and the Schedule 7A assumptions do not specifically allocate any patient days to charity care but according to CON application #10420, page 99, an additional five percent of program volume is forecast to be provided to charity care patients.

F. SUMMARY

Baptist Hospital of Miami, Inc. d/b/a Baptist Hospital of Miami (CON application #10420) proposes to establish an adult inpatient autologous and allogeneic bone marrow transplantation program at Baptist Hospital of Miami, in Miami, Florida, OTSA 4. BHM presently does not provide outpatient adult bone marrow transplant services.

Project costs total \$8,303,255. The project involves 14,750 GSF of renovated space (no new construction) with total renovation costs of \$6,337,500. Total project costs include building, equipment, project development and start-up costs.

The applicant proposes to condition the project as shown on page four of this report.

Need/Access

There is no fixed need pool publication for adult bone marrow transplantation programs. It is the applicant's responsibility to demonstrate the need for the project.

There are presently three operational adult inpatient bone marrow transplant programs in OTSA 4, with no CON approved adult inpatient bone marrow transplantation programs pending licensure. These three operational programs are at the following locations: Good Samaritan Medical Center (Palm Beach County), Memorial Hospital West (Broward County) and University of Miami Hospital & Clinics (Miami-Dade County).

The applicant projects 31 (year one ending 2018), 46 (year two ending 2019) and 52 (year three ending 2020) adult inpatient bone marrow transplants to be drawn from OTSA 4. Considering all cases, including anticipated in-migration, the applicant projects 40 (year one) and 65 (year three) total adult inpatient bone marrow transplants. The applicant contends that the following support need for the proposed project:

- To achieve the overall health policy goal to ensure that local South Florida BMT patients have a quality, patient acceptable, local BMT service option which will support a larger portion of local residents staying within the South Florida area to obtain BMT services
- Existing adult BMT providers are not offering adequate service to meet local needs
- Actual provider selection made by local residents and the actual patient decision to not use local programs document that a new service offering is needed to appropriately meet local needs

- Outmigration is a significant local cancer treatment system limitation and a reduction of this outmigration level is a major driver in developing the proposed program
- Existing area adult BMT providers are mature, stable programs with varying focuses that can withstand the proposed project

The Agency notes that the applicant has demonstrated some patient preference to opt to receive the service outside OTSA 4. The election to receive a service outside the service area does not in and of itself demonstrate a lack of availability or a lack of accessibility. The Agency notes that outpatient adult bone marrow transplantation services may be provided by BHM without CON approval.

Quality of Care

The applicant demonstrated plans to meet the rule requirements per Chapter 59C-1.044, Florida Administrative Code, with regard to the provision of quality of care for the proposed transplant program. Demonstrated quality of care measures through numerous awards and recognitions are shown. Policies and protocols to accommodate the proposed project are in place or are in development and will be complete prior to initiation of service.

Agency complaint records indicate that the parent's (BHSF's) six hospitals had seven substantiated complaints for the three-year period ending November 18, 2015. BHM had two of the seven complaints.

The applicant has described its ability to provide quality of care.

Cost/Financial Analysis

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

Medicaid/Charity Care Commitment

- According to the Agency's 2013 FHURS Data Report, BHM provided 19.58 percent of its total annual patient days to Medicaid/Medicaid HMO patients and 5.30 percent to charity care patients in FY 2014
- BHM is a LIP but not a DSH participating hospital. For the 2015-2016 fiscal year, BHM was allocated \$1,220,091 in LIP funding but as of December 10, 2015, BHM had received \$0.00 of this allocation

- According to Schedule 7A, BHM intends to provide in the proposed adult allogeneic and autologous bone marrow transplantation program 21.3 percent Medicaid/Medicaid HMO and 0.00 percent self-pay in year one (ending September 2018) and 21.4 percent Medicaid/Medicaid HMO and 0.00 percent self-pay in year two (ending September 2019) total annual patient days
- According to Schedule 7A and the Schedule 7A assumptions, no specific allocation of patient days to charity care is indicated, however, BHM indicates that an additional five percent of program volume is forecast to be provided to charity care patients
- Baptist Hospital conditions that the applicant will provide at least 10 percent of transplant case volume on an annual basis to Medicaid/Medicaid Managed Care/charity/self-pay patients

Architectural Analysis

- 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

G. RECOMMENDATION

Approve CON #10420 to establish an adult inpatient autologous and allogeneic bone marrow transplantation program in Organ Transplantation Service Area 4. The total project cost is \$8,303,255. The project involves 14,750 GSF of renovated space and a total renovation cost of \$6,337,500.

CONDITIONS:

- The proposed adult BMT program will be located at Baptist Hospital of Miami, located at 8900 North Kendall Drive, Miami, Florida.
- A fully qualified adult allogeneic and autologous bone marrow transplant Medical Director, meeting all allogeneic and autologous criteria requirements will be in place and active in the BMT program prior to program initiation.
- Baptist Hospital will delicense 12 acute care beds upon the completion of the 4 Main East renovation and the establishment of the new bone marrow treatment program.
- Baptist Hospital will provide at least 10 percent of transplant case volume on an annual basis to Medicaid/Medicaid Managed Care/charity/self-pay patients.

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