

**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 #10490**  
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 #10490)** submitted letters of support from community members and patients, members of the Florida legislature and local government officials, academic faculty, health care providers and organizations affiliated with Baptist Health South Florida.

Form letters were present among the majority of letters of support.

Themes of the letters of support are documented below:

- Twenty-seven percent of south Florida Residents requiring inpatient bone marrow transplantation out-migrated for care which presents a significant emotional and financial burden on severely ill patients. South Florida residents need greater access to bone marrow transplantation services locally.

- The demand for adult bone marrow transplant services will increase as the south Florida population ages and elderly individuals migrate to south Florida for care.
- Baptist Hospital is one of the largest providers of cancer care in south Florida and an adult bone marrow transplantation program would enhance the organization's capacity to expand clinical research and quality cancer care to the residents of south Florida.
- Baptist Health's commitment to the community is unmatched by any other local health system.
- Good Samaritan Hospital did not accurately report bone marrow transplantations performed in CY 2016 and as a result use rates for bone marrow transplantation are lower than predicted.
- The opening of Miami Cancer Institute on Baptist Hospital campus and partnerships with Memorial Sloan Kettering situates Baptist Hospital of Miami to accommodate and manage new adult bone marrow transplants.
- Baptist Health provides millions of dollars in charity care and community benefits, services Medicaid recipients at a cost which typically exceeds reimbursement.
- Technology, resources and novel treatments available at the proposed project.

Letters of support are noted from the following individuals:

***Florida Legislature***

- Georgia Moraitis, State Representative, House District 93
- Richard Stark, State Representative, House District 104
- Daisy J. Baez, State Representative, House District 114
- Katie Edwards, State Representative, House District 98
- Anitere Flores, State Senator (President Pro Tempore), District 39
- Rene Garcia, State Senator, District 36
- Kristin Jacobs, State Representative, District 96
- Evan Jenne, State Representative, District 99
- Shevrin D. Jones, State Representative, District 101
- Holly Raschein, State Representative, District 120
- Cynthia A. Stafford, State Representative (House Minority Policy Chair), District 109

***Local Government Officials***

- Peggy R. Bell, Mayor, Cutler Bay, Florida
- Orlando Lopez, Mayor, Sweetwater, Florida
- Eduardo H. Muhina, Mayor, West Miami, Florida
- Jeff Porter, Mayor, Homestead, Florida
- Esteban Bovo, Jr., Chairman, Board of County Commissioners, District 13
- Javier D. Souto, Commissioner, Miami-Dade County, District 10

- Xavier L. Suarez, Miami-Dade County Commissioner, District 7
- Daniel Levine Cava, Commissioner, Miami-Dade County, District 8
- Juan Carlos Bermudez, Mayor, Doral, Florida
- Joseph M. Corradino, Mayor, Pinecrest, Florida
- Audrey M. Edmonson, Vice Chairwoman, Board of County Commissioners, Miami-Dade County
- Eugene P. Flinn, Jr., Mayor, Palmetto Bay, Florida
- Sally A. Heyman, Miami-Dade County Commissioner, District 4

***Health Care Providers, Academic Faculty, and Health Organizations***

- Minesh P. Mehta, MD, Deputy Director and Chief of Radiation Oncology, Miami Cancer Institute
- Becky Montesino-King, DNP, RN, NEA-BC, CENP, Vice President and Chief Nursing Officer, Baptist Hospital of Miami
- John A. Rock, MD, Founding Dean and Senior Vice President for Health Affairs, Florida International University, Herbert Wertheim College of Medicine
- Michael J. Zinner, MD, CEO, Miami Cancer Institute
- Sergio Gonzalez-Arias, MD, PhD, FAANS, FACS<sup>1</sup>
- Jeanne Dariotis, MBA, MT(ASCP), SBB, Senior VP of Laboratory Services, OneBlood, Inc.

**Letters of Opposition**

The Agency received letters of opposition to Baptist Hospital of Miami, Inc.'s certificate of need application to establish an adult allogeneic and autologous bone marrow transplantation program in OTSA 4 from representatives of University of Miami Hospital & Clinics (Miami-Dade), Memorial Hospital West (Broward County) and H. Lee Moffitt Cancer Center and Research Institute Hospital (Hillsborough County), all are existing adult bone marrow transplant providers in OTSA 4 except for H. Lee Moffitt Cancer Center and Research Institute Hospital which is licensed in OTSA 2.

The Agency notes that all written opposition statements received from representatives of South Broward Hospital District d/b/a Memorial Hospital West, H. Lee Moffitt Cancer Center and Research Hospital, Inc. and the University of Miami were received on the omissions deadline,

<sup>1</sup> Executive Associate Dean – Clinical Affairs, Chair – Department of Neuroscience, Professor and Chief – Division of Neurosurgery, Director – Continuing Medical Education, FIU Herbert Wertheim College of Medicine

June 28, 2017. An attachment to the statement submitted by the University of Miami Hospital and Clinics statement was received after the 5 p.m. June 28, 2017 deadline via email on June 28, 2017 at 5:21 p.m.

***University of Miami Hospital & Clinics***

University of Miami Hospital & Clinics (UMHC) has a CON-approved adult bone marrow transplantation program (BMT) in OTSA 4, located in Miami-Dade County, Florida. UMHC's adult allogeneic and autologous bone marrow transplant program began operations in 2008, following certificate of need approval.<sup>2</sup> UMHC identifies as a specialty-hospital which houses the Sylvester Comprehensive Cancer Center. UHMC also indicates that the University of Miami, UMHC's licensee, additionally operates the Don Soffer Clinical Research Center which houses laboratories and various cancer center researchers. UMHC notes that the University of Miami is one of 11 Prospective Payment System (PPS) exempt cancer centers along with H. Lee Moffitt Cancer Center and Research Institute Hospital.<sup>3</sup> UMHC indicates that the facility has been selected to receive special appropriations from the legislature in order to receive status as a National Cancer Institute-Designated Cancer Center and is a part of the Comprehensive Cancer Center Consortium for Quality Improvement.

UMHC notes that there are three existing providers in OTSA 4 and there is no basis to approve CON #10490. UMHC discusses how CON application #10420 to establish an adult allogeneic and autologous bone marrow transplantation program in OTSA 4 previously was denied to Baptist Hospital of Miami by final order from the Agency issued on June 13, 2017. UMHC states that nothing has significantly changed in the present set of circumstances to change the fundamental outcome of CON application #10420's denial and emphasizes that Baptist Hospital of Miami (BHM) still lacks the requisite research and teaching programs to support a sustainable adult BMT program. UMHC states that the development and establishment of research facilities requires time and commitment. UMHC denies that sufficient demand exists to support an additional BMT program and refutes the assertion that an additional program is needed to improve access, availability, and utilization of BMT services within the service area. UMHC anticipates that the addition of the proposed BMT program would result in the duplication of services without increased benefit and insists that BHM's existing staff is insufficient and inadequate to support the needs of the proposed BMT program.

<sup>2</sup>Agency records indicate that CON #10041 was issued to the University of Miami on March 31, 2009 and according to Agency records, the provider performed its first procedure on August 29, 2011.

<sup>3</sup> [https://www.cms.gov/Medicare/Medicare-Fee-for-Service/Payment/AcuteInpatientPPS/PPS\\_Exc\\_Cancer\\_Hospasp.html](https://www.cms.gov/Medicare/Medicare-Fee-for-Service/Payment/AcuteInpatientPPS/PPS_Exc_Cancer_Hospasp.html)

UMHC asserts that need for the proposed program at BHM stems from institution-specific interests to possess a hallmark program to underscore the development of Miami Cancer Institute, which UMHC determines does not meet statutory criteria or reflect legitimate health planning rationales. UMHC additionally states that BHM lacks an active medical fellowship program and research platforms to advance clinical practice and as a result will rely on future potentials to join a teaching institution with these resources. UMHC asserts that these relationships and resources must exist prior to certificate of need approval and maintains that it is costly to establish and maintain these relationships and questions the long-term financial feasibility of the proposal before clinical program costs are also accounted for.

***Reliance on Erroneous Reported Data***

UMHC states that Good Samaritan Medical Center terminated its adult bone marrow transplantation program in CY 2004 but continued to provide bone marrow transplantation data to the Local Health Council without a certificate of need to resume services. UMHC notes that Good Samaritan Medical Center is absent from the Foundation for Accreditation of Cellular Therapy (FACT), the Center for International Bone Marrow Transplantation (CIBMTR), contractor for the national Health Resources and Services Administration (HRSA), and the Blood & Marrow Transplant Information Network. UMHC describes how all other all other bone marrow transplant programs in Florida appear in all of the previously listed organizations and maintains that Good Samaritan Medical Center does not have a bone marrow transplant program.

***Out-Migration from OTSA 4 Occurs to Lee Moffitt Cancer Center & Research Institute, a Preeminent Provider of Adult Bone Marrow Transplantation***

UMHC conducts an out-migration analysis of adult (aged 15 years+) BMT cases for MS-DRGs 014, 016, and 017 in CY 2016 and determines that 77 percent of out-migration cases went to H. Lee Moffitt Cancer Center & Research Institute.

The table demonstrating UMHC's analyses are included below:

<b>Adult Bone Marrow Cases by County of Residence in OTSA 4 Outmigration</b>		
<b>Out-Migration From</b>	<b>Cases</b>	<b>Percent</b>
Broward County	22	8.4%
Collier County	16	6.1%
Miami-Dade County	11	4.2%
Monroe County	1	0.4%
Palm Beach County	32	12.2%
<b>Total</b>	<b>82</b>	<b>31.3%</b>

Source: UMHC, Opposition Statement, Page 4

<b>Adult Bone Marrow Cases: County of Residence in OTSA 4 Outmigration and Hospital of Transplant</b>						
<b>Hospital of Out-Migration</b>	<b>County of Residence within TSA 4</b>					<b>Total Cases</b>
	<b>Broward</b>	<b>Collier</b>	<b>Miami-Dade</b>	<b>Monroe</b>	<b>Palm Beach</b>	
H. Lee Moffitt Cancer Center	18	12	3	0	29	62
Johns Hopkins All Children's Hospital	2	2	0	0	1	5
Mayo Clinic	0	1	1	0	0	2
Nicklaus Children's Hospital	2	1	7	1	2	13
<b>Total</b>	<b>22</b>	<b>16</b>	<b>11</b>	<b>1</b>	<b>32</b>	<b>82</b>

Source: UMHC, Opposition Statement, Page 5

The reviewer notes that UMHC does not provide an explanation of the methodology used to obtain the above analyses.

UMHC states that Baptist Hospital of Miami will pose an unsupportable position if Baptist asserts that the pediatric bone marrow providers that report adult transplants accounting for 18 cases would be available for this program and that two cases that went to Mayo Clinic would be for available for its start-up. UMHC maintains that to assert that a significant capture rate of out-migrating cases could occur for a start-up program without any direct experience in adult BMT stretches credibility.

***Numeric Demand Does Not Exist for Another Program***

UMHC provides an analysis of predicted use rates based on July 2016 and July 2021 population estimates by OTSA 4 county and a baseline adult BMT case volume of 262 transplants. Based on this forecast,, the applicant predicts an adult BMT use rate of 0.0501 for residents of OTSA 4, a statewide adult BMT use rate of 0.0617, 277 BMT transplants by July 2021 in OTSA 4 and 1,104 BMT transplants statewide (UMHC, Opposition Statement, Page 5). UMHC states that the assumption that the forecasted increase in 15 adult BMT cases would be available to BHM does not account for growth of adult BMT programs at existing providers.

UMHC also states that when forecasted projections account for pediatric patients who “age out” and receive BMT care through variance, the projected case volume that is expected to be absorbed by Baptist is less

than estimated. UMHC anticipates that in order to achieve sustainable caseloads, Baptist would have to acquire cases from Memorial Hospital West and UMHC. UMHC anticipates that with the assumption that the BMT program caseload is 10 in CY 2021, the caseload at Memorial Hospital West would be reduced to zero and the caseload at UMHC would be reduced to 151. UMHC anticipates that the applicant will have to acquire a volume of patients beyond the 10 cases identified in rule, which would adversely impact existing programs in OTSA 4 and concludes that BHM cannot produce a credible forecast. Analyses of these projections are included on pages six through seven of the UMHC opposition statement.

**Governmental Payers Account for Just Over One-Third of Coverage**

UMHC provides an analysis of payer sources for OTSA 4 residents who received BMT care. Based on this analysis, UMHC determines that BMT programs receive the majority of reimbursement from commercial insurance plans.

UMHC notes that governmental payers, specifically Medicaid and Medicare, account for 34.4 percent of the payer sources of OTSA 4 transplant recipients in CY 2016. UMHC describes how procedural approvals are required for governmental payers before reimbursement is secured and provider selection, for this reason UMHC concludes that being a current Medicaid or Medicare provider does not immediately precipitate an opening to care for Medicaid or Medicare patients.

**Payers for Adult Bone Marrow Cases by County of Residence in OTSA 4**

Payers for Adult Bone Marrow Cases by County of Residence in OTSA 4							
Cases							
Payer	Broward	Collier	Miami-Dade	Monroe	Palm Beach	Total Cases	Percent
Commercial Health Insurance	61	10	64	4	31	170	64.9%
<b>Medicaid</b>	<b>1</b>	<b>0</b>	<b>3</b>	<b>0</b>	<b>0</b>	<b>4</b>	<b>1.5%</b>
<b>Medicaid Managed Care</b>	<b>9</b>	<b>2</b>	<b>17</b>	<b>1</b>	<b>8</b>	<b>37</b>	<b>14.1%</b>
<b>Medicare</b>	<b>13</b>	<b>5</b>	<b>13</b>	<b>0</b>	<b>14</b>	<b>45</b>	<b>17.2%</b>
<b>Medicare Managed Care</b>	<b>1</b>	<b>0</b>	<b>1</b>	<b>0</b>	<b>2</b>	<b>4</b>	<b>1.5%</b>
Other	0	0	1	0	0	1	0.4%
Self - Pay	0	0	1	0	0	1	0.4%
<b>Grand Total</b>	<b>85</b>	<b>17</b>	<b>100</b>	<b>5</b>	<b>55</b>	<b>262</b>	<b>100%</b>

Source: UMHC Opposition Statement, Page 8

UMHC states that Medicaid requires FACT accreditation and participation in Center for International Blood and Marrow Transplant Research (CIBMTR), as required by HRSA, in order to be designated as an authorized provider. For this reason, UMHC does not expect that

Baptist will be able to accept Medicare or Medicaid patients until full accreditation and participation occurs, given that sufficient time will be required to gain the experience for qualification for participation.

***Access within OTSA 4 Exists and No Improvement Occurs with a Program at Baptist Hospital of Miami***

Based on a geographical analysis of drive times between the UMHC and Baptist, UMHC determines that residents of OTSA 4 receive coverage from existing programs and that no improvement to access will result from an additional provider. UMHC also determines that the applicant has failed to demonstrate that need exists to enhance access to care for residents of OTSA 4.

***The Impact on the University of Miami Hospital's Program***

UMHC states that due to the proximity of UMHC and Baptist, adverse impact is expected from implementation of the proposed program. UMHC anticipates that if approved, the proposed program at Baptist would lure staff and personnel from UMHC to Baptist and furthermore alleges that Baptist has made attempts to lure staff away from UMHC who are skilled in BMT based on testimony provided at DOAH for Case No. 16-1698CON.

UMHC also indicates that BMT referrals from Baptist to UMHC would cease and result in adverse financial impact to UMHC.<sup>4</sup> UMHC also anticipates that implementation of the proposed project would result in the dilution of BMT cases among existing providers resulting in a reduced capacity to conduct research at UMHC and elsewhere, particularly on rare diseases represented within BMT cases. UMHC determines that a reduced capacity to perform research is a public policy concern and counter to statutory requirements.

***The availability of resources including health personnel, management personnel, and funds for capital operating expenditures for project accomplishment and operation***

UMHC discusses the specially licensed and experienced staff that are necessary to deliver high quality BMT services. UMHC makes reference to testimony at DOAH for Case No. 16-1698.

UMHC also states that Baptist possesses neither the pharmacy or laboratory services onsite nor the capacity to contract for necessary services to care for BMT patients.

<sup>4</sup> The reviewer notes that the number of referrals from Baptist to UMHC are not provided in attestation of the adverse volume or financial impact expected to UMHC



***The extent to which the proposal will foster competition that promotes quality and cost-effectiveness***

UMHC anticipates that the proposed project will not foster competition and as a result of cases being lost to Baptist, the proposed project will result in financial detriments to UMHC, adverse cost-effectiveness and quality among existing providers of OTSA 4 as patient volumes are split among an increased number of providers and a duplication of services. UMHC indicates that existing barriers in consumer-based competition in the healthcare industry will prevent the proposed project from fostering competition to promote quality and cost-effectiveness. UMHC also notes that patient care costs do not change according to the number of providers and increased competition will not result in reduced patient care costs. UMHC anticipates that labor costs will increase as a result of the small specialized labor pool required to treat BMT patients. UMHC restates conclusions provided in the Recommended Order for Case No. 16-1698CON.

***BHM is not a research hospital***

UMHC states that Baptist does not promote or market itself as a research hospital. While UMHC notes that Florida International University and BHSF have a teaching affiliation, UMHC determines that this relationship is insufficient to consider Baptist a teaching hospital. UMHC states that a low volume of oncology clinical trials occurs at Baptist and do not reflect that an established research-oriented oncology program exists at Baptist. UMHC states that research conducted at Baptist is mainly for national trials that are also available to other institutions. UMHC further questions Baptist's capacity to implement research facilities and further questions the extent to which plans to operate research facilities at the Miami Cancer Institute can be implemented. UMHC also states that no evidence exists to demonstrate what space or equipment have been allocated to research activities throughout the Baptist Health system.

***BHM does not have an established research oncology program***

UMHC states that Baptist cannot demonstrate that it has an established research oncology program and describes how the productivity of past oncology research activities at Baptist has been exceedingly low. UMHC states that staff indicated to provide research oncology services are "essentially community hospital clinicians whose resumes do not show any career history to conduct laboratory investigation, publications or other research activity to advance the field". UMHC states that plans to operate a research program at the Miami Cancer Institute are aspirational and do not meet statutory requirements.

***Conclusion***

UMHC determines that Baptist cannot meet the research and clinical statutory criteria for BMT criteria and that numeric need does not demonstrate need for an additional bone marrow transplant provider.

***Memorial Hospital West***

Memorial Hospital West (MHW) is an existing BMT provider in OTSA 4 operated by South Broward Hospital District d/b/a Memorial Healthcare System which has submitted a statement of opposition to CON application #10490. MHW notes that South Broward Hospital District (SBHD) is an independent taxing district established in 1947 and a safety-net provider to the uninsured and underinsured within and outside of the SBHD. MHW identifies its operational affiliations with Memorial Regional Hospital, Memorial Regional Hospital South, Joe DiMaggio Children's Hospital, Memorial Hospital Pembroke and a number of other health care facilities located throughout southern Broward County. MHW describes the scope of services available throughout the Memorial Healthcare System and specifically notes that MHW offers an extensive array of innovative high quality health care services like advanced cardiac, oncology and neurology programs.

Specific to BMT, MHW provides a historical account of its provision of BMT care for more than 10 years initially on an outpatient basis prior to receiving CON approval for an adult autologous and allogeneic BMT program.<sup>5</sup> MHW also provides a summary of statutory criteria for consideration of BMT programs.

MHW indicates that prior to CY 2004, Baptist received approval and initiated a bone marrow transplantation program which was terminated on June 17, 2004. MHW states that the Baptist program provided adult autologous bone marrow transplantation and peripheral stem cell transplantation and notes that in July 1987 outpatient services were eliminated from certificate of need review which allowed BHM to provide autologous BMT and peripheral stem cell transplantation on an outpatient basis. MHW maintains that Baptist has an alternative consistent with its community mission and capabilities to expand cancer treatments.

MHW asserts that sufficient forecasted volume must exist to establish a program and that the forecasted volume must consider impacts on existing providers in light of the relationship between patient survival rates and successful program operations. MHW describes how low

<sup>5</sup> The Agency issued CON #10108 to South Broward Hospital District d/b/a Memorial Hospital West to establish an adult inpatient autologous and allogeneic bone marrow transplant program in OTSA 4 on March 29, 2011 and performed its first procedure on May 3, 2011.

patient volumes jeopardize program longevity and increase complication rates. MHW notes that errors in reporting from facilities overstates the use rates of BMT.

***Baptist Hospital of Miami Seeks a Signature Program***

MHW notes that while Baptist has demonstrated a major expense for the construction and expansion of its cancer treatment pavilion, the hospital lacks a signature program that distinguishes it from competitors in the market. MHW determines that the Baptist’s proposal is a market strategy to increase admissions within and outside of District 11.

MHW states that BHM lacks the specialty and subspecialty staff, research and teaching programs to provide BMT services or conduct BMT research. MHW states that numerical demand does not exist for the proposed program.

***The Persistence of Data Reporting Errors within OTSA 4 Overstates Demand***

MHW notes that Good Samaritan Medical Center inaccurately reported bone marrow transplants to the Agency and provides a corrected summary of cases of bone marrow transplants performed in all OTSAs by calendar year from 2012 – 2016 on page five of the written opposition statement.

***Population Estimates Form the Basis of Future Demand***

MHW presents population forecasts that mirror midpoint population projections in July 2016 and July 2021 for OTSA 4 presented in the “Numeric Demand Does Not Exist for Another Program” subheading on page nine of the opposition statement submitted by UMHC. MHW notes that the statewide adult population growth rate (1.2 percent) exceeds the OTSA 4 adult population growth rate (1.1 percent) and determines that population growth does not support the basis that an adult BMT program is needed to address need, improve access or expand availability.

MHW provides an analysis of the use rate with the exclusion of cases reported by Good Samaritan Medical Center, which is reproduced below:

<b>OTSA 4 Corrected and Uncorrected BMT Use Rate Comparisons</b>			
<b>Area</b>	<b>Use Rate CY 2016 Uncorrected/1,000</b>	<b>Use Rate CY 2016 Corrected/1,000</b>	<b>Difference</b>
<b>OTSA 4</b>	0.0440	0.0360	0.008
<b>STATE</b>	0.0609	0.0584	0.0025
<b>Year 2021, Adult Bone Marrow Transplants</b>			
<b>OTSA 4</b>	243	199	44
<b>STATE</b>	1,089	1,045	45

Source: MHW, Opposition Statement, Page 7

MHW reiterates that the inclusion of transplants from Good Samaritan results in the overstatement of the adult BMT use rates. An analysis of the CY 2016 bone marrow transplants for adults aged 15+ for DRGs 014, 016 and 017 is provided as obtained from the Agency Inpatient Database. MHW analysis reflects the analysis provided on page seven of the UMHC opposition statement with an OTSA 4 baseline use rate per 1,000 of 0.501.

***Out-Migration for Adult Bone Marrow Transplants***

MHW restates the outmigration analysis provided by UMHC, noting that Palm Beach County accounted for 12.2 percent of out-migration cases in CY 2016. MHW reiterates that variances occur to allow pediatric patients who “age out” to receive transplant care at their pediatric institution, like Jackson Memorial Hospital.<sup>6</sup> MHW also notes that four hospitals within OTSA 4 without an authorized BMT program performed four transplants on residents from the service area. MHW determines that 180 cases or 68.7 percent of residents requiring a BMT remain within the service area. MHW identifies H. Lee Moffitt Cancer Center and Research Institute as preeminent cancer center program with a robust market share of residents from OTSA 4.

***Patient Origin Use Rates and Forecasted Cases to CY 2021***

MHW restates forecasted case projections by OTSA 4 county as presented in the UMHC opposition statement and determines that the 15 adult BMT case increase projected for OTSA 4 in CY 2021 does not justify demand for an additional program, since the Baptist program does not take into account expected growth in the existing programs at MHW and UMHC. In order to obtain forecasted volumes, MHW anticipates that cases would be shifted from existing providers to a new program without experience (Baptist). MHW states that variance cases would reduce the available volume of adult BMT cases from 15 to four, therefore the Baptist program would ultimately rely on in-migration into OTSA 4 to support its forecasted volume.

MHW notes that the Public Health Trust of Miami-Dade County which governs and operates Jackson Health System. Holtz Children’s Hospital within the Jackson Health System operates a pediatric BMT program and has filed petitions for variances in order to perform BMTs on individuals between the ages of 15 and 20. MHW notes that Rule 59C-1.044(2)(c), Florida Administrative Code defines a pediatric patient as one under the age of 15, yet the age range for pediatric patients differs for different programs, e.g. CMS defines pediatric patients as individuals under age 18, Agency guidelines define Medicaid pediatric BMT patients under age 20, and Children’s Medical Services provides care to children up to age

<sup>6</sup> The reviewer notes that justifications and outcomes for variance cases are not presented, MHW only notes that they occur.

21 with special health care needs. With the differences in pediatric patient definitions. MHW states that Holtz seeks variances in an attempt to provide continuity of care to pediatric BMT patients.

MHW does not identify pediatric BMT patients receiving care through variance as a potential need justification for Baptist's proposed project, evidence of a lack of available adult programs or evidence of a lack of accessibility for BMT within OTSA 4. MHW notes that there may be patients or managed care programs that lead patients to receive BMT services outside of OTSA 4, however OTSA 4 providers have adequate capacity to accommodate future demand.

***The extent to which the proposed services will enhance access to health care for residents of the service district***

MHW indicates that access includes geographic, programmatic and financial access in addition to eligibility and provides a two-hour map around MHW. MHW states that financial access for residents within the service area demonstrates a range of payers for BMT procedures that MHW and UMHC share. MHW determines that no basis exists to: determine that service area residents are underserved or that residents of OTSA 4 do not have access to existing providers or that the addition of a new provider would substantially enhance services presently available.

***Payers for Bone Marrow Transplant reflect reliance on commercial insurance***

MHW provides an analysis of adult BMT cases by payer and facility and notes that governmental payers account for 34.4 percent of payers for adult BMT care and commercial payers account for 64.9 percent of payers for adult BMT care. The analysis appears to reference data in the table provided on page eight of the UMHC opposition statement, but lists the data by payer and facility instead of cases by payer and county. Tables are included on page 15 through 16 of the opposition statement.

***The availability of resources, including health personnel, management personnel, and funds for capital and operating expenditures, for project accomplishment and operation***

MHW states that BMT programs require specialty licensed and experienced staff to ensure the delivery of high quality services and anticipates that existing OTSA 4 providers will be adversely impacted in their capacity to recruit highly specialized professionals. MHW asserts that its program payer mix will be negatively impacted as well with the introduction of the proposed program.

MHW anticipates that an additional program would dilute volumes and jeopardize existing clinical studies required for national accreditation agencies like: American College of Surgeons (ACOS): CIBMTR and the Foundation for the Accreditation of Cellular Therapy (FACT). MHW also

notes that attaining requisite cases for accreditation is challenged by managed care requirements and guidelines that result in patients being referred to National Cancer Institute (NCI) designated centers.

MHW notes that a number of approved programs have discontinued as a result of low case volumes, the ability to secure and retain specialized clinical and support staff and changes in reimbursement and/or managed care contracting provisions. MHW provides a summary of BMT program closures from 2002–2013.

MHW notes that its qualification as a managed care Center of Excellence for allogeneic BMTs was compromised by its capacity to obtain the requisite number of cases in the necessary time period.

MHW discusses the clinical partnership between Memorial Health System and Moffitt formed in May 2017 in order to enhance the care of leukemia and lymphoma and establish a comprehensive Blood and Marrow Transplant Cellular Therapy Program for south Florida residents scheduled to begin July 1, 2017. MHW expects for the partnership to allow for the Memorial Health System and MHW to provide services locally to patients who had been travelling to Moffitt in Hillsborough County. The partnership is also expected to allow both MHW and Moffitt access to research protocols and genetically based immunotherapy protocols which may replace chemotherapy. MHW provides the operational and staffing descriptions of this partnership on page 19 of the opposition statement.<sup>7</sup>

Overall, MHW expects for an additional BMT program to reduce patient volumes at existing programs and harm the capacity to obtain and maintain national accreditation, to secure and retain specialized clinical and support staff and would leave MHW vulnerable to changes in reimbursement and/or managed care contracting provisions.

***The extent to which the proposal will foster competition that promotes quality and cost-effectiveness***

MHW reiterates that existing barriers in consumer-based competition in the healthcare industry will prevent the proposed project from fostering competition to promote quality and cost-effectiveness. MHW indicates that Medicare and Medicaid account for over 40 percent of hospital charges in Florida and HMO/PPOs account for almost 46 percent of charges. MHW notes that price competition exists between commercial payers but not amongst fixed government payers. MHW additionally notes that non-government payers use Medicare reimbursement as a starting point for price negotiation.

<sup>7</sup> Neither Memorial Hospital West nor H. Lee Moffitt Cancer Center and Research Institute provided a sample of a binding agreement attesting to this partnership

MHW notes that over 87 percent of hospital charges in Florida are generated by patients whose payer source is a third-party payer like Medicare, Medicaid, an HMO or PPO and third-party payers insulate patients or users from direct costs and do not incentivize searching for alternatives. Opposition contends that patient care expenses do not change with increased competition but increased competition is expected to increase labor costs as a result of the small specialized labor pool required to treat BMT patients. An additional BMT program is anticipated to result in lower patient volumes, an underutilization in resources and lower operating margins of existing facilities.

MHW states that an additional BMT program carries implications on the costs of health care delivery particularly when services are duplicated.

***Conclusion***

MHW opposes the implementation of the program and determines that MHW's program should be allowed to progress before an additional provider is approved.

***H. Lee Moffitt Cancer Center and Research Institute***

H. Lee Moffitt Cancer Center and Research Institute Hospital, Inc. (Moffitt) has submitted an opposition statement to Baptist Hospital's application to establish an adult allogeneic and autologous transplant program (CON application #10490). The reviewer notes that H. Lee Moffitt Cancer Center is not a licensed existing provider of BMT services in OTSA 4.

Moffitt notes that Baptist Hospital was previously denied a certificate of need and the Agency's Final Order was issued June 13, 2017. Moffitt states that the previous application was denied for the following reasons:

- No need for Baptist's proposed BMT program
- Baptist is not a teaching or research hospital
- Baptist lacks the staff, expertise, and other resources to operate a quality, financially sustainable BMT program
- Baptist's proposed BMT program is contrary to public policy objectives designed to ensure highest quality health care

Moffitt notes that Memorial's BMT program is partially state-funded and is operating below full capacity. Moffitt discusses the clinical partnership between Moffitt and MHW in building a robust BMT program and Moffitt provides additional descriptions of the operational functions to be shared between Moffitt and MHW.

The reviewer notes that throughout the opposition statement references to “Baptist’s 2016 Application” are made in description of CON application #10420 submitted on December 21, 2015 during the October 2015 Other Beds and Program Batching Cycle, preliminarily approved by the Agency on February 19, 2016 and denied via Final Order issued by the Agency on June 13, 2017.

Moffitt determines that there is no need for an additional provider in OTSA 4, the addition of a new provider would adversely impact existing providers, Baptist does not have the financial ability or resources to operate a quality BMT program and CON application #10490 is unlikely to have remedied deficiencies presented in the Recommended Order for DOAH Case No. 16-1698CON for CON application #10420.

**C. PROJECT SUMMARY**

**Baptist Hospital of Miami, Inc. d/b/a Baptist Hospital of Miami (CON application #10490)**, also referenced as BHM or the applicant, is a not-for-profit Class I Hospital affiliated with Baptist Health South Florida (BHSF).

The current licensed bed capacity of BHM is as follows:

- Baptist Hospital of Miami - 728 Beds
  - Acute Care – 669 Beds
  - Comprehensive Medical Rehabilitation – 23 Beds
  - Neonatal Intensive Care Unit – Level II – 22 Beds
  - Neonatal Intensive Care Unit – Level III – 14 Beds

The applicant proposes to establish a new adult autologous and allogeneic BMT program at BHM, primarily to serve the residents of OTSA 4 in addition to other Florida residents and residents of the United States and international patients who rely on BHSF resources for their health care needs. In Schedule 5 of CON application #10490, the applicant states that the proposed project will entail the conversion of an existing 18-bed inpatient unit to accommodate the six inpatient beds and all associated support spaces required for the BMT program. The applicant indicates that Schedule 5 assumes that 12 beds will be delicensed upon completion of the proposed project. BHM states that the establishment of an outpatient autologous BMT program is currently underway and anticipated for initiation in the 4<sup>th</sup> quarter of 2017.

The applicant states that the parent organization, BHSF, currently services and operates numerous facilities throughout south Florida and has an extensive historical record of providing exceptional patient care to all segments of the local communities it serves.



The applicant currently operates the following licensed acute care hospitals:

- BHM (including Baptist Children's Hospital)
- Doctors Hospital
- Homestead Hospital
- Mariners Hospital
- South Miami Hospital
- West Kendall Baptist Hospital

The applicant also states that Fisherman's Community Hospital in Monroe County, Bethesda Memorial Hospital East and Bethesda Memorial Hospital West (Palm Beach County) will also become a part of the BHSF. The applicant additionally identifies operating a number of other healthcare facilities, outpatient centers, and providing a variety of services throughout south Florida in Palm Beach, Miami-Dade, and Monroe County.

Baptist Hospital of Miami currently operates an outpatient cancer facility Miami Cancer Institute (MCI) and intends to expand Miami Cardiac & Vascular Institute within its healthcare network. The applicant states that the opening of the Miami Cancer Institute in January 2017 consolidated the BHSF network of outpatient cancer services and specialists while expanding cancer treatment technology and resources and introducing cancer clinical research programs, a center for genomics, and disease-specific multi-disciplinary programs. BHM states that MCI will offer a new level of needed care to south Florida residents. The applicant indicates that MCI has joined the Memorial Sloan Kettering Cancer Alliance, which BHM expects to afford south Florida residents with the benefits and expertise of Memorial Sloan Kettering's (MSK) cancer program. The applicant also states that the hematology and oncology physician and Advanced Practice Provider (APP)<sup>8</sup> network, Advanced Medical Specialties, joined Baptist Health Medical Group which will contribute to BHSF's resources for the proposed program. The applicant expects for existing operational attributes, quality and staffing to support the proposed BMT program. The applicant maintains that the vast majority of the clinical and non-clinical infrastructure to support the proposed new BMT program already exists at BHM.

<sup>8</sup> Advanced Practice Provider' is a general title used to describe individuals who have completed the advanced education and training that qualifies them to (1) manage medical problems and (2) prescribe and manage treatments within the scope of their training. Some specific types of APPs include clinical nurse specialists, nurse practitioners, and physician assistants.  
<http://www.sccm.org/Education-Center/Administration/Pages/Advanced-Practice-Providers-Series.aspx>

The total project cost of the proposed project is \$7,624,433 which consists of \$6,232,295 in building costs, \$850,000 of equipment, \$105,000 of project development, and \$437,138 of start-up costs. The project will involve 8,800 gross square feet (GSF) of renovation.

The applicant expects issuance of licensure December 2018 and initiation of service in January 2019.

The applicant includes the following Schedule C Conditions:

- The proposed adult BMT program will be located at Baptist Hospital of Miami, located at 8900 North Kendall Drive, Miami, Florida
- Baptist Hospital will delicense 12 acute care beds upon the completion of the 4 Main East renovation and the establishment of the proposed new bone marrow treatment program
- Baptist will provide at least 10 percent of the adult inpatient 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.*

#### **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, Bianca Eugene, analyzed the application with consultation from Financial Analyst Eric West of the Bureau of Central Services, who evaluated the financial data, and Scott Waltz, 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 BMT programs. Therefore, it is the applicant's responsibility to demonstrate the need for the project, including a projection of the expected number of adult BMTs that will be performed in the first years of operation.

There are currently three operational adult inpatient BMT programs in OTSA 4, with no CON approved adult inpatient BMT programs pending licensure in OTSA 4.<sup>9</sup> OTSA 4 includes District 10, District 11, Collier County (District 8) and Palm Beach County (District 9). The operational programs are at Good Samaritan Medical Center (Palm Beach County), MHW (Broward County) and the UMHC (Miami-Dade County).

Data reported to the Agency for the most recent reporting period, January 1, 2016 through December 31, 2016 show the following adult BMT utilization data.

<sup>9</sup> The reviewer notes that CON application #10420 was initially approved to Baptist Hospital of Miami, Inc. d/b/a Baptist Hospital of Miami on February 19, 2016 and subsequently denied through litigation at the DOAH. The Final Order to deny CON application #10420 was issued on June 13, 2017.

<b>Florida Adult Bone Marrow Transplantation Program Utilization: January 2016 - December 2016</b>			
<b>Hospital</b>	<b>OTSA*</b>	<b>District</b>	<b>Total Procedures</b>
UF Health Shands Hospital	1	3	125
Mayo Clinic	1	4	106
H. Lee Moffitt Cancer Center*	2	6	447
Florida Hospital-Orlando	3	7	118
Good Samaritan Medical Center **	4	9	42
Memorial Hospital West	4	10	4
Univ. of Miami Hosp. & Clinics	4	11	184
<b>Total</b>			<b>1,026</b>

Source: Agency for Health Care Administration Utilization Data for Adult Organ Transplantation Programs, published March 31, 2017.

\*H. Lee Moffitt Cancer Center and Research Inst. Hospital.

\*\*The reviewer notes that in the CY 2016 Condition Compliance submitted to the Agency, Good Samaritan Medical Center reported 0 BMTs (inpatient or outpatient)

Below is a chart to account for adult inpatient bone marrow transplants for the five-year period ending on December 31, 2016.

<b>Adult Inpatient Bone Marrow Transplantation Procedures: January 1, 2012 through December 31, 2016</b>							
<b>Facility</b>	<b>TSA</b>	<b>1/12 - 12/12</b>	<b>1/13 - 12/13</b>	<b>1/14 - 12/14</b>	<b>1/15 - 12/15</b>	<b>1/16 - 12/16</b>	<b>Total</b>
UF Health Shands	1	120	104	97	175	125	621
Mayo Clinic	1	72	97	88	80	106	443
H. Lee Moffitt Cancer Center	2	402	446	441	419	447	2,155
Florida Hospital	3	107	149	142	133	118	649
Good Samaritan Medical Center	4	0	0	73	99	42***	214
Memorial Hospital West*	4	9	15	20	15	4	63
Jackson Memorial Hospital**	4	1	0				1
UM Hospital & Clinics	4	97	132	137	170	184	720
<b>Total</b>		808	943	998	1,091	1,026	4,866

Source: Agency for Health Care Administration Utilization Data for Adult Organ Transplantation Programs, July 2015 Planning Horizon – July 2019 Planning Horizon

\* Memorial Hospital West became operational on 5/3/2011

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

\*\*\* The reviewer notes that in the CY 2016 Condition Compliance submitted to the Agency, Good Samaritan Medical Center reported 0 BMTs (inpatient or outpatient)

Rule 59C-1.044(9)(b), Florida Administrative Code, states that adult allogeneic BMT programs shall be limited to teaching and research hospitals. Baptist Hospital of Miami is not currently a statutory teaching hospital.

Below is a table to account for adult residents of OTSA 4 (age 15+) who were discharged with a blood and BMT procedure and their source of care.

<b>Transplant Service Area 4 Adult Residents (15 and older): Blood or Bone Marrow Transplant Discharges (MS - DRGs 14, 16, and 17) CY 2016</b>		
<b>Hospital</b>	<b>Total Discharges</b>	<b>Percentage</b>
Broward Health Medical Center	1	0.44%
Delray Medical Center	1	0.44%
H. Lee Moffitt Cancer Center	62	27.56%
Jackson Memorial Hospital	3	1.33%
Mayo Clinic	2	0.89%
Memorial Hospital West	5	2.22%
Naples Community Hospital	1	0.44%
Nicklaus Children's Hospital	2	0.89%
University of Miami Hospital	1	0.44%
University of Miami Hospital and Clinics	147	65.33%
<b>Total</b>	<b>225</b>	<b>100.00%</b>

Source: Florida Center for Health Information and Transparency database:  
Run Date: June 28, 2017

Based on the provision of care reflected in the chart, outmigration among OTSA residents occurred in 73 of 225 cases or 32.44 percent.

In response to this criteria, the applicant reiterates that the Agency does not publish a fixed need pool forecast for adult autologous and allogeneic BMT services and identifies need as outlined by Rule 59C-1.044 and Rule 59C-1.044(9), F.A.C. The applicant indicates that the proposed project will be located at BHM in Miami-Dade County within OTSA 4. BHM identifies volume thresholds related to new BMT programs as outlined in Rule 59C – 1.044(9)(b)-(c), F.A.C.

***Service Area Population Profile<sup>10</sup>***

The applicant provides charts depicting the population of OTSA 4 in 2016 and 2020 using AHCA Population Estimates and Projections, released February 2015. The applicant discusses the population profile and notes that the population of Miami – Dade County comprises between 42 and 43 percent of the total service area’s population in 2016.

Charts depicting existing and projected population changes for all age groups are provided on pages 30 – 31 of CON application #10490 with charts depicting forecasted population changes from 2016 – 2020 reproduced below.

<sup>10</sup> Italicized subheadings appear as presented in CON application #10490

Organ Transplant Service Area 4 2016 - 2020 Population Growth								
County	Pop. 0 -14		Pop 15-64		Pop. 65+		Total	
Miami-Dade	11,495	2.4%	66,005	3.7%	46,581	11.4%	124,081	4.6%
Monroe	-154	-1.7%	-2,209	-4.6%	2,048	13.1%	-315	-0.4%
Broward	2,166	0.7%	3,015	0.3%	37,524	12.7%	42,705	2.4%
Palm Beach	8,390	3.7%	25,197	3.0%	34,385	10.8%	67,972	4.9%
Collier	2,333	4.2%	11,531	5.8%	13,163	13.4%	27,027	7.6%
<b>Service Area Total</b>	<b>24,230</b>	<b>2.2%</b>	<b>103,539</b>	<b>2.5%</b>	<b>133,701</b>	<b>11.8%</b>	<b>261,470</b>	<b>4.1%</b>

Source: CON application #10490, page 31.

Organ Transplant Service Area 4 2016 - 2020 Population Growth				
County	2016 Pop. 15+	2020 Pop. 15+	2016-2020 Pop. 15 + Growth	
Miami-Dade	2,200,937	2,313,523	112,586	5.1%
Monroe	64,112	63,951	-161	-0.3%
Broward	1,494,895	1,535,434	40,539	2.7%
Palm Beach	1,166,537	1,226,119	59,582	5.1%
Collier	298,144	322,838	24,694	8.3%
<b>Service Area Total</b>	<b>5,224,625</b>	<b>5,461,865</b>	<b>237,240</b>	<b>4.5%</b>

Source: CON application #10490, page 31.

The applicant notes that the population aged 15+ targeted for the proposed BMT program is expected to increase by 4.5 percent from 2016 – 2020 (90.7 percent of total population growth). The 15+ population of Miami-Dade County will account for 47 percent of OTSA 4 growth within the 15+ population group. Population growth within the 65+ cohort is forecasted to increase by 11.8 percent within OTSA 4 (35 percent of growth within the total 65+ population of OTSA 4). The applicant identifies “strong elderly growth” as important within the context of BMT treatment (Page 32, CON application #10490). The applicant references 2014 data from CIBMTR which documents that 35 percent of BMT cases in 2014 were performed on patients 61+ who also accounted for two-thirds of growth of total BMT cases from 2010 to 2014. A chart depicting 2010 – 2014 hematopoietic cell transplantations (HCTs) by age performed in the United States is provided on page 32 of CON application #10490.

**Florida Bone Marrow Transplant Providers and Provider Volume**

The applicant provides a summary of the existing number of BMTs published in the AHCA Adult and Pediatric Transplantation Programs for January 2016–December 2016. The applicant states that the 1.026 adult BMTs for January 2016–December 2016 consists of inpatient and outpatient autologous and allogeneic BMT cases. The Agency notes that only inpatient BMT procedures are CON-regulated, outpatient procedures are not included in the Agency’s publication unless erroneously reported by a licensed provider facility. BHM describes the BMT program at Good Samaritan Medical Center, an existing OTSA 4 provider in Palm Beach County, as a limited services program. The applicant notes that Good Samaritan Hospital only offers adult

autologous BMT services and further asserts that Good Samaritan Medical Center exclusively operates an outpatient as a result of no inpatient volume reported during “recent years” (CON application #10490, Page 32). The applicant notes and the Agency confirms that BMT volumes reported to the Agency do not reflect actual BMT cases performed at the hospital.<sup>11</sup>

Since its establishment in 2011, the applicant notes that the adult BMT program at MHW has never reached allogeneic or autologous BMT volume levels as defined in the Agency’s CON rules for BMT services.<sup>12</sup> BHM questions the viability of MHW as a full service allogeneic provider and does not consider MHW as an alternative to the proposed BMT program.

The applicant identifies UMHC as having performed the second largest BMT program volume in Florida (184 adult transplants) and H. Lee Moffitt as the largest BMT adult transplant provider (447 adult transplants performed). BHM states that within OTSA 4, 230 total adult BMT transplants were performed in CY 2016 and that this volume of BMT transplants consists of inpatient and outpatient autologous and allogeneic cases. Historical trends in the provision of adult BMT transplants from 2012 - 2016 as published in the Agency Organ Transplantation Data are summarized by the applicant on page 33 – 34 of CON application #10490. Overall, the applicant notes that the number of transplants increased by 27 percent from 2012 – 2016 and UMHC experienced the largest numerical growth in BMT volume with an overall increase of 90 percent growth in cases from 2012 – 2016. The applicant notes that the UMHC attested that 100 percent of BMT volume was provided on an inpatient basis during testimony at DOAH for Case No. 16-1698CON.

The reviewer notes that based on Agency inpatient data and the information provided on the floridahealthfinder.gov compare care tool at <http://www.floridahealthfinder.gov/CompareCare>, UMHC had an average length of stay (ALOS) of 25 days for BMTs for CY 2016 for all

<sup>11</sup> The reviewer notes that Debra Parsons, Controller from Good Samaritan Medical Center, confirmed by email on June 14, 2017, that the numbers that have been submitted to the Health Council of Southeast Florida are not for bone marrow transplant procedures but for bone marrow biopsies. At present, the Agency has not received any official notification that the program is defunct.

<sup>12</sup> The reviewer notes that Rule 59C-1.044(9)(b)-(c), F.A.C., state:

(b) Applicant 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.

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



adults (age 18+). Based on UMHC’s reported number of transplants of 184 for CY 2016, UMHC has approximately 4,650 patient days for adult BMTs, or an average daily census 12.60 patients. The reviewer notes that CON 10041 stated that 12 private inpatient rooms (of 40 total beds) at UMHC would be dedicated to the adult BMT program. The 12-bed census is further legitimized by UMHC’s own website, <http://sylvestor.org/patients/treatment/stem-cell-transplant>, which confirms that the facility has a 13,964 square-foot inpatient unit with 12 specialized transplant beds.

***Bone Marrow Transplant Inpatient Cases and Transplant Services Planning Area 4 Resident BMT Volume***

The applicant states that data submitted for the *Agency Organ Transplant Program Utilization Data* is self-reported and does not take into account the number of inpatient bone marrow transplant cases that were performed on residents of south Florida or on residents of OTSA 4. The applicant states that the Agency Inpatient Discharge Database is the only source of reliable data for reviewing BMT transplants, though the Agency Inpatient Database only captures residents treated in a Florida BMT facility. The applicant notes that Florida residents can be treated at national BMT Centers like MSK, which are not included in the Inpatient Discharge Database. The applicant also states that the Agency Inpatient Discharge Database does not take into account outpatient BMT cases and for these reasons the applicant determines that the Agency Inpatient Discharge Database undercounts the actual number of Florida resident BMT cases.

The applicant uses Agency Discharge Data for the 12 months ending September 2012 – 2016 for Florida and OTSA 4 adults aged 15+ for MS – DRG classifications: 014 (allogeneic BMT), 016 (autologous BMT with complications or major complications) and 017 (autologous DRG without complications or major complications) which is reproduced below. <sup>13</sup>

<b>Total Florida Inpatient Bone Marrow Transplant Volume Patients Age 15+, 12 Months Ending September 2016</b>					
<b>MS-DRG</b>	<b>12 Mnths End Sept. 2012</b>	<b>12 Mnths End Sept. 2013</b>	<b>12 Mnths End Sept. 2014</b>	<b>12 Mnths End Sept. 2015</b>	<b>12 Mnths End Sept. 2016</b>
<b>DRG 014 Allogeneic</b>	226	308	321	365	371
<b>DRG 016 Autologous W CC/MCC</b>	380	449	394	446	496
<b>DRG 017 Autologous W/O CC/MCC</b>	65	39	40	38	50
<b>Total</b>	<b>671</b>	<b>796</b>	<b>755</b>	<b>849</b>	<b>917</b>

Source: CON application #10490, page 35

<sup>13</sup> The reviewer notes that CY 2016 Adult Inpatient BMT data was available from the Florida Center for Health Information and Transparency



Based on the time-period considered in the analysis, the applicant notes that BMT volume increased by 37 percent from September 2012 – September 2016.

<b>OTSA 4 Residents Inpatient Bone Marrow Transplant Volume Patients Age 15+, 12 Months Ending September 2016</b>		
<b>MS-DRG</b>	<b>Total All Hospitals Discharges Age 15+</b>	<b>CON Approved Hospitals Discharges Age 15+</b>
<b>DRG 014 Allogeneic</b>	99	90
<b>DRG 016 Autologous W CC/MCC</b>	104	102
<b>DRG 017 Autologous W/O CC/MCC</b>	24	23
<b>Total</b>	<b>227</b>	<b>215</b>

Source: CON application #10490, page 35

***Transplant Services Planning Area 4 Adult Resident BMT Patient Flow***

The applicant also provides a table depicting outmigration patterns of BMT patients, this table is reproduced below:

<b>OTSA 4 Residents Inpatient BMT Patient Outmigration, Patients Age 15+, 12 Months End 09/16</b>					
<b>MS- DRG</b>	<b>CON Approved Hospitals Discharges Age 15+</b>	<b>Cases Performed in OTSA 4</b>	<b>Cases Performed Outside of OTSA 4</b>	<b>% Cases Performed in OTSA 4</b>	<b>% Cases Performed Outside of OTSA 4</b>
DRG 014 Allogeneic	90	53	37	59%	41%
DRG 016 Autologous W CC/MCC	102	79	23	77%	23%
DRG 017 Autologous W/O CC/MCC	23	22	1	96%	4%
<b>Total</b>	<b>215</b>	<b>154</b>	<b>61</b>	<b>72%</b>	<b>28%</b>

Source: CON application #10490, page 36

Based on the data included in the applicant’s analysis, outmigration accounted for 27 percent of all adult BMT cases reported for OTSA 4 residents, including non-CON providers, or 28 percent of adult BMT cases performed at CON approved programs. The applicant states that outmigration patterns have been relatively stable over the past nine years and persists as a significant burden on patients. The applicant references arguments proposed in CON application #10041, submitted by UMHC, as a parallel justification for access limitations that will be remedied by the proposed BMT program.

The applicant maintains that outmigration patterns of OTSA 4 residents contribute to need for the proposed BMT program. BHM intends to provide a high quality local program to OTSA 4 residents in order to allow patients to access care close to home and reduce the costs and inconvenience associated with travelling outside of their service area.

BHM states that post-transplant care and follow-up care are exceptionally burdensome to patients and provides an example narrative scenario for allogeneic and autologous patients on page 37 of CON application #10490.

In reference to previous outmigration analyses by MS-DRG provided on page 36 of CON application #10490, the applicant notes that the highest level of outmigration was observed in allogeneic BMT patients which accounted for 41 percent of outmigration cases. BHM states that these patients require the longest post-discharge treatment regimen and for this reason high levels of outmigration are evidence of a significant problem. Autologous cases with complications account for 23 percent of outmigration cases and autologous patients without complications account for four percent of outmigration cases. The applicant reiterates that the proposed project is expected to target these patients as a local alternative to care outside of OTSA 4.

The applicant also states that based on the UMHC provision of BMT care to Medicaid Managed Care/Medicare Managed Care/self-pay patients for the 12 months ending September 30, 2016 and \$0 of inpatient charity care for FY 2015 (2015 Actual Financial Final Report submitted to the Agency)-- Medicaid/Medicare Managed Care/self-pay patients and patients with little or no financial access to BMT care are determined to have outmigrated for care while the UMHC reported a \$153 million operating margin in FY 2015.

***Transplant Services Planning Area 4 Adult Resident BMT Use Rates***

The applicant provides analyses of actual adult BMT use rates for OTSA 4 residents which demonstrates that local residents access BMT at a lower rate than the rate observed statewide in Florida for the 12 months ending September 30, 2016.

The reviewer has consolidated the tables depicting these comparisons below:

<b>Resident BMT Use Rates, Age 15+ per 100,000: Transplant Service Area 4 and Florida BMT Use Rates</b>				
	<b>Allogeneic</b>	<b>Autologous with Complications</b>	<b>Autologous without Complications</b>	<b>Total All BMT Cases</b>
<b>OTSA 4 Resident Adult 2016 BMT Cases</b>	90	102	23	215
<b>OTSA 4 Resident Adult (age 15+) 2016 Population</b>	5,224,625	5,224,625	5,224,625	5,224,625
<b>OTSA 4 Resident Adult BMT Use Rate</b>	1.72	1.95	0.44	4.12
<b>Florida Residents Adult 2016 BMT Cases</b>				
<b>Florida Adult (age 15+) 2016 Population</b>	16,654,217	16,654,217	16,654,217	16,654,217
<b>Florida Adult BMT Use Rate</b>	2.05	2.76	0.25	5.07
<b>Florida - Without OTSA 4 Data Use Rate</b>	2.20	3.13	0.17	5.50
<b>OTSA 4 as a % of the Florida Use Rate</b>	84.0%	71.0%	176.0%	81.0%
<b>TSPA 4 as a % of the Florida Use Rate - Without OTSA 4 Data</b>	78%	62%	259%	75%

Source: CON application #10490, pages 38-39. BMT resident cases treated in Florida CON approved hospitals for the 12 months ending 09/30/16 from the agency discharge database. Use Rates calculated by dividing resident cases by applicable populations (100,000s).

The applicant identifies a disparity in the BMT adult resident use rates within OTSA 4 and the remainder of Florida and an even larger disparity in the adult BMT use rate when excluding OTSA 4 data from the overall use rate. BHM maintains that the proposed program can address this disparity through enhancing local access to care within the service area.

The applicant lastly includes an analyses of adult BMT use rate comparisons within the United States using 2014 CIBMTR data for adults aged 20+ and Florida adult BMT cases derived from the Agency Organ Transplant Program Utilization Data for CY 2016. The applicant notes that the Florida use rate in this analysis reflects a different data set than used in the previous resident use rate analyses. Overall the applicant determines that the use rate for adult BMT cases in the United States (7.3 total BMT cases per 100,000) is larger than the total Florida BMT use rate (6.2 per 100,000).

The applicant provides the following chart depicting differences in the BMT use rate comparisons between the United States and Florida:

<b>Adult BMT Use Rate Comparisons: United States (2014) and Florida (2016)</b>		
	<b>United States (2014)</b>	<b>Florida (2016)</b>
<b>Adult BMT Cases</b>	<b>Age 21+</b>	<b>Age 15+</b>
	17,303 Cases	1,026 Cases
<b>Adult Population</b>	<b>Age 21+</b>	<b>Age 15+</b>
	236,721,454	16,654,217
<b>Adult BMT Use Rate Cases per 100,000 pop.</b>	7.3	6.2

Source: CON application #10490, page 40

BHM maintains that the proposed program can address the disparity between Florida BMT use rates and US BMT use rates and that the proposed program will enhance local access to care within the service area to all residents regardless of transplant type or financial resources, particularly for allogeneic and autologous with complications transplants. The applicant also restates that the program will also enhance access to care and reduce disparities for BMT patients in Medicaid/Medicare Managed Care and charity payer categories.

***National Bone Marrow Transplant Volume Trends***

The applicant references data from the CIBMTR (7/28/16) which demonstrates that the volume of BMTs for both autologous and allogeneic transplants have risen from 1980 to 2015 and specifically “over the past ten years” in the United States (CON application #10490, Page 41). Referencing the same data source, the applicant notes that CIBMTR data demonstrates a 19 percent increase in the volume of BMT cases from 2010 to 2014 and that preliminary data from CIBMTR demonstrates a seven percent increase in the volume of BMT cases from 2014 to 2015.

***Forecast Inpatient Bone Marrow Transplant Services Planning Area 4 Resident Volume***

The applicant forecasts BMT volumes using two approaches. The applicant states that the one projection uses 2016 resident adult inpatient BMT cases forecast to 2019 and 2020 based on a continuation of historical BMT volume growth trends. The applicant states that Florida BMT use rates were applied to forecast 2019 and 2020 OTSA 4 adult population to establish an adult inpatient BMT volume forecast based on actual Florida statewide use rate levels. The applicant references OTSA 4 inpatient BMT volume for patients aged 15+ (ending September 30, 2016) as previously depicted on page 35 of CON application #10490 to forecast volume, assuming OTSA 4 adult BMT cases will grow at historical rates. The applicant also states that

historical BMT growth rates exceed comparable population growth rates demonstrating that the use of historical growth rates to predict future volume is reasonable and appropriate.

The applicant applies three annual growth rates (five percent, seven percent and nine percent) to the baseline 2016 adult BMT case volume for OTSA 4. The five percent annual growth rate was obtained from 2010 through 2014 US volume data from CIBMTR, the seven percent annual growth rate was obtained from 2012 through 2016 Florida provider reported volume data and the nine percent annual growth rate is obtained from the 2012 through 2016 Florida inpatient BMT volume data set. The applicant indicates that the UHMC’s adult BMT volume growth has experienced an average annual growth of over 22 percent per year from 2012 through 2016 and determines forecasts for its BMT proposal reflect a reasonable planning approach. The applicant maintains that for all projections provided, no adverse impact is expected for existing providers.

The applicant provides the following table to depict its forecasted adult inpatient volume for the first two years of operations.

<b>BHM Forecasted Adult BMT Cases: 2019 and 2020</b>				
	<b>Adult BMT Cases All Hospitals</b>	<b>All Hospital BMT Case Volume Above Baseline</b>	<b>Adult BMT Cases CON Approved Hospitals Only</b>	<b>CON Approved Hospital BMT Case Volume Above Baseline</b>
<b>2016 Baseline Cases</b>				
	227		215	
<b>2019 Forecast Cases</b>				
<b>5% Per Year</b>	263	36	249	34
<b>7% Per Year</b>	278	51	263	48
<b>9% Per Year</b>	294	67	278	63
<b>2020 Forecast Cases</b>				
<b>5% Per Year</b>	275	48	261	46
<b>7% Per Year</b>	297	70	281	66
<b>9% Per Year</b>	320	93	303	88

Source: CON application #10490, page 43

<b>BHM Forecasted OTSA 4 Adult (Age 15+) BMT Cases Based on Florida Average Use Rates</b>				
	<b>Allogeneic</b>	<b>Autologous with Complications</b>	<b>Autologous without Complications</b>	<b>Total All BMT Cases</b>
OTSA 4 Adult Population	5,403,720	5,403,720	5,403,720	5,403,720
OTSA 4 Adult 2020 Population	5,461,865	5,461,865	5,461,865	5,461,865
Florida Use Rate Per 100,000 Pop.	2.05	2.76	0.25	5.07
OTSA 4 Forecast 2019 Adult BMT Cases	111	149	14	274
OTSA 4 Forecast 2020 Adult BMT Cases	112	150	14	276

Source: CON application #10490, page 44

Florida BMT adult inpatient use rates calculated by dividing resident cases for the 12 months ending 09/16 from the Agency discharge database by Florida adult population estimates for July 2016

<b>BHM Forecasted OTSA 4 Adult (Age 15+) BMT Cases Based on Florida Average Use Rates (excluding TSPA 4 Cases and Population)</b>				
	<b>Allogeneic</b>	<b>Autologous with Complications</b>	<b>Autologous without Complications</b>	<b>Total All BMT Cases</b>
TSPA 4 Adult Population	5,403,720	5,403,720	5,403,720	5,403,720
TSPA 4 Adult 2020 Population	5,461,865	5,461,865	5,461,865	5,461,865
Florida Use Rate Per 100,000 Pop.	2.20	3.13	0.17	5.50
TSPA 4 Forecast 2019 Adult BMT Cases	119	169	9	297
TSPA 4 Forecast 2020 Adult BMT Cases	120	171	9	300

Source: CON application #10490, page 45

Florida BMT adult inpatient use rates calculated by dividing resident cases for the 12 months ending 09/16 from the Agency discharge database by Florida adult population estimates for July 2016

The applicant states that the application of the statewide average use rates derived from BMT cases performed at CON approved hospitals, to 2016 population data for OTSA 4, demonstrates that OTSA 4 residents should have generated 265 adult inpatient BMT cases in 2016 and that OTSA 4 residents were underserved. The applicant maintains that the proposed projects volumes are attainable without material impact on existing providers, if existing 2016 case volumes of other providers are maintained.

***Forecast Baptist Hospital of Miami Adult Inpatient Bone Marrow Transplant Volume***

The applicant states that market share capture rates for the proposed BMT program at BHM were estimated using a review of current BMT patient flows from the planning area and knowledge of BHM and BHSF current market positions. The applicant anticipates that in the first year of operation (2019), the BMT program will capture 10 percent of the average of the baseline 2016 OTSA 4 range (215 to 227) resident inpatient volume—with 10 allogeneic cases and 12 autologous cases. BHM maintains that the estimated volume assumes that no additional growth beyond 2016 baseline volume and no additional in-migration to the new program from beyond OTSA 4.

The applicant projects 30 BMT cases in year two (15 allogeneic and 15 autologous) and assumes that 10 percent of the forecasted volume would be treated at the new service with an additional five to ten percent of total patients served would originate from beyond the south Florida/OTSA 4 Area. Of the 30 BMT cases, BHM states that 29 cases are projected to originate from OTSA 4 and five percent of cases are estimated to originate from outside of the OTSA 4 geographic area.

The applicant provides funding and accreditation expectations for case volumes in the first year of operation for allogeneic and autologous transplants respectively on page 46 of CON application #10490.

***No Material Adverse Impact on Existing Adult BMT Providers***

The applicant states that based on its projections that the OTSA 4 resident adult inpatient BMT case volume is projected to increase by 34-67 additional cases above 2016 baseline volumes by 2019 and 46-93 additional cases above 2016 baseline in 2020, the applicant determines that forecasted case volume for the first two years of operation for the proposed BMT program is adequate to support its BMT program and will present no adverse impact on existing providers.

***Documentation of Community Support for the Proposed Adult BMT Program***

The applicant provides excerpts from letters of support for the proposed project from local patients, healthcare providers and state government officials on pages 47 to 53 of CON application #10490.

Among these selected excerpts, letters of support are noted from the following individuals:

- Michael J. Zinner, M.D., FAGS, CEO & Executive Medical Director, Miami Cancer Institute
- John A. Rock, M.D., Dean & Sr. Vice President of Health Affairs, Florida International University, University Herbert Wertheim College of Medicine
- Esteban Bovo, Jr. Chairman, Miami – Dade County, Board of County Commissioners

In addition to the need narrative previously summarized, the applicant also provides the following explanations for need for the proposed BMT program on pages four and 24 of CON application #10490:

BHM states that historical trends demonstrate growth in the volume of BMTs and the following trends support continued growth in the number of bone marrow transplants:

- BMTs are increasingly effective with continual improvements in treatment outcome

- BMTs are increasingly safer, with constantly favorable survival rates
- The number of diseases for which BMT is indicated continues to grow
- The sources of donor cells and the number of suitable matches are expanding
- An aging population is increasing the proportion of people who are susceptible to diseases for which BMT is indicated
- Modified transplantation regimens have facilitated safer procedures despite an increase in the median patient age

BHM states that the proposed project is needed to provide additional patient-focused adult bone marrow transplant services within the south Florida area and to provide an acceptable south Florida adult BMT alternative for local residents currently leaving the local area to access adult BMT care and to support an increase in south Florida BMT use rates to levels consistent with Florida and/or national use rate levels. On page 28 of CON application #10490 the applicant indicates that the proposed project is being developed to resolve access problems that are currently inherent within the “Planning Area” (i.e. OTSA 4), as evidenced by the documented high outmigration levels, the low use rates and the lack of charity care provided by the University of Miami program. The applicant additionally states that the proposed program expresses a commitment from Baptist to provide care to all segments of the adult BMT marketplace and will provide enhancements in providing care to patients with limited financial resources as evidenced by the payer class condition provided in Schedule C.

**2. 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).**

The reviewer notes that BHM is not currently a statutory teaching hospital.

In response to this criterion, the applicant attests to BHM’s medical/clinical teaching experiences and research activities which are used to form the applicant’s self-qualified active teaching hospital status.



The applicant notes that two current BMT providers that were previously approved by the Agency, University of Miami Hospital and Clinics and Memorial Hospital West, do not have statutory teaching hospital status and for this reason the applicant asserts that this criterion should not be used as a basis to preclude BHM from being approved.

Specifically, the applicant describes the teaching activity of BHSF hospitals officially affiliated with FIU's Herbert Wertheim College of Medicine (HWCOC), fellowship teaching activity associated with the Doctors Hospital-UHZ Sports Medicine Institute Fellowship Program, graduate medical education/resident rotations at West Kendall Baptist Hospital and Doctors Hospital, graduate health care education for pharmacy and nursing, research activities of medical students of FIU College of Medicine under the supervision of BHSF physicians facilitated by its Center for Research and Grants, continuing education programs for physicians and allied health professionals, and clinical research activity and capabilities (CON application #10490 pages 92 – 105 of CON application 10490).<sup>14</sup>

The applicant additionally describes the professional and academic collaboration of BHSF facilities and FIU College of Medicine. The applicant notes that over 400 BHSF physicians and administrators have voluntary teaching positions at FIU College of Medicine and medical students from FIU College of Medicine are trained by BHSF physicians throughout all four years of medical school training. The applicant provides a list of BHSF staff with positions at FIU's HWCOC demonstrating the relationship that BHSF staff maintains with FIU College of Medicine on page 93 of CON application #10490.

The applicant states that BHM and BHSF together have a large number of ongoing research studies and possess research and infrastructure systems to support existing and future clinical research activity. BHM also notes that many BHSF staff are research faculty at FIU HWCOC and BHSF also maintains a Nursing and Health Sciences Research Department.

BHSF maintains that cancer research is a major portion of its research activity, with 240 ongoing clinical research studies. The applicant provides a list of ongoing clinical research studies in

<sup>14</sup> The reviewer notes that the applicant uses "undergraduate medical education" to refer to academic, professional, research and teaching activities associated with medical students and "graduate medical education" to refer to academic, professional, research and teaching activities associated with medical school graduates and/or postgraduate academic, professional, research and teaching opportunities.

Appendix 8 of CON application #10490 and research profiles of physicians and researchers overseeing research initiatives at the applicant's outpatient center, Miami Cancer Institute, on pages 97 through 104 of CON application #10490.

The applicant discusses ongoing developments of a 140,000 square foot research facility currently under construction at Miami Cancer Institute scheduled for completion in Fall 2017. A description of Miami Cancer Institute's Clinical Research facility is included on page 102 of CON application #10490. The applicant notes that research activity at Miami Cancer Institute is supported by the Miami Cancer Institute's Clinical Trials Office (CTO), established in 2015 with administrative negotiations and disease management collaborations culminating in an alliance with MSK in January 2017.

The applicant states that its outpatient alliance with Memorial Sloan Kettering has resulted in:

- Adoption of MSK standards of care into everyday practice
- Integrated learning
- Access to MSK clinical trials

Overall the applicant states that the CTO centralizes administration of protocol development, review, implementation, regulatory compliance monitoring and quality assurance in addition to managing all cancer clinical trials at Miami Cancer Institute. The CTO also provides administrative, personnel, budgetary and regulatory oversight in support of interventional trials in inpatient and outpatient BHSF facilities. The applicant also identifies affiliation with US Oncology Network through a Research Services Agreement and restates partnerships with FIU HWCOR through the recruitment of physician and non-physician researchers and institutional partnerships between BHSF and the development of research programs.

- (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 forecasts 22 combined inpatient allogeneic and autologous adult transplants in year one and 30 combined inpatient allogeneic and autologous adult transplants in year two. Ten allogeneic transplants are forecasted for year one and 15 allogeneic transplants are forecast in year two.

- (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.**

The applicant identifies Lyle Craig Feinstein, MD, as the Medical Director for the proposed BMT program. The applicant states that Dr. Feinstein meets all the requirements identified in 59C-1.044(9)(b) and (9)(c), F.A.C. The applicant indicates that Dr. Feinstein has extensive experience in BMT and acute leukemia cases involving high-dose chemotherapy. The applicant notes and the reviewer confirms via Florida DOH MQA Search Portal, that Lyle Feinstein is board certified in Internal Medicine and Oncology by the American Board of Internal Medicine.<sup>15</sup> The applicant notes that Dr. Feinstein has directed the Memorial Cancer Institute's BMT from its development to inception. Dr. Feinstein is listed as a hematologist and oncologist on Baptist Health of South Florida Miami Cancer Institute's website.<sup>16</sup> BHM states that Dr. Feinstein has also been responsible for the evaluation and management of all patients undergoing BMT and provides a copy of Dr. Feinstein's CV and list of research publications in Appendix 4 of CON application #10490.

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

The applicant states that it currently has a talented and qualified staff of credentialed nurses with experience in providing quality care to chronically ill patients (e.g. BMT patients) in addition to providing support to patients' families. BHM provides a description of its existing oncology services which includes: a 48-bed Oncology Unit (5 Clarke) which is contained within BHM. The applicant indicates 12 of the 48 beds are considered progressive care beds committed to "stepdown" level of care. The applicant states that patients admitted to this unit are either acutely or chronically ill with cancer. The applicant states that nursing staff aim to reduce the patient's cancer burden and other serious complications through the delivery of high-quality evidence-based nursing care.

<sup>15</sup><https://apps.mqa.doh.state.fl.us/MQASearchServices/HealthCareProviders/Details?LicInd=81515&ProCde=1501>

<sup>16</sup><https://baptisthealth.net/en/health-services/cancer-services/pages/find-a-doctor.aspx#!profile/lyle-craig-feinstein-md-65805/education>

The applicant states that the unit reports to the nursing director and a Masters-prepared patient care manager who is certified in oncology nursing with more than 20 years of oncology nursing experience. BHM states that the fixed staff of the 5 Clarke Unit consists of advanced practice providers, three Masters-prepared clinical nurse leaders with significant oncology experience and a dedicated clinical nurse educator. The applicant maintains that the unit is also staffed by nurses equipped to care for the special needs of oncology patients and works collaboratively in an interdisciplinary capacity with other physicians and departments.

BHM states a preference for hiring nurses with a minimum of a Bachelor of Science in Nursing (BSN) and notes that 82 percent of nurses staffed in the 5 Clarke Unit are BSN-prepared and the remainder of the staff is currently pursuing education to obtain a BSN. The applicant indicates that new nurse hires to 5 Clarke are considered after the completion of an 18-week residency specific to 5 Clarke and the care of cancer patients. Nurses hired to the 5 Clarke Unit are subject to annual competency and skill validation specific to the 5 Clarke Unit and patient needs. A list of nurses who will serve the applicant's proposed program is provided on page 107 of CON application of #10490 and CVs of select staff is provided in Appendix 4 of CON application #10490. The applicant states that additional staff will be hired as indicated in Schedule 6A of CON application #10490.

The applicant notes that 130 nurses are currently employed in BHM's Critical Care Unit (CCU)—with 86 percent of nurses within the unit having a BSN degree or higher and are experienced with competencies in the care of critically-ill immunosuppressed patients. Nurses are eligible for hire to the CCU after the completion of a 24-week "Specialty Transition Residency" and critical care competencies of nurses within the CCU are evaluated annually with learning needs addressed with ongoing educational opportunities. Select nurses from the Oncology Unit will be transitioned from the CCU to support the BMT program.

- (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 that the current BMT team at BHM consists of board certified hematologists, oncologists and advanced practice practitioners with specific expertise in hematology, oncology, immunological diseases, neoplastic diseases (including hematopoietic and lymphopoietic malignancies) and non-neoplastic disorders. The applicant notes that the BMT program at Miami Cancer Institute has extensive experience in hematological malignancies and blood and marrow transplantation with training at the Fred Hutchinson Cancer Center. The applicant notes that Dr. Feinstein was previously the Director of the Blood and Marrow Transplantation program at MHS (CV, Appendix 4, CON application #10490). The applicant identifies two physicians currently on staff at the outpatient facility, MCI, Dr. Steven Fein<sup>17</sup> and Dr. Allen Leonard Greenberg<sup>18</sup> who will be on staff for the proposed program and notes that two additional BMT physicians will be recruited in addition to a Chief of Hematology Malignancy for the BMT program. The applicant states that the physicians will collectively direct the management of BMT care and the maintenance of immunosuppressive therapies for BMT patients.

The applicant also states that skilled advanced practice providers with experience in caring for BMT and hematologic malignancy patients will support and care for BMT patients in inpatient and outpatient settings.

In addition to maintaining physician cancer specialists, the applicant also describes the capacity of BHM medical specialists to provide specialty support services to BMT patients when needed. BHM states that medical support services will be available 24-hours daily and that its medical support staff will provide: intensive care, cardiology (including invasive and electro-physiology), pulmonary medicine (interventional pulmonologists), infectious disease specialists familiar with the care of severely immune-compromised patients, neurology, neurosurgery,

<sup>17</sup> Per Florida Department of Health's MQA Search Portal, Steven Gary Fein is a licensed medical doctor with a primary practice address at Baptist Hospital of Miami. Dr. Fein is board certified by the American Board of Internal Medicine in Internal Medicine, Oncology, and Hematology. Dr. Fein also appears on staff at Miami Cancer Institute's website

<sup>18</sup> Per Florida Department of Health's MQA Search Portal, Allen Greenberg is a licensed medical doctor with a primary practice address at Miami Cancer Institute on Baptist Hospital of Miami's campus. Dr. Greeneberg is board certified by the American Board of Internal Medicine in Hematology and Internal Medicine. Dr. Greenberg also appears on staff at Miami Cancer Institute's website.

gastroenterology (including interventional and non-invasive gastroenterology), ophthalmology, dermatology, ENT, thoracic surgeons, vascular surgeons, interventional radiology, psychology and psychiatry, sub-specialty radiology, orthopedics and urology.

The applicant states that post-transplant care will be provided by the BMT team in both inpatient and outpatient settings and patients will be evaluated by BMT nurses, APPs (Advanced Practice Providers) and physicians using treatment protocols and a patient's status following a transplant. Patients will also be followed by the Survivorship Program which will support BMT patients with issues related and unrelated to BMT follow-up as well as a team of survivorship practitioners to assist patients in providing well-care guidance, social, psychological, financial and spiritual support.

- (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.**

The applicant proposes a new, all private room, six-bed adult BMT unit on the Hospital's Four Main/East patient floor, anticipating that the six-bed unit will have relatively low annual occupancy during the initial years of operation and will incrementally increase the bed-capacity according to occupancy rates. The proposed unit will be 8,800 square feet and designed for the particular needs of inpatient BMT patients following ablative conditioning (chemotherapy or radiation to kill the targeted cancer cells and suppress immune system response) and subsequent infusion or injection of healthy stem cells to support the growth of health and non-cancerous blood cells. The applicant indicates that each room will be oversized to support private bathing facilities, a family zone, headwall electrical, data and medical gases to support intended patient acuity levels. Each room will also be maintained under a positive pressure relative to the adjacent corridor and have a minimum exchange rate of 12 per hour. The applicant states that the inpatient BMT area will require a new air handling unit, approximately 18,000 cfm and will have MERV 17 (HEPA) final filters and MERV 8 (30 percent) pre-filters as well as be equipped with variable speed drives and UV lights while providing positive air pressure and reverse isolation procedures in support of BMT patient care.

- (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.**

The applicant states that its existing radiation oncology department is under the direction of a board-certified radiation oncologist—staffed by a total of 10 radiation oncologists, 17 medical physicists and supported by more than 90 nurses, therapists, and dosimetrists. Minesh Mehta, MD, is identified as the Chief of Radiation Oncology and a board-certified radiation oncologist. Dr. Mehta’s CV is included in Appendix 9 of CON application #10490.<sup>19</sup> The applicant indicates that BHM’s radiation therapy services at the Miami Cancer Institute consist of sublethal x-irradiation, bone marrow ablation, and total lymphoid irradiation. BHM states that the current radiation therapy team is trained to deliver these BMT therapies. The applicant identifies Matthew Hall, MD, a radiation oncologist at Miami Cancer Institute as an expert in delivering radiation therapy. BHM states that the area housing conventional (photon) equipment will be contiguous with south Florida’s first fully equipped proton therapy unit (a three-rom, pencil beam equipped facility). The applicant describes additional radiation services to be offered on page 110-111 of CON application #10490.

- (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.**

The applicant states that monoclonal antibodies will not be used by the proposed BMT program. Cellular processing services will be provided by OneBlood through contractual agreement. The applicant states that T-cell depletion is not anticipated, but, OneBlood will initiate the service in the event it is needed. In the event that OneBlood is unable to provide T-cell depletion, the applicant indicates that an alternative accredited laboratory will be used to fulfill this service. The applicant provides a sample of a

<sup>19</sup> Per Florida Department of Health’s MQA Search Portal, Minesh P. Mehta is a licensed medical physician with a Clear/Active medical license. Dr. Mehta’s primary practice address is listed at Baptist Hospital of Miami. Dr. Mehta possesses staff privileges at Baptist Hospital of Miami and South Miami Hospital. Dr. Mehta is also board-certified in Radiation Oncology by the American Board of Radiology. Dr. Minesh P. Mehta is also listed as a radiation oncologist on staff with BHSF.

letter and sample agreement from OneBlood confirming support for the proposed BMT program and the scope of services available from OneBlood in an addendum in Appendix 10 of CON application #10490.

The reviewer notes that in Appendices 4 and 10 of CON application #10490, a letter from Jean Dariotis, Senior VP of Laboratory Services at One Blood is provided and states:

*“We are pleased to offer the services of OneBlood, Inc. in support of the Baptist Hospital of Miami adult autologous and allogeneic bone marrow transplant program in Miami-Dade County. OneBlood is a full-service blood center offering a spectrum of blood products and related services to our hospital partners. These offerings include a FACT-accredited Cellular Therapy Laboratory capable of providing bone marrow and stem cell processing, freezing, storage, thawing, stem cell collections and associated laboratory testing, including CD 34 cell counts, T-cell subset characterization, sterility cultures and cell viability assays. Based on business imperatives, we also have the capability of initiating additional services such as T-cell depletion of grafts as indicated”*

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

The applicant states that bone marrow evaluation and cryopreservation will be fulfilled through contractual agreements with OneBlood. The applicant provides a sample of a letter and sample agreement from OneBlood confirming support for the proposed BMT program and the scope of services available from OneBlood in an addendum in Appendix 10 of CON application #10490.

The applicant states that an onsite laboratory for bone marrow evaluation and cryopreservation will be established, if required. The reviewer notes that pursuant to the current language of 59C-1.044, (9)(b)8., Florida Administrative Code, an on-site laboratory equipped for the evaluation and cryopreservation of bone marrow is required for approval of the proposed service.

**(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.**



The applicant states that BHM and the Miami Cancer Institute both have a strong and expanding research program integrated within the hospital and within the BHS. The applicant states that a number of ongoing clinical research studies are being conducted within BHM and MCI which include outcome monitoring and long-term patient care follow-up. The applicant provides descriptions of research being conducted at the Miami Cancer Institute in Appendix 9 of CON application #10490.

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

The applicant reiterates that BHM and the Miami Cancer Institute both have a strong and expanding research program integrated within the hospital and within the BHS. The applicant restates that a number of ongoing clinical research studies are being conducted within BHM and MCI which are evidence of a research-orientated oncology program. The applicant provides descriptions of research being conducted at the Miami Cancer Institute in Appendix 9 of CON application #10490 as evidence of a research-oriented oncology program.

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

The applicant states that BHM currently works with local hotels to ensure that patients and their families have accessible housing resources during extended hospital stays or extended recuperative stays. The applicant provides a list of hotels that work with BHM in this capacity in Appendix 11 of CON application #10490. The applicant states that BHM has several apartments for patients, caregivers and families and social work staff provide resources to all patients in order to access housing and assistance with nonmedical needs. The applicant states that BHM is in the process of constructing a new hotel facility on campus, to be completed by mid-2018, located on the northwest corner of the campus and accommodate 184 rooms mostly intended for extended-stay. The applicant states that the on-campus residential resource will be focused on supporting the residential needs of BHM patients and family members, particularly in the post-transplant monitoring and evaluation. The applicant will also provide shuttle services to assist with transportation, drawings of the proposed hotel facility are included on page 113 of CON application #10490.

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

The applicant states that an outpatient unit for close supervision of discharged patients is currently under-construction and will be located on the third floor of the Miami Cancer Institute's Clinical Research Building, in the northeast sector of the BHM campus. The applicant states that patients will be seen in the outpatient BMT unit throughout the various pre-and post-transplant phases. The applicant describes the scope of services and facilities of the outpatient unit on pages 113 – 114 of CON application #10490.

**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 states to possess the staff and resources necessary to support blood and marrow transplant patients on a 24-hour basis. BHM describes its team of 27 board-certified hematologists and oncologists currently on staff. The applicant notes that three of its 27 physicians are currently trained and experienced to care for adult BMT patients. The applicant maintains that this team has the capacity to provide patient care in the inpatient and outpatient setting and to support nine multidisciplinary tumor site teams which also include a team for hematological malignancies and blood and bone marrow transplantation.

The applicant includes a list of hematologists and oncologists currently on staff at BHM and the Miami Cancer Institute and a list of cancer specialists at Miami Cancer

Institute in Appendix 3 of CON application #10490. CVs for select BMT medical and clinical staff are also included in Appendix 4. A profile of the Medical Director for the applicant's proposed project, Lyle Feinstein, is included on pages 54 through 55 of CON application #10490. In addition to maintaining physician cancer specialists, the applicant also describes the capacity of BHM medical specialists to provide specialty support services to BMT patients, when needed. BHM states that medical support services will be available 24-hours daily. BHM's medical support staff includes 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, neurologists, neurosurgeons, gastroenterologists (including interventional gastroenterologists), ophthalmologists, dermatologists, ENT physicians, thoracic surgeons, vascular surgeons, interventional radiologists, psychologists and psychiatrists as well as sub-specialty radiologists, orthopedists and urologists.

BHM also provides a description of the following supportive services for BMT patients that are available 24-hours, seven days weekly on pages 56 through 59 of CON application #10490:

- Nursing services
- Pharmacy services
- Respiratory services
- Infusion services
- Radiation oncology services
- Laboratory services
- Food services
- Clinical dieticians
- Psychological services
- Pharmacy: clinical pharmacist, pharmacy technicians, research pharmacists, support and administrative
- Inpatient nursing staff and resources
- Respiratory therapy staff and resources
- Outpatient infusion staff and resources
- Intervention radiology
- Radiation oncology
- Laboratory staffing
- Nutrition department staffing
- Cancer support services staffing
- Diagnostic Imaging department staffing

The applicant maintains that its existing service and staff complement demonstrate that BHM has the capacity and resources necessary to care for a patient's chronic illness prior, during and following the BMT transplantation period.

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.**

The applicant states that the Baptist Hospital Critical Care Unit (CCU) has 32 beds divided into four eight-bed pods. BHM also maintains an additional four medical Critical Care beds as an extension of the CCU. BHM maintains that critical care beds are staffed with Critical Care Intensivists who are board-certified in Critical Care Medicine, some Critical Care Intensivists are board-certified in other specialties as well. The applicant indicates that coverage in the CCU is 24-hours daily and includes a Critical Care Advanced Practice Nurse.

BHM states that patients in the CCU are monitored through a remote monitoring system by Critical Care intensivists and nurses through Baptist Health eICU also referenced as Visicu eICU. The applicant maintains that this remote monitoring system is a telemedicine system that offers continuous monitoring of patients, but is not a replacement for intensivists in the CCU. The applicant additionally states that the CCU maintains comprehensive spectrum of services including: post open-heart, post neurosurgery, continuous renal dialysis, hypothermia management and care for immunosuppressed patients. BHM also maintains a satellite pharmacy, stat lab for blood gases, and immediate access to the Baptist Hospital Laboratory and Blood Bank within its CCU. The applicant indicates that the CCU is currently

managed by a medical director, vice-president/chief nursing officer, nursing director, nurse manager, and pharmacist (the applicant notes staff members in each position on page 60 of CON application #10490). BHM also notes that its facility employs 130 critical care clinical nurses experienced and competent in the care of critically-ill immunosuppressed patients within the CCU. The applicant also notes that Baptist Hospital of Miami is an American Nurses Credentialing Center (ANCC)-accredited Magnet Hospital.

The applicant does not specifically reference facilities for prolonged reverse isolation but explains that additional support is being developed for treating BMT patients in the CCU and will be implemented through the conversion of an existing Critical Care room into a “Protective Environment” room. The modification scheme for this plan is included on page 60 of CON application #10490. Elsewhere in the application, BHM states that each room in the six-bed BMT unit will be oversized to support private bathing facilities, a family zone, headwall electrical, data and medical gases to support intended patient acuity levels. Each room will also be maintained under a positive pressure relative to the adjacent corridor and have a minimum exchange rate of 12 per hour. The applicant states that the inpatient BMT area will require a new air handling unit, approximately 18,000 cfm and will have MERV 17 (HEPA) final filters and MERV 8 (30 percent) pre-filters as well as be equipped with variable speed drives and UV lights while providing positive air pressure and reverse isolation procedures in support of BMT patient care. The applicant indicates that this BMT unit will address the unique needs of inpatient bone marrow transplant patients after the patient’s ablative conditioning (chemotherapy or radiation to kill the targeted cancer cells and suppress immune system response) and subsequent infusion or injection of healthy stem cells to support the growth of healthy non-cancerous blood cells.

The applicant additionally identifies the conditions in which BMT patients will be transferred to the CCU and components, design elements, staffing, and supportive systems associated with the CCU on page 61 of CON application #10490. BHM maintains that the inpatient BMT area will operate in a positive pressure environment and provides additional facility information about the BMT inpatient unit in Schedule 9 of CON application #10490.

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

BHM states that a clinical review committee will evaluate all potential patients regarding their eligibility and suitability. The applicant states that the clinical review committee will be chaired by the BMT program Medical Director with an interdisciplinary group of physicians, clinical, and support staff that will participate in the patient evaluation process.

The applicant identifies a list of members of the clinical review committee on page 62 of CON application #10490. The applicant states that the committee members at a minimum will include:

- Chairman
- BMT physician staff
- Advanced practice providers
- Supportive medical staff
- BMT team support staff

The applicant indicates that the committee will meet weekly and new potential BMT patients will be presented by the attending BMT physician who consulted with the patient. In the event that the potential BMT patient is identified as a candidate for BMT, the patient will undergo a comprehensive pre-transplantation evaluation in which the attending physician and other BMT team members discuss the appropriateness or inappropriateness of transplantation and potential treatment alternatives. BHM states that the clinical review committee will also review patients undergoing various phases of transplantation, an assessment of patient outcomes, long-term follow-up, quality measures and applicable performance improvement measures.

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

The applicant indicates that written protocols for the proposed BMT program will be finalized prior to the initiation of the outpatient BMT program in Fall 2017. BHM states that protocols and policies will be used to address all aspects of care for BMT patients and include recipient and donor

selection criteria, evaluation and management during the pre-hospital, in-hospital and immediate post-discharge phase of care and guidelines for the management of the patient's long-term post-BMT survivorship care.

The applicant indicates that additional policies and procedures will be created or updated for the treatment and management of allogeneic recipients and their donors. BHM states that a draft of HLA typing will be updated based on research and recommendations of HLA experts.

The applicant states that protocols and guidelines will utilize standards of care defined by FACT, National Comprehensive Cancer Network (NCCN), the National Marrow Donor Program, and the American Society for Blood and Marrow Transplantation. BHM states that the BMT Medical Director, Lyle Feinstein, will direct the finalization of protocols, policies, treatment plans and guidelines for selection, evaluation, treatment and management of BMT patients. Drafts of these documents are attached in Appendix 5 of CON application #10490.

The applicant indicates that written policies describing the care of BMT patients will include:

- Patients referred for transplant
- Criteria for patient selection
- Pre-transplant consult and evaluation guidelines
- Clinical evaluation procedures for all BMT patients
- Clinical laboratory evaluation – for all BMT patients
- Additional studies for allogeneic transplant patients
- Collection of hematopoietic cell sources
- In-hospital criteria
- Admission process
- Infection control
- Conditioning regimen
- Leaving the hospital

Descriptions of these policy areas are included on pages 63 through 67 of CON application #10490.

**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 and policies defining therapeutic and evaluative procedures for the acute and long-term management of each BMT patient are being finalized for the Fall 2017 initiation of the outpatient BMT program and for the development of its proposed inpatient program. BHM indicates that these protocols and policies will address all aspects of post-transplant care of BMT patients including commonly encountered complications. BHM states that the proposed project will integrate Miami Cancer Institute's Survivorship Program and Symptom Management/Palliative Medicine Service to provide an expansive care model for post-transplant patients.

The applicant reiterates that its detailed therapeutic and evaluative procedural protocols and guidelines will be consistent with FACT standards, NCCN guidelines, the National Marrow Donor Program and the American Society for Blood and Marrow Transplantation. BHM also states that BMT patients require continuous lifelong care following a transplant and ongoing evaluation by a qualified BMT team. The applicant explains that BMT is an effective treatment for several types of cancer with various side effects. The applicant details the processes of care for common side effects of BMTs including infection and graft versus host disease on pages 68 through 70 of CON application #10490.

The applicant states that BHM will have written protocols defining therapeutic and evaluative procedures for the long-term management of each BMT patient following discharge from the BMT service back to the patient's initial treating or referral physician. The applicant states that these guidelines will include the process for discharging a patient back to the referring physician, target patient evaluation intervals (100 days post-transplant/6 months post-transplant/ one-year post-transplant and annually thereafter). The applicant references post-discharge guidelines in Appendix 5 of CON application #10490.



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

This is not applicable to bone marrow transplantation programs.

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

The applicant states that BHM maintains a contractual agreement with LabCorp for tissue-typing services. The applicant indicates that LabCorp of America is accredited by the American Society for Histocompatibility and Immunogenetics and CMS Clinical Laboratory Improvement Amendments and licensed in the State of Florida. BHM references LabCorp's accreditation and licensure documentation included in Appendix 6 of CON application #10490. A sample of a contractual agreement is included in Appendix 6 of CON application #10490.

- 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.**

The applicant states that the laboratory department at BHM offers a full range of services that assist with medical staff's determination of the cause and course of diseases through tissue analysis, blood and other bodily fluids. The applicant states that the laboratory department possesses the staff, resources and expertise to fully support the proposed BMT program and medical needs of patients. The applicant states that OneBlood and LabCorp are external resources that support its laboratory department's pathology services. The applicant provides information related to OneBlood's existing and future affiliation with BHM and endorsement of the inpatient BMT program in Appendix 10 of CON application #10490 (Page 73, CON application #10490).

The applicant identifies the following scope of services available at its laboratory department:

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

BHM states that laboratory services are available 24 hours, daily. The applicant states that staffing is adjusted to meet testing demands and indicates that the laboratory features fully integrated information systems for complete computerization of order entry, test results and reporting.

The applicant identifies Dr. Edwin Gould, M.D., as the Medical Director of the laboratory department at BHM. The applicant provides a copy of Dr. Gould's CV in Appendix 4 of CON application #10490.<sup>20</sup> The applicant additionally notes that all pathologists within the laboratory department are board certified and all technical laboratory personnel are licensed by the State of Florida. BHM provides additional descriptions of the credentials and qualifications for laboratory staff on page 72 of CON application #10490.

BHM also discusses BHM's sponsorship of a laboratory symposium and support of participation in the College of American Pathologists (CAP) competency program; the applicant indicates that the laboratory department at BHM is accredited by the College of Pathologists, licensed by the Agency for Health Care Administration, maintains a CLIA Laboratory Certificate of Accreditation, and complies with all other applicable local, state and federal laws and regulations.

<sup>20</sup> Per Florida Department of Health's MQA Search Portal, Edwin Gould is a licensed medical doctor with a Clear/Active medical license. The physician's primary practice address is listed at Baptist Hospital of Miami. Dr. Gould is certified in Dermatology and Anatomic and Clinical Pathology by the American Board of Pathology. Dr. Edwin Gould is also listed as a Pathologist with the same affiliations on the Baptist Health South Florida website:

Copies of these accreditations and licensure documents are provided in Appendix 6 of CON application #10490.

**10. Blood banking facilities.**

The applicant states that the existing blood banking and transfusion facilities and services at BHM are appropriate for supporting the blood requirements associated with the proposed BMT program. BHM notes that the existing blood banking facilities and services are supported by OneBlood. The applicant states that with OneBlood serving as the area's centralized blood collection, storage and distribution hub—all necessary blood banking services are available and supported.

BHM further indicates that OneBlood will provide specialty BMT blood/marrow processing and storage services in order to fully meet the blood and blood banking needs of BMT patients and external complex antibody identification. The applicant provides information related to OneBlood's existing and future affiliation with Baptist Hospital of Miami and endorsement of the inpatient BMT program in Appendix 10 of CON application #10490.

The applicant additionally describes the services offered by BHM's transfusion service department which is stated to provide blood, components, products and services. Dr. Edwin Gould is identified as the Medical Director of the Blood Banking/Transfusion Service at BHM and the applicant previously identified Dr. Edwin Gould as Medical Director of the laboratory department. The reviewer notes that the applicant does not identify whether blood banking operations are integrated or separate from laboratory department operations.

The applicant states that the Transfusion Service Medical Director serves as a liaison between the transfusion service department and the organization's medical staff. The applicant includes a description of the most common pre-transfusion procedures performed, blood/components availability, and organizational regulatory requirements and standards of the Transfusion Services Department on page 73 of CON application #10490.

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

The applicant states that Baptist Hospital's Clinical Learning Department develops and manages training and education initiatives. The parent organization, BHSF, is also stated to possess extensive staff training and an educational infrastructure that is used to support each staff member's ability to provide optimal care to every patient within BHSF's network.

The vision of Baptist Clinical Learning Department is stated as follows:

“Clinical Learning shall focus on enhancing competency and clinical outcomes by delivering evidence-based initial education and professional development courses. The Clinical Educators provide nursing the knowledge and skills necessary to achieve excellence in clinical practice”

Source: CON application #10490, Page 74.

The applicant additionally notes that the Clinical Learning Department also offers continuing education and specialty practice internships for all areas of the Hospital's operations and is contained within the BHSF Health Human Resources Department. BHM states that educational programs to support the learning needs of clinical staff are developed and facilitated based on identified needs.

The applicant identifies key staff of the Clinical Learning Department which is stated to consist of 30 experienced clinicians and educators on page 74 of CON application #10490. BHM states that the Clinical Learning Department supports the expert members of the BMT team who provide BMT program education and identifies the following individuals as experts in BMT care who will provide BMT education:

- Lyle Feinstein, MD, Medical Director, BMT
- Maria M. Rios, RN, BSN, OCN, BMT-CN Director of Clinical Operations, BMT
- Judith L. Luck, MSN, ARNP, CHTC, BMT-CN, BMT APP Supervisor
- Maria Encinas, RN, MSN, OCN, CNL, BMT Clinical Educator
- Rosa Casieda, MSW, Manager of Social Work

The applicant additionally notes that learning initiatives, activities, and the proposed project will also be supported by: a learning management system, the clinical informatics department, the nursing research department, nurse scientists, Baptist's continuing medical education department, the medical library department, and the pastoral care department. Descriptions of these auxiliary supports, initial and continuing staff education and the Versant RN Residency Program are included on pages 75 – 78 of CON application #10490.

The clinical educator, Maria Encinas, and Maria Rios, Director of clinical operation of the BMT program are responsible for the education, training and development of staff. The applicant states that upon hire staff attend a live BHSF General Nursing Orientation Program which includes: hand hygiene, IV therapy, blood product administration, central line management, prevention of central line associated blood stream infections and safe chemotherapy administration. The applicant notes that staff are also required to complete 24 online modules within 30 days of hire.

The applicant states that BMT staff have a set of competencies which must be validated by either the clinical educator or BMT nursing leadership. Action plans and corrective/remediation actions are implemented for staff with incompetent skillsets and a description of this action plan is included on page 79 of CON application #10490.

A list of BMT nursing competencies, identified by the applicant are included below:

- General BMT orientation
- Central line care
- Blood product administration
- Chemotherapy/biotherapy administration

- Mobilization regimen administration
- Hematopoietic stem cell apheresis
- Hematopoietic stem cell product thawing
- Hematopoietic stem cell product reinfusion (transplant)

The applicant also states that nursing staff must participate in a Blood and Marrow Transplant (BMT) training program and complete the Oncology Nursing Society 20.5 Contact Hour online course “The Fundamentals of Blood and Marrow Transplantation”, and attend a two-day live-didactic program presented by the Miami Cancer Institute Blood and Marrow Transplantation Program. Staff education materials and a supplement for the live-didactic program are included in Appendix 7 of CON application #10490.

Summaries of education offerings available through the educational program are included on pages 79 – 80 of CON application #10490.

The applicant states that nursing staff are subject to annual competency assessments developed by the Clinical Educator and BMT nursing staff. The applicant states that upon approval of the proposed project, the Miami Cancer Institute Blood and Marrow Transplant team will collaborate with BHM to develop education and training materials related to the management and care of allogeneic transplant prior to and post transplantation.

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

BHM states that patients, caregivers, and families will receive education targeted to their assessed needs and preferred learning styles and be directed to access BHM’s comprehensive health information resources. The applicant indicates that pre-transplant education is also mandated for all patients and their caregivers. The applicant states that education will be directed by the BMT nurse coordinator and supported by other staff. The applicant has included a copy of its BMT Patient Caregiver and Educational Manual in

Appendix 7 of CON application #10490 and also provides a list of external educational materials on page 80 of CON application #10490. The applicant cites understanding bone marrow transplant, patient and caregiver responsibilities, the transplant process, post-transplant, and discharge from the transplant program among topics included in the educational 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.**

The applicant states that BHM has a broad and experienced staff of physicians with expertise in treating the diseases commonly associated with bone marrow transplant patients. The applicant states that 27 hematologists and oncologists are currently on staff at BHM and have the capacity to support patients in need of hematological malignancy care. BHM states that specific BMT physicians and Advanced Practice Providers (APPs) with specialized training and expertise will be mainly responsible for the treatment of BMT patients. The applicant maintains that BMT physicians and APPs will also consult with referring physicians affiliated and outside of the Baptist network. BHM indicates that hematologists and oncologists currently refer patients who meet the criteria for transplant eligibility to other centers for evaluation and assessment. The applicant states that evaluations and assessments that are currently being referred will be conducted internally upon CON approval of the proposed project, but, patients will be referred to the center of their choice for a transplant consult if the physician feels the patient would be better served at another institution. The applicant includes a list of BHM and affiliate Miami Cancer Institute hematologists, oncologists and other cancer specialists supporting these BMT patients in

Appendix 3 and references the select CVs of selected members of the BMT medical and clinical staff included in Appendix 4 of CON application #10490.

The applicant identifies Lyle Feinstein, MD, as the Medical Director of the Blood and Marrow Transplant Program at Miami Cancer Institute, an outpatient affiliate center located on the BHM Campus and Steven Fein, MD and Allen Greenberg, MD as BMT staff physicians. The applicant states that two additional BMT physicians and a Chief of the Hematological Malignancy Program who may also serve as a BMT physician are currently being recruited.

BHM presented the employment of extensive radiation oncology staff and radiation therapy resources available at Miami Cancer Institute. The applicant further states that BHM currently employs multiple infectious disease physicians with the experience to treat immunosuppressed patients and identifies J. Milton Gaviria, MD as an infectious disease consultant currently working with the Miami Cancer Institute hematology malignancy team as a physician with one-year experience in the management of infectious disease. The applicant notes that Dr. Gaviria is board certified in both internal medicine and infectious disease. Dr. Gaviria is also identified as a fellow of the American College of Physicians and a member of the Infectious Disease Society and HIV Medical Association. Dr. Gaviria completed a fellowship in infectious disease at the University of Washington in Seattle and worked as the Director of the Infection Control Program and Instructor at the University of Washington.<sup>21</sup>

<sup>21</sup> Per Florida Department of Health's MQA Search Portal, Jose Milton Gaviria is a medical doctor with a Clear/Active medical license. Dr. Gaviria possesses staff privileges at Baptist Hospital of Miami, Doctors Hospital, and South Miami Hospital. Dr. Gaviria is board-certified in Internal Medicine and Infectious Disease by the American Board of Internal Medicine. Gaviria is also listed as a member of the Board of Directors of the Dade County Medical Association: [http://miamimed.com/www\\_dcma/users/1498](http://miamimed.com/www_dcma/users/1498)



- 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.**

The applicant again identifies Lyle Feinstein, MD, as the Medical Director of the proposed BMT Program. Lyle Feinstein is currently the Medical Director of the BMT program at the Miami Cancer Institute. The applicant states that Lyle Feinstein is board certified in hematology and oncology, has formal training in bone marrow transplantation, and has experience in the treatment and management of adult oncological cases involving high dose chemotherapy or radiation.<sup>22</sup>

- 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.**

The applicant states that Baptist Hospital of Miami currently has a talented and qualified staff of credentialed nurses with experience in providing quality care to chronically ill patients (e.g. BMT patients) in addition to providing support to patients' families. BHM provides a description of its existing oncology services which includes: a 48-bed Oncology Unit (5 Clarke). The applicant indicates 12 of the 48 beds are considered progressive care beds committed to "stepdown" level of care. The applicant states that patients admitted to this unit are either acutely or chronically ill with cancer. The applicant states that nursing staff aim to reduce the patient's cancer burden and other serious complications through the delivery of high-quality evidence-based nursing care.

The applicant states that the unit reports to the Nursing Director and a masters-prepared patient care manager who is certified in oncology nursing with more than 20 years of oncology nursing experience. BHM states that the fixed staff

<sup>22</sup> Per Florida Department of Health MQA Search Portal, Lyle Craig Feinstein is a medical doctor with a Clear/Active medical license. Dr. Feinstein is board certified in Internal Medicine and Oncology by the American Board of Internal Medicine.

of the 5 Clarke Unit consists of APPs, three masters-prepared clinical nurse leaders with significant oncology experience and a dedicated clinical nurse educator. BHM indicates that the unit is also staffed by nurses equipped to care for the special needs of oncology patients. Based on the Press Ganey survey, the applicant notes that patient satisfaction for the 5 Clarke Unit was in the 99<sup>th</sup> percentile and the HCAHPS hospital rating was in the 90<sup>th</sup> percentile on November 7, 2016. BHM also states a preference for hiring nurses with a minimum of BSN and notes that 82 percent of nurses staffed in the 5 Clarke Unit are BSN-prepared and the remainder of the staff is currently pursuing education to obtain a BSN. The applicant indicates that new nurse hires to the 5 Clarke are considered after the completion of an 18-week residency specific to 5 Clarke and the care of cancer patients. Nurses hired to the 5 Clarke Unit are subject to annual competency and skill validation specific to the 5 Clarke Unit and patient needs.

The applicant provides a list of staff proposed to serve the BMT program on page 85 of CON application #10490, the applicant references resumes of these staff members in Appendix 4 of CON application #10490 and states that additional staff will be hired as outlined in Schedule 6A. Lastly, BHM intends to hire nurses with BMT experience and competencies for the proposed program within and outside of the BHSF and MCI network.

**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.**

The applicant reiterates that existing blood-banking and transfusion facilities at Baptist Hospital will be used to support the blood banking requirements associated with the proposed BMT program. BHM reiterates that the existing blood banking facilities and services are supported by OneBlood. The applicant states that OneBlood serves as the area's centralized blood collection, storage and distribution hub, all necessary blood banking services are available and supported (CON application #10490, page 85).

BHM further indicates that OneBlood will provide specialty BMT blood/marrow processing and storage services in order to fully meet the blood and blood banking needs of BMT patients and external complex antibody identification. The

reviewer notes that OneBlood was previously identified by the applicant as an external source of support for pathology services at the Laboratory Department of Baptist Hospital of Miami (page 71 CON application #10490). The applicant provides information related to OneBlood's existing and future affiliation with Baptist Hospital of Miami and endorsement of the inpatient BMT program in Appendix 10 of CON application #10490 (CON application #10490, page 73 and page 86). The applicant recounts: the most common pre-transfusion procedures offered at the BHM Transfusion Services Department, blood/components available at the BHM Transfusion Services Department, and organizational regulatory parameters that the BHM Transfusion Services Department operates within (CON application #10490, page 86). Edward Gould, MD, is again identified as the Medical Director of the Transfusion Services Department.

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

The applicant states that BHM and the Miami Cancer Institute employs registered dieticians who are Certified Specialists in Oncology Nutrition. BHM contends that these qualifications meet the needs of patients with immunocompromised patients. Registered dieticians are also licensed by the State of Florida. The applicant also notes that an interdisciplinary team of professionals also supports the nutritional and critical care needs of oncology patients. BHM states that nutritionists will support the enteral and parenteral needs of BMT patients and provide applicable dietary advice to maintain the appropriate caloric and fluid needs of patients in order to prevent food-borne illnesses.

In particular, the applicant states that nutritionists will conduct a pre-transplant evaluation of the patient and caregiver's ability to provide required nutritional support of transplant patients; assessments will also be available to patients throughout the transplant phase in the inpatient and outpatient setting. An emphasis will be made to ensure that patient caloric and fluid intakes are appropriate during the immediate post-transplant period.

The applicant identifies the following dietitians who work 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

BHM identifies these staff as an experienced core group of nutrition support professionals that will collectively serve as a starting point for establishing the nutritional support services for the proposed BMT inpatient program. The applicant indicates that existing resources can be extended to meet the needs of new BMT patients. Resumes for some of these professionals are included in Appendix 4 of CON application #10490.

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

BHM states that 83 Registered Respiratory Therapists (RRTs) are currently employed within the Respiratory Department at Baptist Hospital of Miami; eight additional RRTs are also employed in the Pulmonary Laboratory. The applicant also states that a team of RRTs who provide respiratory support will be assigned to provide coverage for the proposed BMT program and the team will be provided with structured education about current standards of respiratory and pulmonary care for bone marrow patients by an expert in the field. The applicant states that the Medical Director of the

Respiratory Department is Juan Barrio, MD, a board-certified pulmonologist<sup>23</sup>. John Bayer<sup>24</sup> is identified as the Director of Internal Management, a Masters-prepared Registered Respiratory Therapist with 20 years of experience. BHM states that the internal management of the Respiratory Department also consists of a department manager and several working supervisors. The applicant states that best evidence-based practices, benchmarking, goal-setting and performance improvement activities are continuously monitored through a monthly Pulmonary Collaborative, co-chaired by the Medical Director and the Respiratory Department Director.

BHM states that RRTs are knowledgeable of the care required for the respiratory needs for every modality within the Hospital, including compromised immunosuppressed patients who become critically ill from sepsis. The applicant also states that RRTs are experienced in providing respiratory support to BMT patients who develop pulmonary complications post-transplant, e.g. pulmonary edema, bronchiolitis obliterans with organizing pneumonia and other post-transplant complications. The applicant additionally underscores that education and skill sets are required and provided for respiratory therapists who work with patients with specific healthcare needs like those being treated within the proposed BMT program.

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 these practitioners.

<sup>23</sup> The reviewer notes that Juan Barrio, MD was listed as Juan Barrios on page 88 of CON application #10490. Juan Barrio is listed as a licensed medical doctor per Florida Department of Health's MQA Search Portal. Dr. Barrio's primary practice address is not Baptist Hospital of Miami, though Dr. Barrio is indicated to have staff privileges at Baptist Hospital of Miami and South Miami Hospital. Dr. Barrio is board-certified by the American Board of Internal Medicine in Pulmonary Disease and Internal Medicine. Dr. Barrio appears as a pulmonologist on Baptist Health South Florida's website.

<sup>24</sup> Per Florida Department of Health's MQA Search Portal, John W. Bayer is listed as a Registered Respiratory Therapist at Baptist Hospital

**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 that Baptist Hospital of Miami has a cohort of psychologists, psychiatrists and social workers who work with patients and generally discusses the professional team of social workers and care provided to oncology patients. The applicant states that the Baptist Hospital Social Work Department will have social workers specifically trained to support bone marrow transplant patients and families. BHM also states that social workers assigned to the BMT program will also be knowledgeable of community resources available to BMT patients throughout the full continuum of care prior and post-transplant care. The applicant states that a financial counselor will be trained specifically to work with the financial needs of bone marrow transplant patients.

The applicant discusses the scope of psychosocial resources being developed at its outpatient facility Miami Cancer Institute on pages 89-90 of CON application #10490. Specific to BMT patients, BHM states that a psychiatrist within the oncology specialty practice will be responsible for completing pre-transplant psychiatric oncology evaluations, providing recommendations and managing the psychological and psychiatric needs of the patient as needed before, during and after their stem cell transplant. Oncology social workers with the psychosocial team at the Cancer Support Patient Center at Miami Cancer Institute and social workers assigned to the proposed BMT program will provide services and psychosocial assessments to patients before and after a transplant—specifically social workers assigned to the BMT program will perform assessments to identify transplant related distress, high risk factors, availability of an adequate support system for patients undergoing transplants, identify any barriers to care and community resources available to eliminate barriers to care. Assessments provided by BMT social workers will also facilitate timely referrals to psycho-oncology clinicians and community resources when indicated. Moreover, the applicant states that inpatient social workers will collaborate with outpatient oncology social workers when appropriate. The applicant identifies Rosa M. Caiseda, MSW as head of the Oncology Social Work

Practice and Beatriz Currier, MD<sup>25</sup> as eminent psychiatrist of the Cancer Support Service Center. The applicant states that Dr. Currier has over 24 years of experience in psychiatry and extensive experience in blood and marrow transplantation and Ms. Caiseda has 25 years of experience in Oncology Social Work Practice. CVs for Ms. Caseida and Dr. Currier are provided in Appendix 4 of CON application #10490.

The applicant expects that the services available at its outpatient facility's Cancer Support Service Center at Miami Cancer Institute will support BMT transplant patients.

**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 Baptist Hospital of Miami will fully cooperate with Agency reporting requirements in addition to submitting data to the CIBMTR and outcome data as part of its research collaboration projects.

**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 #10490.

<sup>25</sup> Maria Beatriz Currier is listed as a licensed medical doctor/psychiatrist per Florida Department of Health's MQA Search Portal. Dr. Currier's address is listed as Miami Cancer Institute. Dr. Currier is board-certified by the American Board of Psychiatry and Neurology in Psychiatry.  
<https://apps.mqa.doh.state.fl.us/MQASearchServices/HealthCareProviders/Details?LicInd=42732&ProCde=1501>  
<https://baptisthealth.net/en/find-a-doctor/pages/doctors.aspx#!profile/maria-beatriz-currier-md-82560>

**CON Action Number: 10490**

Driving Distances in Miles – CON application #10490 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](http://www.Mapquest.com)

The chart above illustrates that from the proposed CON application #10490, the nearest adult inpatient bone marrow transplant provider (University of Miami Hospital & Clinics) is 13.9 miles. As indicated previously in item E. 1. a. of this report, for the five year period ending June 30, 2015, the highest volume provider in OTSA 4 was the UMHC and the highest volume provider statewide was H. Lee Moffitt Cancer Center.

Data reported to the Agency for the most recent reporting period, January 1, 2016 through December 31, 2016 show the following adult inpatient bone marrow transplant utilization data:

Florida Adult Bone Marrow Transplantation Program Utilization: January 2016 - December 2016			
Hospital	OTSA*	District	Total Procedures
UF Health Shands Hospital	1	3	125
Mayo Clinic	1	4	106
H. Lee Moffitt Cancer Center**	2	6	447
Florida Hospital-Orlando	3	7	118
Good Samaritan Medical Center***	4	9	42
Memorial Hospital West	4	10	4
Univ. of Miami Hosp. & Clinics	4	11	184
<b>Total</b>			<b>1,026</b>

Source: Agency for Health Care Administration Utilization Data for Adult Organ Transplantation Programs, published March 31, 2017.

\*OTSA denotes Organ Transplant Service Area as defined in Rule 59C-1.044(2)(f) Florida Administrative Code and is synonymous with 'TSA' or "Service Area" for this review.

\*\*H. Lee Moffitt Cancer Center and Research Inst. Hospital.

\*\*\*The reviewer notes that in the CY 2016 Condition Compliance submitted to the Agency, Good Samaritan Medical Center reported 0 bone marrow transplantations



<b>Transplant Service Area 4 Adult Residents (15 and older): Blood or Bone Marrow Transplant Discharges (MS - DRGs 14, 16, and 17) CY 2016</b>		
<b>Hospital</b>	<b>Total Discharges</b>	<b>Percentage</b>
Broward Health Medical Center	1	0.44%
Delray Medical Center	1	0.44%
H. Lee Moffitt Cancer Center	62	27.56%
Jackson Memorial Hospital	3	1.33%
Mayo Clinic	2	0.89%
Memorial Hospital West	5	2.22%
Naples Community Hospital	1	0.44%
Nicklaus Children's Hospital	2	0.89%
University of Miami Hospital	1	0.44%
University of Miami Hospital and Clinics	147	65.33%
<b>Total</b>	<b>225</b>	<b>100.00%</b>

Source: Florida Center for Health Information and Transparency database:  
Run Date: June 28, 2017

The applicant states that need for its proposed adult BMT program is based on an overall health policy goal to ensure that local south Florida BMT patients have needed access to a high quality local BMT service option which will support appropriate usage of BMT care for all local residents staying within the south Florida area.

The applicant determines that the inpatient adult BMT use rates for residents of OTSA 4 indicate that local south Florida resident are accessing BMT care at a rate well below that of the rate observed statewide. The applicant states “...overall TSPA 4 adult inpatient BMT use rate is 19 percent below the statewide average adult inpatient BMT use rate – with lower than statewide use rates concentrated in the allogeneic and autologous with complications BMT cases” (CON application #10490, Page 122). The applicant states that when applying the OTSA 4 use rate to the remainder of the State (excluding the OTSA 4 data from the average) shows a larger disparity with local south Florida residents in accessing BMT care at a rate 25 percent lower than the remainder of Florida—the disparity is identified as being concentrated in the allogeneic and autologous with complications BMT cases.

The applicant states that if the OTSA 4 adult population in 2016 utilized adult inpatient BMT services at the same rate as the remainder of Florida, 2016 adult inpatient BMT cases would have increase by at least 67 above actual 2016 utilization which is above the 22 BMT cases projected in year one and 30 BMT cases forecast by Baptist for the first two years of operation.

The applicant expects that the proposed BMT program is necessary to resolve this purported low use rate and access to care limitation. The applicant states that in addition to below average use rates, adult inpatient BMT patient flow data for OTSA 4 demonstrates that a

significant number of south Florida residents obtain adult BMT care outside of the local area. Using data for the 12 months ending 09/16, the applicant states that 61 adult BMT patients were treated out of the local area. The applicant contends that since 2008 the actual number of patients leaving the local area to obtain required care has remained even with an increase in the total number of adult inpatient BMT patients and the introduction of BMT programs at the UMHC and MHW.

The applicant identifies historical need justifications presented in CON application #10041 and states that access limitations persist within OTSA 4 and the proposed program is “necessary to enhance these access limitations” (CON application #10490, page 123). BHM states that significant patient and family costs in the form of time, money and psychosocial impacts are associated with outmigration for treatment. The applicant concludes that patient out-migration demonstrates that the existing adult inpatient BMT network is not providing adequate services to meet local needs. The applicant states that the majority of this outmigration is associated with allogeneic and autologous transplants with complications, which require the longest and most extensive treatment regimens and outmigration demonstrate the significance of this issue.

Among the three existing TSPA 4 providers, BHM states that only the UMHC BMT program is a true viable alternative to the applicant’s proposed program. The applicant notes that the BMT program at Good Samaritan Hospital is a limited services program and CON approved to offer only autologous BMT services. The applicant states that Good Samaritan Medical Center only operates an outpatient program with no inpatient volume reported during recent years. The applicant also notes that Good Samaritan Medical Center is not listed in national BMT program inventories and states that apparent discrepancies exist between BMT volumes reported to the Agency and those performed at the hospital. The applicant also notes that MHW, has not met the Agency rule requirement that adult allogeneic BMT providers should reach 10 allogeneic cases by the third year of operations. BHM contends that MHW program is not a realistic full service allogeneic provider and should not be considered a comparative alternative to this proposed BHM program.

The applicant references descriptions of the UMHC BMT program is presented in a “recent legal hearing”. BHM states that the UMHC BMT program is providing a mix of autologous and allogeneic exclusively on an inpatient basis and no outpatient cases. BHM notes that patients served by the BMT program at UMHC treats patients throughout south Florida, from Palm Beach to Monroe County. BHM identifies that case volumes for bone marrow transplantations reported by UMHC have nearly doubled from 2012 – 2016 as reported in Agency’s Organ

Transplantation Program Utilization Data publications for the April 2013 – April 2017 Batching Cycles. Overall, the applicant notes that UMHC has the second largest adult BMT program in Florida and is part of an operation that had a \$150 million margin in 2015. For these reasons, the applicant states that the proposed adult inpatient BMT program will have no material impact on the UMHC program.

BHM forecasts 22 cases in year one and 30 cases in year two for 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.**

The applicant states that BHM possesses a historical record of providing patient care that is among the highest quality within the industry. The applicant states that residents of south Florida rely on the Baptist Health network and BHM specifically to provide high quality health care with skill and compassion. The applicant states that BHSF staff strive to continuously enhance patient safety and quality of care, implement new efficiencies and keep pace with recent medical developments. BHSF expresses a prioritization of patient and family centered-care that seeks patient feedback to ensure that the organization adheres to a mission of caring patients with skill and compassion is central to BHM's mission.

The applicant states that BHM has established a formal and structured process to ensure that high quality care is provided to all patients and to enable the organization to continuously enhance operational quality and efficiency. BHSF states that quality care is organized through Baptist Health Board's Committee on Quality and Patient Safety which establishes and monitors overall patient quality and safety goals and tasks operational staff at the system and hospital level to implement these directives. A chart documenting the organizational patient quality and safety approach is provided on page 125 of CON application #10490.

Furthermore the applicant also utilizes a Center for Performance Excellence, which was established to support quality initiatives. BHM's Center for Performance Excellence is directed by Louis Gidel, PhD, MD, the Chief Medical Informatics and Quality Officer for BHSF. The mission of the center is to improve the patient experience, promote superior clinical outcomes and optimize the utilization of resources. The applicant states that staff within the Center for Performance Excellence are dedicated to clinical, service and organizational excellence by fostering evidence-based practices, patient/family-centered care and staff engagement maintained through providing high quality training, consulting and data analysis.

The organizational structure of the Center for Performance Excellence is provided on page 126 of CON application #10490. The applicant also provides a detailed description of the Baptist Hospital Performance Improvement Plan is presented in Appendix 12 of CON application #10490. The applicant states that the Performance Improvement (PI) plan is designed to promote awareness and provide guidance in the continuous improvement of clinical practice, support services, patient safety and leadership. The applicant states that the foundation of the PI Plan is based on the mission, vision, values, and strategic plan of the organization and the plan outlines collaborative efforts throughout the BHSF network to ensure that patient care and services meet or exceed customer expectations. BHSF makes use of high-tech and low-tech resources like eICU LifeGuard, an electronic monitoring system used to monitor critically ill patients, and pet therapy. On pages 127 – 130 of CON application #10490, the applicant notes that BHSF has been awarded and recognized by U.S. News & World Report, The Joint Commission, the American College of Surgeons' Commission on Cancer, The Commonwealth Fund, Press Ganey, Leapfrog Group, Consumer Reports, and a number of other organizations for its quality performance. The applicant notes that BHM received four out of five quality stars in the last reporting period for CMS, placing it in the 20 percent of hospitals nationwide. The applicant notes that the Baptist Hospital's HCAHPS rating was also four out of five stars.

BHM states the organization's historically proven approach to providing high-quality patient-centered health care services will be expanded to the proposed inpatient BMT program and adult outpatient BMT program. The applicant provides a final draft of the BMT Program's Quality Management Plan for Clinical and Collection Facilities in Appendix 12 of CON application #10490.

BHSF currently operates six hospitals in District 11 with a total of 1,762 licensed beds. The following table accounts for the substantiated complaint categories across the applicant's licensed facilities. The reviewer notes that an individual complaint can encompass multiple complaint categories.

<b>Baptist Health South Florida: 36 Months Ending May 25, 2017</b>		
<b>Facility</b>	<b>Complaint Category</b>	<b>Number Substantiated</b>
Baptist Hospital of Miami	Quality of Care/Treatment	2
Baptist Hospital of Miami	Nursing Services	2
Doctors Hospital	Emergency Access	1
Doctors Hospital	Resident/Patient/Client Assessment	1
Doctors Hospital	Nursing Services	1
Homestead Hospital	Emergency Access	3
Homestead Hospital	Residential/Patient/Client Assessment	1
Homestead Hospital	Infection Control	1
Homestead Hospital	Nursing Services	1
South Miami Hospital	Quality of Care/Treatment	1
<b>Total</b>		14

Source: Agency Complaint Records May 25, 2014 – May 25, 2017

Agency records indicate that for the three-year period ending on May 25, 2017, BHSF had 14 substantiated complaints.

- 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 benchmarks established from financial ratios collected from Florida acute care hospitals. While not always a perfect match to a particular CON project it is a reasonable proxy for health care related entities. The below is an analysis of the audited financial statements of Baptist Health South Florida, Inc. and Affiliates (Applicant) where the short term and long term measures fall on the scale (highlighted in gray) for the most recent year.

<b>Baptist Health South Florida, Inc. and Affiliates</b>		
	<b>Sep-16</b>	<b>Sep-15</b>
Current Assets	\$529,188,911	\$483,409,070
Total Assets	\$4,888,721,856	\$4,621,951,005
Current Liabilities	\$629,659,636	\$538,363,412
Total Liabilities	\$1,723,639,945	\$1,639,605,833
Net Assets	<b>\$3,165,081,911</b>	<b>\$2,982,345,172</b>
Total Revenues	\$2,376,141,876	\$2,357,325,196
Excess of Revenues Over Expenses	\$175,628,809	<b>(\$81,462,752)</b>
Cash Flow from Operations	\$263,490,965	\$224,828,325
<b>Short-Term Analysis</b>		
Current Ratio (CA/CL)	0.8	0.9
Cash Flow to Current Liabilities (CFO/CL)	41.85%	41.76%
<b>Long-Term Analysis</b>		
Long-Term Debt to Net Assets (TL-CL/NA)	34.6%	36.9%
Total Margin (ER/TR)	7.39%	-3.46%
<b>Measure of Available Funding</b>		
Working Capital	<b>(\$100,470,725)</b>	<b>(\$54,954,342)</b>

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

The applicant indicates on Schedule 2 capital projects totaling \$195,861,319 which includes med/surg/ICU bed tower, helipad relocation, routine capital budget FY17, this CON (\$7,674,433), and routine capital projection FY2018. The applicant provided a copy of its September 30, 2016 and 2015 audited financial statements. These statements were analyzed for the purpose of evaluating the applicant'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.

**Conclusion:**

Funding for this project by cash on hand should be available as needed. As shown above, the applicant reported \$263.5 million in cash flow from operations but negative \$100.5 million in working capital. Funding for the entire capital budget is uncertain.

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

**Analysis:**

Our comparison is of the applicant’s estimates to its latest FHURs report.

Because the proposed bone marrow transplant program cannot operate without the support of the hospital, we have evaluated the reasonableness of the projections of the entire hospital including the project. The applicant will be compared to its latest AHCA filing which was September, 2016. Inflation adjustments were based on the new CMS Market Basket, 3rd Quarter, 2016.

	PROJECTIONS PER APPLICANT		Actual Data Inflated to 2020
	Total	PPD	
Net Revenues	1,005,518,500	5,393	5,329
Total Expenses	961,828,208	5,159	5,100
Operating Income	43,690,292	234	229
Operating Margin	4.35%		

The bone marrow transplant program represents .5 percent of the hospital’s total revenue and .6 percent of the hospital’s expenses. Projections indicate a -\$577,077 profit margin at the end of year two.

Because the transplant program is such a minor part of the hospital’s overall operations, the hospital could easily support the bone marrow transplant program even if extended losses were projected to continue.

**Conclusion:** This project appears to be financially feasible and the projected NRPD, CPD and profitability appear to be attainable.

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

**Analysis:**

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

**Conclusion:**

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

In addition, the reviewer notes that the applicant will not be a PPS-exempt cancer hospital, as UMHC is designated, and therefore reimbursement to the two proposed Miami-Dade providers from Medicare will be different. The reviewer notes that according to the U.S. Government Accountability Office (GAO), in 2012, Medicare payments received by the 11 PPS-exempt cancer hospitals were, on average, 42 percent more per discharge than what Medicare would have paid a local PPS teaching hospital to treat cancer beneficiaries with the same level of complexity. The GAO also found that the PPS-exempt cancer hospital's payment methodology lacks strong incentives for cost containment and has the potential to result in substantially higher total Medicare expenditures. The GAO concludes that until Medicare pays PPS-exempt cancer hospitals to encourage efficiency, Medicare remains at risk for overspending.

According to FloridaHealthFinder.gov, based on data submitted to the Agency through the inpatient database, UMHC had 160 bone marrow transplants with charges ranging from (on average) \$403,740 (25<sup>th</sup> percentile) to \$662,662 (75<sup>th</sup> percentile) with an ALOS of 25.0 days for CY 2016 for all adults 18+. The statewide total charges, for the same time period, ranged (on average) from \$188,363 to \$458,097 with an ALOS of 22.8 days. MHW's program did not appear on the site as it did not have enough data (patients for CY 2016) to calculate.

BHM indicates that the 65+ population in Miami-Dade is growing significantly and that, according to CIBMTR data, the elderly population is a group that accounts for a significant portion of the growth of total BMT cases from 2010-2014 nationwide. The reviewer notes that the 65+ population is more likely to utilize Medicare as a payer source.

In regards to difference in treatments, the reviewer notes that the applicant indicates that it will perform both inpatient and outpatient procedures. Data indicates that UMHC only performs inpatient procedures. Some studies show that patients that are suitable for an outpatient BMT have a sizeable lower total charge, and a lower mean total charge to payers. The reviewer notes that a lack of caregivers can limit the availability of outpatient transplants and that an outpatient option is not always a viable for a substantial portion of the population eligible for BMTs.



**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. Approval from the Agency for Health Care Administration’s Office of Plans and Construction is required before the commencement of any construction involving a hospital, nursing home or intermediate care facility for the developmentally disabled.

**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) 2015 provided by the Agency’s Florida Hospital Uniform Reporting System (FHURS).

<b>Medicaid and Charity Care: Baptist Hospital of Miami and District 11 FY'15</b>			
<b>Facility/Region</b>	<b>Medicaid and Medicaid HMO Days</b>	<b>Charity Care</b>	<b>Charity Care and Medicaid</b>
Baptist Hospital of Miami*	17.64%	4.19%	21.83%
District 11 Average	23.23%	4.16%	27.39%

Source: Fiscal Year 2015 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 applicant did not participate in the disproportionate share hospital (DSH) program for FY 2015-2016 as of June 7, 2017.

The applicant states that Baptist Hospital of Miami and its parent organization Baptist Health South Florida, Inc. have a proven history of providing health services to Medicaid patients and the medically indigent and that the proposed BMT program will provide adult bone marrow transplant services to all patients including Medicaid and medically indigent patients who are medically appropriate to participate in the program. The applicant states that in FY 2016, Baptist Health provided approximately \$300 million in total community benefit at cost and this provision of care is approximately 13 percent of BHSF's net patient revenue after bad debt and greater than BHSF's not-for-profit tax exemption of \$60 million for 2016. The applicant additionally states that community benefit from FY 2016 also includes approximately \$96 million in charity care at cost and \$149 million of uncompensated services from Medicaid shortfall at cost.

BHSF indicates that community benefit was provided for:

- Community educational programs, free screenings and similar free services
- Community clinic donations
- Physician payments for the care of indigents
- Physician education programs
- Chaplaincy program
- Payment of the Florida indigent patient care tax

The applicant also provides a list of community education programs and community clinics supported through community benefit on page 135 of CON application #10490. BHM notes that the amount of charity care provided at each BHSF facility varies with the hospital location and the economics of its service area. In reference to Agency 2015 Hospital Financial Data, the applicant notes that BHM's charity care deductions (charges) totaled greater than \$133 million or 3.8 percent of the hospital's gross revenues. Second to Jackson Memorial Hospital, the applicant states that BHM provided the second largest amount of charity care within Miami-Dade County when excluding specialty providers. The applicant notes that BHM and BHSF Hospitals in Miami-Dade had a higher percentage of charity care than the county average when including and excluding Jackson Memorial Hospital.

Furthermore, the applicant states that BHM provides care to individuals <300 percent of the Federal Poverty Level and thereby exceeds the income specifications of charity care defined by the State of Florida. The applicant states that based on the Agency's 2015 Hospital Financial Data, Homestead Hospital provided the highest percentage (36.2 percent)

of total patient days to Medicaid patients (Medicaid and Medicaid Managed Care) and BHM provided 18 percent of total inpatient days to Medicaid.

The applicant provides the following chart depicting the provision of charity care among select providers in Miami-Dade County:

<b>Miami-Dade County Acute Care Hospital Profile - 2015 (Specialty Hospitals Excluded)</b>					
	<b>Baptist Hospital</b>	<b>Homestead Hospital</b>	<b>All Baptist Miami - Dade Hospitals</b>	<b>All Miami-Dade Acute Care Hospitals</b>	<b>Miami - Dade Hospitals w/out Jackson</b>
<b>Charity \$\$s (000s)</b>	\$133,405	\$80,906	\$332,349	\$1,115,924	\$793,905
<b>Gross Revenue (000s)</b>	\$3,525,133	\$887,690	\$7,792,766	\$33,030,126	\$28,515,465
<b>% Charity</b>	3.8%	9.1%	4.3%	3.4%	2.8%

Source: CON application #10490, Page 136; 2015 Financial Prior Year Reports submitted to the Agency (most recent publically available data)

BHSF reiterates that BHSF and BHM have a history of providing significant services to the Medicaid population and will continue to provide care to Medicaid, indigent and traditionally underserved populations.

<b>BHM, Inc. Projected Payer Mix</b>						
	<b>Medicaid HMO</b>	<b>Medicare Medicare</b>	<b>Medicare HMO</b>	<b>Other Managed Care</b>	<b>Other Revenue</b>	<b>Total</b>
<b>Year One Patient Days</b>	19	169	47	225	47	507
<b>Year Two Patient Days</b>	47	159	47	405	47	705
<b>% Year One</b>	3.7%	33.3%	9.3%	44.4%	9.3%	100.0%
<b>% Year Two</b>	6.7%	22.6%	6.7%	57.4%	6.7%	100.0%

Source: CON application #10490, Schedule 7. Year one corresponds to December 2019 and year two corresponds to December 2020.

BHM indicates that the “Other Revenue” category denotes charity care. The applicant states that a higher than expected percentage of patient days are forecast to be in the “Other Revenue” category in year one due to allogeneic BMT inpatients not being eligible for reimbursement from a number of payer sources due to allogeneic program certification not expected until the second year of operation.

The applicant forecasts 9.3 percent charity care and 3.7 percent Medicaid HMO in year one and 6.7 percent charity care and 6.7 percent Medicaid HMO in year two.

The applicant has conditioned CON application #10490 on the provision of a minimum of 10 percent of BMT transplant cases to Medicaid/Medicaid Managed Care/self-pay/charity patients.

The applicant determines that this level of care to Medicaid and charity care populations will result in expanded BMT access to these patient groups and will provide an additional local south Florida BMT resource to support the needs of all patients requiring bone marrow transplant care, those with resources and those with limited or no financial resources. Based on the 2015 Financial Prior Year Report, the applicant notes that the UMHC reported zero charity care for inpatient services. BHM notes that UMHC reported zero Medicaid Managed Care and self-pay BMT inpatients in the Agency Discharge Database (12 months ending September 30, 2016) which demonstrates to the applicant that the Medicaid population and local charity patients are without access to care. The applicant states that the lack of provision of care to inpatient charity care by the UMHC stems from the operational focus of the organization. BHM ultimately determines that the proposed BMT program will provide financial access to all parts of south Florida, including individuals with limited financial resources and those who do not have adequate access to quality care locally.

**F. SUMMARY**

**Baptist Hospital of Miami, Inc. d/b/a Baptist Hospital of Miami (CON application #10490)**, also referenced as BHM or the applicant is a not-for-profit Class I Hospital affiliated with BHSF.

BHSF, the parent organization of the applicant, also operates six acute care hospitals in Florida and identifies three additional licensed acute care hospitals that will be operated under BHSF.

The applicant proposes to establish a new adult autologous and allogeneic BMT program at BHM, primarily to serve the residents of OTSA 4 (Miami – Dade, Monroe, Broward, Palm Beach and Collier Counties) in addition to other Florida residents and residents of the United States and international patients who rely on BHSF resources for their health care needs. BHM states that the establishment of an outpatient autologous BMT program is currently underway and anticipated for initiation in the 4<sup>th</sup> quarter of 2017.

The total project cost of the proposed project is \$7,624,433 which consists of \$6,232,295 in building costs, \$850,000 of equipment, \$105,000 of project development, and \$437,138 of start-up costs (CON application #10490, Schedule 1, pages 142 – 143). The project will involve 8,800 GSF of construction with all GSF of construction is listed as renovation.

The applicant expects issuance of licensure December 2018 and initiation of service in January 2019.

The applicant proposes three Schedule C conditions.

**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 BMT programs in OTSA 4, with no CON approved adult inpatient BMT programs pending licensure in OTSA 4. 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 reviewer notes that Good Samaritan Medical Center performed no BMTs in CY 2016.

BHM states that historical trends demonstrate growth in the volume of BMTs and the following trends support continued growth in the number of bone marrow transplants:

- BMT is increasingly effective with continual improvements in treatment outcome
- BMT increasingly safer, with constantly favorable survival rates
- The number of diseases for which BMT is indicated continues to grow
- The sources of donor cells and the number of suitable matches are expanding
- An aging population is increasing the proportion of people who are susceptible to diseases for which BMT is indicated
- Modified transplantation regimens have facilitated safer procedures despite an increase in the median patient age

BHM states that the proposed project is needed to provide additional patient-focused adult BMT services within the south Florida area and to provide an acceptable south Florida adult BMT alternative for local residents currently leaving the local area to access adult BMT care and to support an increase in south Florida BMT use rates to levels consistent with Florida and/or national use rate levels.

The applicant also states that the proposed project is being developed to resolve access problems that are currently inherent within the "Planning Area", as evidenced by the documented high outmigration levels, the low use rates and the lack of charity care provided by the UMHC program.

The applicant additionally states that the proposed program expresses a commitment from BHM to provide care to all segments of the adult BMT marketplace and will provide enhancements in providing care to patients with limited financial resources as evidenced by the payer class condition provided in Schedule C.

Based on UMHC's reported 184 BMTs for CY 2016, UMHC has approximately 4,650 patient days for adult BMTs, or an ADC of 12.60 patients. The reviewer notes that CON #10041 stated that 12 private inpatient rooms (of 40 total beds) at UMHC would be dedicated to the adult BMT program and <http://sylvestor.org/patients/treatment/stem-cell-transplant>, confirms that the facility has a 13,964 square-foot inpatient unit with 12 specialized transplant beds.

The Agency finds that the two viable programs in OTSA 4 of adult BMTs (UMHC and MHW) have significantly different programs and vastly different extents of utilization of health services to the residents of OTSA 4. UMHC appears to be over-utilized—with approximately 80 percent of total discharges from OTSA 4 and an ADC of 12.60 (in a 12-bed unit)—while MHW appears to be under-utilized, having just five total discharges (according to the inpatient discharge data) or four total procedures (according to local health council data) in CY 2016. Other circumstances, that were considered not normal, presented by the applicant include lack of charity care provided by UMHC, significant outmigration and substantial growth of OTSA 4's population including the elderly population. The reviewer notes that an additional not normal circumstance is that UMHC is one of eleven (in the nation) PPS-exempt designated cancer institutes along with H. Lee Cancer and Research Institute Hospital in Hillsborough County. The reviewer also notes that the Public Health Trust of Miami-Dade County (Jackson Memorial) had a temporary variance from 59C-1.044, from April 6, 2016 until April 6, 2017 to treat patients 15 to 20 for bone marrow transplants and subsequently asking for an extension to this variance which was not granted although two additional variances have been granted for particular instances—indicating that the 15 to 20 age cohort does not currently have access to bone marrow transplants in OTSA 4. In one instance, the patient was requesting transfer from an existing health system that provides 15+ BMTs in OTSA 4, in another the evaluating physician was a member of a health system's staff that provides 15+ BMTs in OTSA 4.

Opposition from UMHC and MHW did not present any clinical reason for the outmigration of residents and the lower use rates in OTSA 4 for BMTs. Nor did opposition present information explaining the gap in services to the 15+ population--leaving lack of access as a viable and reasonable explanation for the disparity of services in OTSA 4.

Pursuant to 59C-1.044, F.A.C., applications for new bone marrow programs shall not normally be approved unless the rule requirements of 59C-1.044 (9), F.A.C., are met. The Agency finds that the applicant presented a number of not normal circumstances and in weighing and balancing the statutory criteria of 408.035 (1), F.S., need for an additional service was established, found that the applicant will enhance access to adult BMT services to the residents of OTSA 4, will foster competition that promotes quality and cost-effectiveness (by having a different payment model and different treatment options) and the applicant's past and proposed provision of health care services to Medicaid patients and the medically indigent is significant.

**Quality of Care**

BHM demonstrated its ability to provide quality of care and illustrated a record of providing quality of care.

The applicant states that BHM has established a formal and structured process to ensure that high quality care is provided to all patients and to enable the organization to continuously enhance operational quality and efficiency. BHSF states that quality care is organized through Baptist Health Board's Committee on Quality and Patient Safety which establishes and monitors overall patient quality and safety goals and tasks operational staff at the system and hospital level to implement these directives.

BHM utilizes a Center for Performance Excellence, which was established to support quality initiatives directed by Louis Gidel, PhD, MD, the Chief Medical Informatics and Quality Officer for BHSF. The mission of the center is to improve the patient experience, promote superior clinical outcomes, and optimize the utilization of resources.

BHM also utilizes a PI Plan designed to promote awareness and provide guidance in the continuous improvement of clinical practice, support services, patient safety and leadership. The applicant states that the foundation of the PI Plan is based on the mission, vision, values, and strategic plan of the organization and the plan outlines collaborative efforts throughout the BHSF network to ensure that patient care and services meet or exceed customer expectations.

Agency complaint records indicate that the parent's (BHSF's) six hospitals had 14 substantiated complaints for the three-year period ending May 25, 2017. Baptist Hospital of Miami accounted for four of the 14 substantiated complaints.

**Cost/Financial Analysis** Funding for this project by cash on hand should be available as needed.

This project appears to be financially feasible and the projected NRPD, CPD and profitability appear to be attainable.

This project is not likely to have a material impact on competition to promote quality and cost-effectiveness based on the financial analysis review of the submitted schedules. However, the applicant will not be a PPS-exempt cancer hospital provider, as UMHC is designated, and therefore reimbursement to the two Miami-Dade providers from Medicare will be different. The reviewer notes that according to the GAO, that in 2012, Medicare payments received by the 11 PPS-exempt cancer hospitals were, on average, 42 percent more per discharge than what Medicare would have paid a local PPS teaching hospital to treat cancer beneficiaries with the same level of complexity. The GAO also found that the PPS-exempt cancer hospital's payment methodology lacks strong incentives for cost containment and has the potential to result in substantially higher total Medicare expenditures.

According to FloridaHealthFinder.gov based on data submitted to the Agency through the inpatient database, UMHC had 160 bone marrow transplants with charges ranging from (on average) \$403,740 (25<sup>th</sup> percentile) to \$662,662 (75<sup>th</sup> percentile) with an ALOS of 25.0 days for CY 2016 for all adults 18+. The statewide total charges for the same time period ranged on average from \$188,363 to \$458,097 with an ALOS of 22.8 days. MHW's program did not appear on the site as it did not have enough data (patients for CY 2016) to calculate.

In regards to difference in treatments, the reviewer notes that the applicant indicates that it will perform both inpatient and outpatient procedures. Data indicates that UMHC only performs inpatient procedures. Some studies show that patients that are suitable for an outpatient BMT have a sizeable lower total charge, and a lower mean total charge to payers. The reviewer notes that a lack of caregivers can limit the availability of outpatient transplants, and that an outpatient option is not always a viable for a substantial portion of the population eligible for BMTs.

**Medicaid/Charity Care Commitment**

According to the Agency's FY 2015 FHURS Data Report, BHM provided 17.64 percent of its total annual patient days to Medicaid/Medicaid HMO patients and 4.19 percent of its total annual patient days to charity care patients

The applicant did not participate in the disproportionate share hospital (DSH) program for FY 2015-2016 as of June 7, 2017.



The applicant forecasts 9.3 percent charity care and 3.7 percent Medicaid HMO in year one and 6.7 percent charity care and 6.7 percent Medicaid HMO in year two.

The applicant has conditioned CON application #10490 on the provision of a minimum of 10 percent of BMT transplant cases Medicaid/Medicaid Managed Care/self-pay/charity patients.

The applicant noted a lack of charity care as reimbursement source provided by UMHC, which is confirmed through the FHURS data (.26 average over the last ten years, with the latest reporting period showing .08 percent).

**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 #10490 to establish a new adult autologous and allogeneic bone marrow transplantation program in District 11, Organ Transplantation Service Area 4, Miami-Dade County. The total project cost is \$7,624,433 and the project will involve 8,800 GSF of construction.

**CONDITIONS:**

- The proposed adult BMT program will be located at Baptist Hospital of Miami, located at 8900 North Kendall Drive, Miami, Florida
- Baptist Hospital will delicense 12 acute care beds upon the completion of the 4 Main East renovation and the establishment of the proposed new bone marrow treatment program
- Baptist will provide at least 10 percent of the adult inpatient transplant case volume on an annual basis to Medicaid/Medicaid Managed Care/charity/self-pay patients
- The applicant will establish an onsite laboratory for bone marrow evaluation and cryopreservation.

**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**