

**STATE AGENCY ACTION REPORT
CON APPLICATION FOR CERTIFICATE OF NEED**

A. PROJECT IDENTIFICATION

1. Applicant/CON Action Number

**Cleveland Clinic Florida Health System Nonprofit Corporation d/b/a
Cleveland Clinic Hospital/CON #10444**

3100 Weston Road
Weston, Florida 33331

Authorized Representative: Dr. Wael Barsoum,
(954) 689-5000

2. Service District/Subdistrict

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

B. PUBLIC HEARING

A public hearing was not held or requested for the proposed project to establish a new adult bone marrow transplant program.

Letters of Support

Cleveland Clinic Florida Health System Nonprofit Corporation d/b/a Cleveland Clinic Hospital (CON application #10444) submitted 21 signed letters of support. The letters were composed by local health care providers, local medical groups and various physicians affiliated with Cleveland Clinic. Support for the proposed program included: Boca Raton Regional Hospital, Jupiter Medical Center, Martin Health System, LifeLink Foundation, Inc. and OneBlood, Inc.

Letters of Opposition

The Agency received one letter of opposition to the Cleveland Clinic proposed project. F. Phillip Blank of Gray-Robison Attorneys at Law submitted the letter of opposition on behalf of South Broward Hospital District d/b/a Memorial Hospital West (MHW). MHW provides statistical data including charts and graphs to illustrate that there is no need for

the proposed project. The opposition provides the following statements against the approval of the proposed project:

- There are presently three operational adult inpatient bone marrow transplant programs in OTSA 4: Memorial Hospital West (Broward County), Good Samaritan Medical Center (Palm Beach County) and the University of Miami Hospital & Clinics (Miami-Dade County). The Agency recently approved an additional adult inpatient bone marrow transplantation program at Baptist Hospital of Miami in Miami-Dade County. The reviewer notes that the approval is currently in litigation and was challenged by University of Miami Hospital and Clinics.
- OTSA 4 currently has 43 percent of the state's operational adult bone marrow transplantation programs. With the approval of Baptist Hospital of Miami, four of eight (50 percent) adult inpatient bone marrow transplant programs will be located within OTSA 4, yet the five counties of OTSA 4 represent less than one-third (31.5 percent) of Florida's adult population.
- In 2015, the 284 adult bone marrow transplantation cases reported by OTSA 4 providers represented a use rate of 5.50 per 100,000 population age 15+. Applied to the 2020 projected adult population, the 5.50 use rate equates to 16 net additional adult inpatient bone marrow transplantation cases over the next five years.
- Outmigration of OTSA 4 residents requiring allogeneic or autologous bone marrow transplantation has declined dramatically over the last three years.
- There is no indication that area residents are underserved or that residents of District 10 (Broward County) or OTSA 4 do not have access to existing providers. The providers in OTSA 4 have adequate capacity to accommodate future demand for this highly specialized and costly treatment.
- The Cleveland Clinic is located less than eight miles from MHW.
- An additional adult bone marrow transplantation program will negatively impact MHW's volumes and jeopardize the ability to be American College of Surgeons (ACOS) accredited with commendation.

C. PROJECT SUMMARY

Cleveland Clinic Florida Health System Nonprofit Corporation d/b/a Cleveland Clinic Hospital (CON application #10444) also referenced as CCH or the applicant, a Florida not-for-profit corporation, proposes to establish a new adult inpatient autologous and allogeneic bone marrow transplantation (BMT) program at Cleveland Clinic Hospital in Weston, Broward County, Florida, District 10, OTSA 4.

The applicant states that CCH is the hospital entity and Cleveland Clinic Florida is the multi-specialty physician group practice. The applicant

states Cleveland Clinic Florida is a “closed staffing model” and is uncommon in south Florida. The closed staffing model is stated to make it easier to coordinate care and implement evidence-based treatments. It is also stated Cleveland Clinic Florida physicians are not community physicians but are on payroll. CCH is licensed for 155 acute care beds. The applicant indicates that the project will predominantly serve the residents of OTSA 4 counties.

The adult bone marrow transplant program, if approved, is to be operational by the fourth quarter of 2018. Project costs total \$2,445,000. The project involves 6,860 gross square feet (GSF) of new construction and with total construction costs of \$1,635,000. Total project costs include building, equipment, project development and start-up costs.

Schedule C includes the following conditions:

1. The Adult Bone Marrow Transplant Program will be located on the Cleveland Clinic campus at 3100 Weston Road Weston, Florida 33331.
2. A dedicated Bone Marrow Transplant Unit will be located in the new patient tower.
3. The applicant will have a fully qualified adult allogeneic and autologous bone marrow transplant Medical Director who meets all allogeneic and autologous criteria requirements. This Medical Director will be in place and active on staff prior to the opening of the BMT Program.
4. The applicant will seek FACT accreditation in two phases. As soon as the Hospital meets the requirements for autologous, FACT accreditation it will be sought. This is expected to occur during Year Two of operation. Upon meeting the allogeneic requirements for accreditation, this additional accreditation will be sought. This additional accreditation is expected to be received in the fourth year of operation of the BMT Program.
5. The applicant will develop an apheresis facility on its Hospital Campus.
6. The applicant will develop a cell processing laboratory on its Hospital Campus.

Should the project be approved, the applicant's proposed conditions would be reported in the annual condition compliance report as required by Rule 59C-1.013 (3) Florida Administrative Code. Pursuant to Section 408.043 (4) Florida Statutes, accreditation by any private organization may not be a requirement for the issuance or maintenance of a certificate of need.

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, Dwight Aldridge, analyzed the application with consultation from Financial Analyst Brian Shoemaker of the Bureau of Central Services, who evaluated the financial data, and Gregory Register of the Office of Plans and Construction, who reviewed the application for conformance with the architectural criteria.

E. CONFORMITY OF PROJECT WITH REVIEW CRITERIA

The following indicate the level of conformity of the proposed project with the criteria and application content requirements found in Florida Statutes, sections 408.035, and 408.037; applicable rules of the State of Florida, Chapter 59C-1 and 59C-2, Florida Administrative Code. The reviewer provides the following analysis and review of CON application #10444 with regard to statutory and rule criteria.

1. Fixed Need Pool

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

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

OTSA 4 includes Districts 10 and 11, Collier County in District 8 and Palm Beach County in District 9. Presently there are three operational adult inpatient bone marrow transplant programs in OTSA 4, Good Samaritan Medical Center in District 9, Memorial Hospital West in District 10 and University of Miami Hospital and Clinics in District 11. The applicant indicates that the proposed program will be located in Broward County. Approval of this project would result in a fifth adult BMT program in the same service area. The reviewer notes that Baptist Hospital of Miami was initially approved for a CON to establish an adult inpatient autologous and allogenic bone marrow transplant program in OTSA 4 and the approval is pending due to litigation.

Data reported to the Agency for the most recent reporting period, January 1, 2015 through December 31, 2015 show the following adult bone marrow transplant utilization data:

Florida Adult Inpatient Bone Marrow Transplantation Program Utilization			
January 2015 – December 2015			
Hospital	OTSA	District	Total Procedures
UF Health Shands Hospital	1	3	175
Mayo Clinic	1	4	80
H. Lee Moffitt Cancer Center	2	6	419
Florida Hospital-Orlando	3	7	133
Good Samaritan Medical Center	4	9	99
Memorial Hospital West	4	10	15
Univ. of Miami Hosp. & Clinics	4	11	170
TOTAL			1,091

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

As shown above, for the 12-month period ending December 31, 2015, within OTSA 4, the highest number of adult inpatient BMT procedures (419) was performed at H. Lee Moffitt Cancer Center and Research Institute Hospital, the next highest number (175) at the UF Health Shands Hospital and the fewest (15) at Memorial Hospital West.

Below is a five-year chart to account for adult inpatient bone marrow transplants ending December 31, 2015.

**Adult Inpatient Bone Marrow Transplantation Procedures
Calendar Year 2011-2015**

Facility/OTSA	1/2011-12/2011	1/2012-12/2012	1/2013-12/2013	1/2014-12/2014	1/2015-12/2015	Total
UF Health Shands Hospital (OTSA 1)	131	120	104	97	175	627
Mayo Clinic (OTSA 1)	69	72	97	88	80	406
H. Lee Moffitt Cancer Center (OTSA 2)	408	402	446	441	419	2,116
Florida Hospital-Orlando (OTSA 3)	73	107	149	142	133	604
Good Samaritan Medical Center (OTSA 4)	0	0	0	73	99	172
Memorial Hospital West* (OTSA 4)	8	9	15	20	15	24
Jackson Memorial Hospital** (OTSA 4)	61	1	0	NA	NA	62
Univ. of Miami Hospital & Clinics (OTSA 4)	23	97	132	137	170	559
State Total	773	808	943	998	1,091	4,613

Source: *Agency for Health Care Administration Utilization Data for Adult Organ Transplantation Programs*, published April 2012 – April 2016

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

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

As shown in the table above, the facilities providing adult inpatient BMTs from most to least procedures to the greatest were as follows: H. Lee Moffitt Cancer Center, UF Health Shands Hospital, University of Miami Hospital and Clinics, Florida Hospital-Orlando, Good Samaritan Medical Center, Mayo Clinic and Memorial Hospital West. As shown in the table above, there were seven facilities providing these procedures in calendar year (CY) 2015, the facilities within OTSA 4 provided 26 percent of the total procedures.

Within the five-year period of CY 2011-2015, the three current providers in OTSA 4 have realized steady volume increases in procedures for each year—with a substantial increase from CY 2014 to CY 2015.

Rule 59C-1.044(9)(b), Florida Administrative Code, states that adult allogeneic bone marrow transplantation programs shall be limited to teaching and research hospitals. According to the Agency’s Hospital Beds and Services List publication (issued July 15, 2016) CCH is not a statutory teaching hospital. However, the applicant identifies itself as a research and teaching institution and as one of the largest non-university based teaching hospitals in Florida with a college of medicine, in the State University System.

The applicant indicates the BMT program will be part of the Cleveland Clinic Florida Transplant Center and part of the larger Maroone Cancer Center growth strategy at CCH. Once awarded the CON, the applicant states it will initially commence services with an autologous transplant program and expand the program to include allogeneic transplantation by its third year of operation. CCH explains that patients requiring BMT are diagnosed with blood cancers and those requiring autologous BMT are diagnosed either with lymphoma or myeloma.

CCH states that need for the proposed project is based on a series of factors that are not normal circumstances related to geographic and programmatic access factors. The applicant contends that all of the following bulleted arguments serve as the applicant's foundation of need:

- *Outmigration of BMT patients from OTSA 4 to BMT programs in other areas of Florida*
- *Outmigration of BMT patients from OTSA 4 to BMT programs in other states*
- *Dominance of outpatient BMT programs in South Florida, potentially limiting high acuity patients from receiving BMT transplants*
- *Maroon Cancer Center Patient Population Appropriate for BMT Transplants*
- *Low BMT utilization rate in OTSA 4: CCH provides statistical data regarding low BMT utilization in the ensuing narrative of CON application #10444. CCH asserts that the disproportionate ratio of BMT volume compared to population ratios is one indication that BMT availability and/or accessibility is suppressed in the service area.*
- *External support for the BMT Program including referrals by unrelated area Cancer Centers*

During the 12-month period ending December 31, 2015, a total of 180 OTSA 4 adult residents (15 years of age or older) were discharged with a blood and bone marrow transplant procedure (MS-DRGs 14,16 and 17), 128 (71.11 percent) received the procedure in OTSA 4¹ and the remaining 52 patients (28.89 percent) received the procedure at a non-OTSA 4 provider. H. Lee Moffitt Cancer Center was the highest volume non-Service Area 4 provider of adult Service Area 4 residents that received the procedure (28.33 percent). Below is a table to account for these totals and percentages.

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

**Transplant Service Area 4 Adult Residents (Age 15 or Older)
With a Blood or Bone Marrow Transplant Discharge (MS-DRGs 14, 16 and 17)
12 Months Ending December 31, 2015**

Hospital	Total Procedures	Percentage
Broward Health Medical Center	2	1.1%
Delray Medical Center	2	1.1%
Good Samaritan Medical Center	3	1.6%
H. Lee Moffitt Cancer Center	51	28.3%
Holy Cross Hospital	2	1.1%
Jackson Memorial Hospital	4	2.2%
John Hopkins Children Hospital	1	0.5%
Larkin Community Hospital	1	0.5%
Memorial Hospital West	14	7.7%
Naples Community Hospital	1	0.5%
Nicklaus Children's Hospital	3	1.6%
University of Miami Hospital	1	1.1%
University of Miami Hospital and Clinics	95	52.7%
Total Procedures	180	100.00%

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

The Agency reviewed the ICD 9 Procedure Codes 41.00 to 41.09 that apply to bone marrow transplantation and stem cell transplantation. During the 12-month period ending December 31, 2015, a total of 103 Service Area 4 adult residents (15 years of age or older) were discharged with a bone marrow or stem cell transplant procedure, 65 (63.1 percent) received the procedure at a OTSA 4 provider and the remaining 38 patients (36.9 percent) received the procedure at a non-OTSA 4 provider. H. Lee Moffitt Cancer Center performed all 38 of 103 procedures outmigration cases. The table below illustrates these totals and percentages.

**Transplant Service Area 4 Adult Residents (Age 15 or Older)
With a Bone Marrow or Stem Cell Transplant Discharge (ICD 9/41.00 – 41.09)
12 Months Ending December 31, 2015**

Hospital	Total Procedures	Percentage
Good Samaritan Medical Center	2	1.9%
H. Lee Moffitt Cancer Center	38	36.9%
Jackson Memorial Hospital	2	1.9%
Memorial Hospital West	10	9.7%
Naples Community Hospital	1	1.0%
Nicklaus Children's Hospital	2	1.9%
University of Miami Hospital	1	1.0%
University of Miami Hospital and Clinics	47	45.6%
Total Procedures	103	100.00%

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

Therefore, based on the above tables, for the 12-month period ending December 31, 2015, the majority of area residents did not migrate outside of Service Area 4 for these procedures.

CCH proposes a 22-page need argument (CON application #10444, pages 35-51 and 60-65), with 21 tables. The applicant’s need justification is briefly discussed below.

Service Area

Using the Agency’s Florida Population Estimates and Projections by AHCA District 2010 to 2030 publication, issued February 2015, CCH provides a population table for age cohort 15+ for 2016 and 2019 through 2021. As the table below illustrates by Year 3 (2021), of the proposed program, the Service Area will grow by 4.6 percent (from 5.2 million to 5.5 million) for adult residents by January 2021. The reviewer notes that the table below, produced by the applicant, shows a 5.1 percent increase, not 4.6 percent. The reviewer also notes that OTSA 4 total population when compared to the state population declines from 2016 (31.4 percent) to 2021 (30.9 percent). See the table below.

**Service Area 4 Population by County
Current and Forecasted Estimates, Age 15+
2016 and 2019 Through 2021**

County	2016	(Year1) 2019	(Year 2) 2020	(Year 3) 2021	Net Change 2016- 2021	% Change 2016- 2021
Broward	1,494,895	1,520,560	1,530,544	1,540,190	45,295	3.0%
Collier	298,144	313,726	319,843	325,789	27,645	9.3%
Miami-Dade	2,200,937	2,271,486	2,229,622	2,299,622	126,352	5.7%
Monroe	64,112	63,987	63,964	63,964	-180	-0.3%
Palm Beach	1,166,537	1,204,242	1,218,929	1,218,929	66,654	5.7%
Total	5,224,625	5,374,001	5,432,902	5,432,902	265,766	5.1%
Florida	16,654,217	17,286,334	17,533,915	17,774,101	1,119,884	6.7%
Service Area Total	31.4%	31.1%	31.0%	30.9%		

Source: CON application #10444, page 37

CCH notes that statewide in 2016, there were 16,654,217 adult residents, of which 5,224,625 persons reside within the five county service area representing 31.4 percent of the State’s adult population. The applicant states the Broward and neighboring Miami-Dade County represent the two most populated in the defined service area (and the State of Florida), with approximately 1.49 million and 2.2 million adult residents respectively. CCH states that nearly 17 percent of the anticipated two and half year growth in population will be within Broward County and 48 percent of the growth will be in Miami-Dade County.

The applicant states that Service Area 4 encompasses 8,059 square miles, spanning the entire southern region of the peninsula. CCH reports that in Florida, the average number of inhabitants per square mile is

350.6 people. The applicant states that Broward County has the second greatest number of inhabitants per square mile of all Florida counties, with an average 1,445 inhabitants per square mile. Miami-Dade County, has 1,316 inhabitants per square mile, Palm Beach County has 670, Collier County has 161 and Monroe County 74 people per square mile.

Inpatient and Outpatient Bone Marrow Transplants

For the past two years within OTSA 4, the applicant maintains that nearly 70 percent of bone marrow transplantations have been performed on an outpatient only basis. The applicant contends that while part of this volume is driven by Good Samaritan Medical Center in Palm Beach County, even the service area’s largest program University of Miami Hospital and Clinics, transplants between 47 and 58 percent of its patients on an outpatient basis. Lastly, CCH states while Memorial Hospital West is the service area’s lowest volume program, it too is split between inpatient and outpatient. During the most recent 12 months ending September 30, 2015—the applicant asserts that 38 percent of its 21 bone marrow transplant volume was administered on an outpatient basis. CCH indicates it will differentiate from other providers as 100 percent of its bone marrow transplantation will be on an inpatient basis. See the table below.

**Service Area Adult Bone Marrow Transplantation, Outpatient
and Total Bone Marrow Transplants Ages 15+,
CY 2013, 2014 and 12 Months Ending 9/30/2015**

Hospital	CY 2013			
	Inpatient	Outpatient	Total	Percent Outpatient
Good Samaritan	1	0	0	--
Memorial Hospital West	15	0	15	0%
University of Miami Hospital & Clinics	64	68	132	51.5%
OTSA 4 Programs	80	68	147	46.3%
Hospital	CY 2014			
	Inpatient	Outpatient	Total	Percent Outpatient
Good Samaritan	0	73	73	100.0%
Memorial Hospital West	12	8	20	40.0%
University of Miami Hospital & Clinics	58	79	137	57.7%
OTSA 4 Programs	70	160	230	69.6%
Hospital	12 Months Ending 9/30/2015			
	Inpatient	Outpatient	Total	Percent Outpatient
Good Samaritan	3	116	119	97.4%
Memorial Hospital West	13	8	21	38.1%
University of Miami Hospital & Clinics	75	67	142	47.2%
OTSA 4 Programs	91	191	282	67.7%

Source: CON application #10444, page 43

CCH notes that the Agency’s published statewide adult inpatient bone marrow transplantation procedures for CY 2015 states that 1,091 procedures were performed with 284 performed by OTSA 4 providers. The applicant indicates that this includes both inpatient and outpatient autologous and allogeneic BMT procedures. The reviewer notes that only inpatient bone marrow transplantation procedures are CON-regulated, not outpatient procedures. Outpatient procedures are not being included in the Agency’s publication.

The applicant maintains that it will not perform any outpatient transplantation as it is not best for the patient. CCH contends that outpatient transplantation places undue burden on the patient and sets the patient up for sub-optimal patient care due to increased cost associated with local accommodations, costs associated with requiring around the clock caregivers and a multitude of patient safety and quality concerns.

Using Agency inpatient hospital discharge data for CY 2013-2015, CCH states a total volume for the past three years have consistently been between 141 and 143 inpatient adult bone marrow transplant discharges for residents defined in the service area. CCH indicates that of these,

approximately 56 to 65 percent have been autologous transplants and the balance were allogeneic. See the table below.

**OTSA 4 Resident BMT Discharges
By Type Ages 15+ for the 12 Months Ending
September 30, 2013-September 30, 2015**

MS-DRG	MS-DRG Description	12 Months Ending 9/30/2013	12 Months Ending 9/30/2014	12 Months Ending 9/30/2015
014	Allogeneic BMT	50	55	62
016	Autologous BMT w CC/MCC	81	81	70
017	Autologous BMT w/o CC/MCC	12	7	9
Total OTSA 4 Resident Cases		143	143	141

Source: CON application #10444, page 48

CCH notes that during the same three years, between 685 and 766 Florida adult residents received a bone marrow transplant. The applicant states that while the service area is home to between 31 and 32 percent of the State’s total adult population (ages 15+) it only represents between 18 and 21 percent of the Florida resident adult bone marrow transplant cases performed for each of the last three years. CCH indicates this is a disproportionate ratio of bone marrow transplant volume compared to population ratios and is one of the indications that BMT availability and/or accessibility is suppressed in the service area. The applicant provides the following table illustrating Florida resident origin BMT volume for the past three years.

**Florida and OTSA 4 Resident BMT Discharges
By Type Ages 15+ for the 12 Months Ending
September 30, 2013-September 30, 2015**

MS-DRG	MS-DRG Description	12 Months Ending 9/30/2013	12 Months Ending 9/30/2014	12 Months Ending 9/30/2015
014	Allogeneic BMT	267	284	33
016	Autologous BMT w CC/MCC	407	368	415
017	Autologous BMT w/o CC/MCC	33	33	28
Total Florida Resident Cases		707	685	776
OTSA 4 Resident Cases		143	143	141
Percent of OTSA 4 of Florida		20.2%	20.9%	18.2%

Source: CON application #10444, page 48

Patient Migration Patterns

The applicant states for each of the past three years, there have been between 134 and 149 inpatient bone marrow transplant cases originating from the five county service area with between 38 and 48 percent leaving the service area for treatment. CCH notes that outmigration varies from

county to county with Miami-Dade having the lowest outmigration because the service area’s largest program, the University of Miami Hospitals and Clinics is located in Miami-Dade County. The applicant notes that the outmigration of Broward County residents, despite Memorial Hospital West’s existing program, has between 25 and 42 percent of residents seeking inpatient treatment outside the service area. Furthermore, CCH states that it is astounded that between 68 and 82 percent of Palm Beach County residents leave the area for inpatient bone marrow transplantation.

The applicant provides the following table illustrating the historical inpatient volume for OTSA 4 residents used to determine the percent of residents who left the service area for bone marrow transplantation. CCH notes the following outmigration statistics include only those residents who left the service area but remained within the State of Florida as provided by the Agency’s Inpatient Data Tapes. See table below.

Adult Inpatient Bone Marrow Transplant Utilization Outmigration from OTSA 4 to Other Parts of Florida Ages 15+, CY 2013, 2014 and 12 Months Ending 9/30/2015				
CY 2013				
Resident County	OTSA 4 Program	Outmigration In Florida	Total Inpatient Cases	Percent Outmigration of Inpatient Cases
Broward	27	24	51	47.1%
Collier	0	14	14	100.0%
Miami-Dade	44	10	54	18.5%
Monroe	1	1	2	50.0%
Palm Beach	7	21	28	75.0%
Total	79	70	149	47.0%
CY 2014				
Resident County	OTSA 4 Program	Outmigration In Florida	Total Inpatient Cases	Percent Outmigration of Inpatient Cases
Broward	25	18	43	41.9%
Collier	0	17	17	100.0%
Miami-Dade	39	6	45	18.5%
Monroe	1	0	1	50.0%
Palm Beach	5	23	28	75.0%
Total	70	64	134	47.0%
12 Months Ending 9/30/2015				
Resident County	OTSA 4 Program	Outmigration In Florida	Total Inpatient Cases	Percent Outmigration of Inpatient Cases
Broward	37	12	49	24.5%
Collier	0	9	9	100.0%
Miami-Dade	39	10	49	20.4%
Monroe	0	0	0	--
Palm Beach	11	23	34	67.6%
Total	87	54	141	38.3%

Source: CON application #10444, page 45

The applicant notes that aside from Collier County (with little volume), Broward and Palm Beach Counties have the most outmigration for bone marrow transplantation. CCH states for each of the last three years (2013-2015), between 25 and 47 percent of Broward County residents have left the service area for bone marrow transplantation and between 68 and 82 percent of Palm Beach County residents have outmigrated despite Good Samaritan Medical Center’s outpatient program. The applicant asserts that Cleveland Clinic has a growing presence in Palm Beach County and is quite accessible to the county. CCH states that outpatient volume is not captured at the resident origin level by any database or publication to determine the true number of service area bone marrow transplant cases. As previously stated by the reviewer, outpatient procedures are not included in Agency publications as those procedures are not CON-regulated.

CCH assumes 50 percent of total service area cases will be outpatient, as the applicant notes that Good Samaritan Medical Center’s outpatient program skews the service area cases (which were 68 to 70 percent). The applicant indicates that during the past few years, University of Miami and Memorial West have provided closer to 50 percent of their cases on an outpatient basis therefore the applicant indicates it is reasonable to assume 50 percent of all cases will be outpatient. CCH summarized total historical inpatient and outpatient BMT case origination from the service area and treated within the State of Florida, based on the 50 percent assumption for total outpatient. See the table below.

Service Area Resident Adult Bone Marrow Transplant Utilization, Inpatient, Outpatient (Estimated) and Total Ages 15+, CY 2013, 2014 and 12 Months Ending 9/30/2015

	CY 2013	CY 2014	12 Months Ending 9/30/2015
Inpatient BMT cases	149	134	141
Outpatient Adjustment Factor	1 Inpatient BMT Case		
Outpatient BMT Cases	149	134	141
Total Inpatient and Outpatient BMT Cases	298	268	282

Source: CON application #10444, page 46

CCH indicates that because outpatient bone marrow transplant is not reported in the Agency’s data base, it is unclear as to the exact number of outpatients who also leave OTSA 4 for outpatient BMT’s. CCH asserts that extrapolating the relationship of outpatient to inpatient transplants with consistent outmigration factors between the two cohorts suggests that an equal number of outpatients left the service area for transplantation but remained within Florida. The applicant reports in

the 12 months ending September 30, 2015, 54 adults residing in OTSA 4 received BMT within Florida but outside their home service area. CCH states applying outpatient estimates based on relationship metrics increases the identified outmigration of 54 cases within Florida to a total of 108 outmigration cases, 54 inpatient and 54 outpatient. The applicant indicates that the inpatient outmigration of 54 cases alone is sufficient volume to warrant approval of the proposed program to mitigate the demonstrated access problem.

The applicant maintains that in addition to the 108 total service area residents who sought treatment outside the area, CCH has identified an additional 50 to 70 patients who leave the state for bone marrow transplantation each year. CCH indicates this data is derived from the MedPar database, which reports only Medicare fee for service utilization, but includes utilization across state lines. The applicant notes that in the most recent available data, CY 2014, 14 of 59 (24 percent) Medicare fee for service patients who originated from the defined service area sought treatment outside the State of Florida. CCH states that in 2013, 10 of 43 (23 percent) Medicare fee for service patients sought treatment outside the State. Medicare fee for service accounts for only one-fifth of all service area inpatient BMT volume. Therefore, the applicant indicates that the 10 to 14 Medicare fee for service patients who received care outside the State in 2013 and 2014 is likely 50 to 70 total cases/all payors. The applicant states that the 282 service area cases within Florida may be adjusted upward by 50 to 70 cases resulting in between 332 and 352 total cases when factoring in those service area residents who leave Florida for BMT transplants.

Cleveland Clinic Florida's Maroon Cancer Center Patient Population

The applicant indicates that The Cleveland Clinic Florida Maroon Cancer Center currently has internal demand for an adult bone marrow transplant program. CCH notes that patients requiring bone marrow transplants are a subset of those diagnosed with lymphoma and myeloma. In the past two years, the applicant reports it had 172 patients (an average of 86 patients per year) who were treated for these cancers or diseases.

CCH states in order to identify internal demand for bone marrow transplantation, it analyzed the historical patient population during the past two years in conjunction with use rates or treatment rates, for both its lymphoma and myeloma patients, to obtain the number of patients who may have been referred to a BMT program. The applicant states that these rates are based on main campus experience (Ohio) and evaluation

by its BMT physicians. CCH expresses that with the proposed BMT program scheduled to begin performing transplants by October 2018, the base line (2014 and 2015) lymphoma and myeloma patient population at Maroone Cancer Center requires adjustment to fourth quarter 2018. See the table below.

**Cleveland Clinic Internal Demand Analysis for Bone Marrow Transplant
Historical and Estimated Lymphoma and Myeloma Cases**

Group	CY 2014	2015 Annualized	Estimated CY 2016	Estimated CY 2017	Estimated CY 2018	Estimated CY 2019
Lymphoma	74	60	68	76	84	92
Myeloma	20	18	21	24	27	30
Total	94	78	89	100	111	122

Source: CON application #10444, page 50

CCH notes the above forecast disregards potential third party referrals from other cancer centers throughout South Florida as indicated by the letters of support from external programs. The applicant notes the subset of lymphoma patients requiring bone marrow transplants that was applied to calculate BMT volume is 10 percent of lymphoma cases and 25 percent of myeloma volume. CCH provides the following forecast of BMT cases for the first three years of operation. See the table below.

**Cleveland Clinic Internal Demand Analysis
for Projected BMT Cases Years 1 through 3**

Blood Diseases	CY 2018	CY 2019	Estimated Percent (Yield) to BMT	Year 1 Forecast	Year 1 Projected BMT Cases	Year 2 Projected BMT Cases	Year 3 Projected BMT Cases
Lymphoma	84	92	10%	9	9	14	17
Myeloma	27	30	25%	7	7	11	13
Total	111	122	--	16	16	25	30

Source: CON application #10444, page 51

CCH asserts that the above projected bone marrow transplant volume of 16 cases in year one, 25 cases in year two and 30 cases in year three will yield pathology work-up, including general laboratory studies, hematopathology and cell processing. The applicant affirms that an apheresis program will be implemented and states that the volume will also require a certain level of inpatient chemotherapy, outpatient infusion, imaging and interventional radiology. In addition to these services CCH maintains that various physician specialists will be required to support patients' needs.

External Support for the BMT Program

CCH states it has the support of other South Florida hospitals such as the ones whom submitted letters in support of the proposed program.

The applicant states that each of these hospitals has its own cancer center but does not have a bone marrow transplant program. CCH notes two of these hospitals are within Palm Beach County, which has the greatest outmigration rate of any county within the OTSA. The applicant suggests that it will seek to establish relationships with other hospitals and cancer centers throughout the region in addition to those who submitted letters supporting the proposed program. These hospitals include:

- Boca Raton Regional Hospital
- Jupiter Medical Center
- Martin Memorial Health System

CCH asserts that it will seek to establish relationship with other hospitals and cancer centers throughout the region as well as maintain the relationships listed above.

Forecasted Utilization

CCH calculated a range of forecasted service area market bone marrow transplant cases based on two sets of discharge use rates. The applicant states the first scenario forecasts future bone marrow transplants by applying historical actual use rates by county to forecasted population for each of the three planning years. This results in 293 bone marrow transplant cases in year one increasing to 299 by year three. CCH states this scenario is based solely on population growth and does not factor in that with greater accessibility and availability of a high quality BMT program residents will obtain treatment at a greater frequency than historical trends.

The second methodology presented by the applicant applies the Florida resident bone marrow transplant use rate per 100,000 population (less OTSA 4) to the service area's forecasted population ages 15+. CCH assumes that with greater availability and accessibility to a high quality BMT program in Broward County, combined with the fact that Baptist Health in Miami-Dade will soon have a program, the BMT use rate in the service area will more closely mirror the patterns in the remainder of the State. See the table below.

**Forecasted CCH Bone Marrow Market Share and Volume
Ages 15+, Year 1 through Year 3**

Methodology 1	Year 1 (Ending 6/30/2019)	Year 2 (Ending 6/30/2020)	Year 3 (Ending 6/30/2021)
Forecasted Service Area Cases	293	296	299
CCH Market Share	4.8%	7.4%	9.0%
CCH Service Area Cases	14	22	27
In-Migration-10%	2	3	3
CCH Cases	16	25	30
Methodology 2			
Forecasted Service Area Cases	412	417	421
CCH Market Share	3.4%	5.3%	6.4%
CCH Service Area Cases	14	22	27
In-Migration-10%	2	3	3
CCH Bone Marrow Cases	16	25	30

Source: CON application #10444, page 65

No Material Adverse Impact on Existing Adult BMT Providers

The applicant has forecasted it will transplant 16 patients in its first year of operation increasing to 30 patients by its third year. CCH states that given the market dynamics, market profile and exorbitant 38.2 percent outmigration in the most recent 12 month period, there will be no adverse impact on any existing licensed or planned adult bone marrow transplant program in OTSA 4. CCH maintains that given the level of outmigration, existing program transplants and including Baptist Hospital of Miami’s forecasted cases, there is sufficient outmigration to more than meet the CCH’s forecasted transplants.

CCH indicates that it will primarily rely on residents of Broward and Palm Beach Counties to support its program. The applicant states that during the 12 months ending September 30, 2015, 12 Broward County residents and 23 Palm Beach County residents left the service area for inpatient bone marrow transplantation. CCH calculates that the same number of residents migrated out for outpatient transplantations. The applicant asserts that a total of 70 Broward and Palm Beach County residents left the service area and between 50 and 70 patients left Florida for treatment altogether. CCH plans to recapture a portion of these out-migrating residents leaving OTSA 4 for other hospitals within Florida.

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).

CCH is not a statutory teaching hospital as defined in Section 408.07(45) Florida Statutes. However, the applicant identifies itself as a research and teaching institution and as one of the largest non-university based teaching hospitals in Florida with a college of medicine, in the State University System. The applicant states it will continue to pave the way in clinical research, specifically cancer research. As the BMT program develops, CCH states there will be related research ongoing just as in the case at the main campus. CCH reports that the main campus located in Ohio, has more than 200 total active clinical trials for cancer patients.

The applicant states it provides training for residents and fellows in 17 medical and surgical disciplines and specialties. For the 2015-2016 academic year, CCH states training the following:

- 68 Clinical Residents
- 36 Fellows
- Two Pharmacy Residents
- 42 Visiting Residents
- 475 Medical Students
- 124 Observers
- 48 Research Fellows
- 80 High School and College Students in its Summer Scholar Program

CCH states in addition to the hospital being a training site for future physicians and other healthcare professionals, more than 85 specialists and subspecialists at the hospital are also professors at the Florida Atlantic University Charles E. Schmidt College of Medicine and 45 specialists and subspecialists dually serve as assistant clinical professors at the Herbert Wertheim College of Medicine at Florida International University.

- (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.**

CCH has proposed to establish an autologous and allogenic bone marrow transplant program on its hospital campus. The applicant

indicates the autologous component will be developed initially followed by the allogeneic component. CCH affirms it will perform a minimum of 10 allogeneic BMT transplants within three years of opening its BMT program. The reviewer notes that the applicant forecasts 16 procedures in year one, 25 in year two and 30 in year three.

- (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.**

CCH states that Dr. Navneet Majhail, MD, MS will become program director of the BMT program. The applicant states that Dr. Majhail is one of four main campus Hematologist/Oncologists who are currently seeking Florida licensure so that they can dually practice in Florida and Ohio. As program director at CCH, the applicant states Dr. Majhail will relocate to Florida.

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

CCH states it has a robust, highly credentialed and proficient nursing staff, which provides quality care to very critically ill patients. The applicant lists 65 nurses on page 86 of CON application #10444 and states that these nurses have experience and competencies in the care of critically-ill immune-suppressed patients. CCH notes that the 68 referenced nurses helped earn the Hospital's ICU its American Association of Critical-Care Nurses' Beacon Award for Excellence, signifying the exceptional care achieved through improved patient outcomes and greater overall patient satisfaction.

CCH states that it will adopt the BMT standard operating procedure manual and the BMT Nurse Training and Competency Standard Operating Procedure manual in place at Cleveland Clinic Main Campus. The applicant states the standard operating procedures outline the initial orientation, competency requirements and documentation to ensure that competency of the BMT nursing staff to provide an appropriate level of care.

According to the applicant, the standard operating procedures provides specific requirements as it relates to nursing licensure, orientation for nurses caring for BMT patients and continuing education and professional development.

- (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 indicates the bone marrow transplant team at CCH will be specially trained in meeting the needs of transplant patients. CCH states the team will be committed to providing comprehensive care in a compassionate setting and includes the following members:

- Transplant physicians
- Physician assistants and nurse practitioners
- Transplant nurse coordinators
- Infectious disease team
- Pharmacologists
- Transplant fellows and residents
- Administrative coordinators
- Nurse manager and assistant nurse manager
- Registered nurses
- Nursing assistants
- Administrator
- Dieticians
- Social workers
- Financial counselors

CCH indicates that it has the requisite medical staff and clinicians to create a renowned interdisciplinary transplant team with experience in hematology, oncology, immunologic diseases and neoplastic diseases. The applicant states the interdisciplinary team will guide the patient through the entire process from evaluation, outpatient work-up, transplantation and both immediate and long-term follow-up care. The applicant states that it has a current staff of eight hematologists and oncologists and the pending addition of four dually licensed physicians from the Main Campus (Ohio). CCH attests that the group of 12 hematologists and oncologists are a skilled and experienced team that will support the need of inpatient BMT patients.

- (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.**

CCH indicates that during the hospital stay for transplant, patient will stay in the 10-bed BMT unit within the broader 26-bed hematology/oncology acute care unit on the third floor of the new bed tower. The applicant states that all patient rooms in the BMT unit will be Protective Environment (PE) rooms because these acute patients are immunocompromised and the BMT unit will have HVAC and HEPA filtration/positive pressure ventilation system in place that limits the formation or sharing of potential airborne pathogens that could put the patient at risk. CCH indicates one of the patient rooms will be a combination of Airborne Infection Isolation/Protective Environment (All/PE). The 10-bed unit will include 10 private rooms ranging between 274 and 310 square feet with private bathrooms. The applicant states that in addition to private rooms, the unit will have a patient lounge, family lounge, separate clean supply and soiled utilities rooms, medication room, nourishment and environmental services space.

- (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.**

CCH states that The Department of Radiation-Oncology at the Cleveland Clinic Maroone Cancer Center has some of the very latest state-of-the-art technology and has very recently acquired some exciting new technology that helps deliver radiation therapy more accurately and quickly. The applicant notes that CCH is one of only a few centers around the world to offer the Varian Edge radiosurgical suite.

The applicant asserts that The Department of Radiation-Oncology at the Cleveland Clinic Florida Maroone Cancer Center is led by the highly regarded board certified Dr. John Greskovich, Jr. CCH states that Dr. Greskovich serves as Medical Director of The Department of Radiation-Oncology and dually serves as co-director

of the Head and Neck Cancer Tumor Board, member of the Radiation Oncology Workflow Enhancement Committee, member of the Physician Wellness Committee and is an assistant professor at Cleveland Clinic Lerner College of Medicine.

CCH states that the Maroone Cancer Center has earned three-year approval with Commendation from the Commission of Cancer (CoC) of the American College of Surgeons, insuring that patients have access to:

- Comprehensive care, including a range of state-of-the-art services and equipment
- A multidisciplinary team approach to coordinate the best treatment options
- Information about ongoing clinical trials and new treatment options
- Access to cancer related information, education and support
- A cancer registry that collects data on type and stage of cancers and treatment results, and offers lifelong patient follow-up
- Ongoing monitoring
- Quality care close to home

- (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.**

CCH states its laboratory and pathology center is qualified to handle the studies identified above. However, with respect to T-cell depletion, the applicant indicates that CCH does not currently have a protocol which includes this process and based on current standards, this will not be implemented at the Hospital. The applicant states if a protocol is adopted in the future then this capability will be incorporated into the laboratory function at the hospital.

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

CCH states it is developing a cell processing laboratory on the Hospital campus in collaboration with the Hospital's Department of Pathology. The applicant indicates the cell processing lab will be located in the current laboratory on the first floor of the hospital

and will be equipped for the evaluation and cryopreservation of bone marrow. CCH states that in addition to developing an on-site cell processing lab, it is also developing its own apheresis facility on the third floor of the hospital in the current dialysis space, which will relocate.

- (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.**

CCH states it will continue to pave the way in clinical research and specifically cancer research. The applicant asserts as the BMT program develops, there will be ongoing related research, as is the case at Main Campus (Ohio) where there are currently 12 ongoing clinical trials specifically having to do with blood and marrow transplant and more than 200 total active clinical trials for cancer patients.

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

The applicant states Cleveland Clinic Florida cancer research staff is dedicated to providing patients with innovative therapies through clinical research trials which include new targeted agents and therapies. CCH provides a detailed description of oncology research on page 26 of CON application #10444.

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

The applicant states it currently collaborates with a host of local hotels to ensure that patients and their families have accessible housing during extended hospital stays. CCH notes specifically having a relationship with the Courtyard Fort Lauderdale Weston at 2000 N. Commerce Parkway, Fort Lauderdale, Florida 33326. CCH states that this hotel is offered to solid organ transplant patients and families. The applicant asserts that CCH social workers provide a resource and assistance to patients and their families requiring local hotel accommodations.

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

CCH states the outpatient area for the BMT patients will be located within the Maroone Cancer Center, where patients are referred, evaluated, and treated pre and post-transplant on an outpatient basis.

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 asserts it has sufficient staff and other resources to care for the BMT transplant patient's chronic illness prior to transplantation, during transplantation and throughout the post-operative period. Services and facilities for inpatient and outpatient care will be available on a 24-hour basis.

CCH again reiterates that transplantation will be performed on an inpatient basis and to ensure highest quality and outcomes. CCH will not be performing transplants on an outpatient basis. The applicant notes that during the hospital stay for transplants, the patient will stay in the 10-bed BMT unit within the broader hematology/oncology acute care unit of the new bed tower currently under development. CCH proclaims that the BMT unit will have HVAC and HEPA filtration systems in place to limit the formation of sharing of potential airborne pathogens that could put the patient at risk.

The applicant states that staff and other resources necessary to support and care for the BMT patient from the initial evaluation and workup to outpatient follow ups, on a 24/7 basis include pathology, pharmacy, radiology, infectious diseases, cardiology, pulmonary/critical care, nephrology, endocrinology, internal medicine and nursing for both inpatient and outpatient care. CCH contends that it has a number of oncology nurses and support staff who will care for BMT patients.

- 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 indicates adult bone marrow transplant recipients will be cared for in a 10-bed BMT unit within the hematology/oncology acute care unit of the new bed tower currently under development. CCH notes that the unit will be a dedicated area with HVAC and HEPA filtration which limits the formation or sharing of potential airborne pathogens that could put the patients at risk. The applicant states that the unit's staff will be specially trained.

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

The applicant states a clinical review committee will be established to evaluate all potential patients to determine their suitability for bone marrow transplantation. CCH indicates the committee will be organized and directed by the program's medical director, and the entire multidisciplinary team will participate on the committee. According to CCH,

the clinical review committee will include the following team members:

- Medical director
- Laboratory, pathology and blood bank staff
- Other physician specialists
- Psychology/psychiatry
- Social work
- Program manager (nursing)
- Financial counselor
- Pharmacist
- Dietician

CCH maintains that the committee will meet on a regular weekly basis with new potential bone marrow transplant patients presented by the BMT physician who initially received the patient referral and performed the initial consult. Patients identified as an appropriate candidate for BMT will undergo a comprehensive pre-transplantation evaluation.

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 states it will adopt similar protocols for its adult BMT program as Cleveland Clinic Main Campus (Ohio) has in place and similar protocols as CCH already has in place for its other three solid organ transplant programs. The applicant states that the Main Campus adheres to the Taussig Cancer Center BMT Standard Operating Procedure Manual for patient selection criteria for patient management and evaluation during the pre-hospital, in-hospital, immediate post discharge and long-term follow up phases of the BMT programs.

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.

CCH states that clinical guidelines summarize evaluations and follow-up for preventing late complications in autologous and allogeneic hematopoietic cell transplantation (HCT)

recipients who have survived one year or more post-transplantation. The applicant states these guidelines are based on CIBMTR/ASBMT/EBMT consensus recommendations for screening and preventive practices for long-term HCT survivors. CCH contends that performing transplants on an inpatient basis only, it is better prepared to manage any commonly encountered complications at their onset.

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.**

CCH states that it has a contract with LifeLink of Florida based in Tampa, Florida for all of its transplant center's histocompatibility needs. The applicant states that LifeLink is a non-profit community service organization dedicated to the recovery of life-saving and life-enhancing organs and tissue for transplantation therapy. LifeLink is one of four organ procurement organizations in the State of Florida and 58 in the County.

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.**

CCH's Division of Pathology and Laboratory processes and interprets approximately 20,000 surgical and cytology specimens yearly. The applicant states the center has the technical resources and expertise necessary to fully support the proposed BMT program. CCH asserts that its team of pathologists has the capabilities of studying and promptly reporting bone marrow transplant patient responses to

transplant and analyzing appropriate biopsy material. The Center of Pathology and Laboratory Medicine at Weston is part of Cleveland Clinic Main Campus (Ohio) which holds a Florida license.

10. Blood banking facilities.

CCH states its existing blood bank has the physical capacity to accommodate additional needs for the BMT program. The Hospital will increase its blood inventory as needed to accommodate bone marrow transplant programming needs and ensure that a sufficient inventory of blood is maintained at all times to accommodate all its transplant programs.

The applicant indicates that OneBlood will have the blood supply and blood product resources available at all times for Cleveland Clinic's BMT as back up if necessary. ABO compatible products of red blood cells, plasma, cryoprecipitate and platelets will be readily available to enhance the inventory of CCH's internal blood bank.

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

CCH states plans to adopt from Cleveland Clinic Main Campus (Ohio) much of the necessary education and training of staff for this project. The applicant states that both the transplant center and the BMT program at Main Campus have been successfully training its staff members in the special care of transplant patients for many years and have the resources readily available to share with the BMT program.

The applicant discusses its transplant team members and how they will know and adhere to the Cleveland Clinic Taussig Cancer Institute Bone Marrow Transplant Standard Operating Procedure Manual.

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

The applicant ensures that CCH's Main Campus (Ohio) has designed an extensive teaching program to help patients and their families learn about the bone marrow transplant

process and individual health needs and medical care before and after the transplant. Notebooks which provide detailed instruction, explanations, expectations, and coping mechanisms in a tabulated format are provided to each patient as a reference tool for the patient to review while awaiting transplant.

CCH states it will have specific patient education manuals that are dispersed to each and every bone marrow transplant candidate prior to evaluation and work up appointment. The applicant indicates it will have separate patient education manuals for allogeneic and autologous transplants. The applicant states the allogeneic and autologous guides for patients contain the following categories of information:

- Introduction to the Blood & Marrow Transplant Program
- Pre-transplant/central line care
- Social work
- Your transplant
- Transplant medicines
- Follow-up care after your BMT
- Graft-versus host diseases (allogeneic patients only)
- Keeping you healthy

CCH assures these guides are comprehensive, include information about different types of autologous and allogeneic transplants. Individualized treatment plans will be provided.

- 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.**

CCH indicates it will initially have a team of four hematologists/oncologists who specialize in BMT prior to the inception of the proposed program. The applicant states that the program will be directed by Dr. Navneet Majhail, who is presently seeking Florida licensure. The applicant provides a brief synopsis for Dr. Majhail's qualifications as well as the qualifications of three other physicians expected to be an integral part in developing the proposed BMT program.

- 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.**

Per the applicant, Dr. Navneet Majhail, MD, is currently the Director of the Cleveland Clinic's Blood and Marrow Transplant Program in Ohio, serves as a staff physician with the Department of Hematology and Oncology at the Taussig Cancer institute and is a Professor of Medicine with the Cleveland Clinic Lerner College of Medicine. Dr. Majhail completed his residency in internal medicine at Cleveland Clinic Ohio and his fellowship training in hematology/oncology at the University of Minnesota in 2007.

- 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.**

CCH indicates that to the extent that over 65 nurses with such experience already work at the hospital, these nurses will be utilized. The applicant states that these nurses have earned the Hospital's American Association of Critical Care Nurse's Beacon Award for Excellence, signifying the exceptional care achieved through improved patient outcomes and greater overall patient satisfaction.

- 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.**

CCH indicates that it has its own blood bank with employees well versed in blood banking who are capable of meeting the unique long term needs to transplant patients. The applicant also has a contract with OneBlood to supplement a gap in service should it arise.

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

The applicant states that it will ensure that nutritionists with expertise in the nutritional needs of bone marrow transplant patients are members of the multidisciplinary team that will care for the adult BMT patient and provide transplant patients with medical nutrition therapy using current scientific principles supported by reliable research to optimize patient care. The applicant states it will make nutritional assessment and diet counseling services furnished by a qualified dietician available to all transplant patients and donors.

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

CCH states that its respiratory therapists will have experience in providing care to transplant patients including training at Cleveland Clinic Main Campus prior to program initiation “as necessary”. It is also stated these therapists will be familiar with providing care to the immunosuppressed.

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.

Cleveland Clinic Hospital states that it will ensure there are social workers, psychologists, psychiatrists and others in the interdisciplinary team, skilled in performing comprehensive assessments, counseling (for patients and family members) as well as financial arrangements and community resources. The applicant states the hospital already has social workers,

psychologists and psychiatrists on staff that evaluate other patient populations.

- 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 stated it will comply with adult bone marrow transplant data reporting requirements.

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 #10444.

Driving Distances in Miles-CON application #10444 Cleveland Clinic Florida Health System Nonprofit Corporation, d/b/a Cleveland Clinic Hospital and Florida Adult Inpatient Bone Marrow Transplant Providers								
Facility	Cleveland Clinic Hospital	Univ. of Miami Hospital & Clinics	Memorial Hospital West	Good Samaritan Medical Center	Florida Hospital -Orlando	H. Lee Moffitt Cancer Center	Mayo Clinic	UF Health Shands Hospital
Cleveland Clinic Hospital		35.0	7.7	59.9	222	256	328	349
University of Miami Hospital & Clinics	35.0		21.0	69.7	235.2	282.2	341.7	332.7
Memorial Hospital West	7.7	21.0		63.8	229.7	263.3	336.2	327.2
Good Samaritan Medical Center	59.9	69.7	63.8		172.5	205.5	281.8	270.1
Florida Hospital-Orlando	222	235.2	229.7	172.5		87.0	137.4	114.4
H. Lee Moffitt Cancer Center	256	282.2	263.3	205.5	87.0		208.0	122.6
Mayo Clinic	328	341.7	336.2	281.8	137.4	208.0		89.1
UF Health Shands Hospital	349	332.7	327.2	270.1	114.4	122.6	89.1	

Source: www.Mapquest.com

CCH states the proposed project will enable south Florida residents to remain within their home region while accessing treatment at the Maroon Cancer Center. The applicant asserts that service area residents can remain close to home throughout the entire process from evaluation to transplantation and follow up care rather than relocating to another unfamiliar place outside south Florida to seek care.

As previously stated, for the 12-month period ending December 31, 2015, the seven adult inpatient bone marrow transplant programs in the State performed 1,091 procedures. H. Lee Moffitt Cancer Center is the largest volume provider of the seven programs with 419 transplants followed by UF Health Shands Hospital in Alachua County with 175 transplants and University of Miami Hospital & Clinic with 170 transplants. The three adult inpatient bone marrow transplant programs in OTSA 4 performed a combined 284 transplants during CY 2015. The applicant notes that there were nearly 1,100 adult bone marrow transplants performed in Florida in 2015 and nearly 300 of them were performed in OTSA 4.

CCH asserts the need for the proposed BMT transplant program is based on a series of factors that evidence not normal circumstances related to access, availability and extent of utilization. The applicant indicates that the data research and analysis and operational characteristics identified and presented herein provide substantive support for development of the proposed BMT program. The applicant discusses outmigration of BMT patients from the OTSA 4 service area.

CCH states that for OTSA 4, there were 282 total bone marrow transplantations performed on service area residents for the 12 month period ending September 30, 2015 resulting in service area use rates of 5.46 per 100,00 population age 15+. The applicant indicates discharge use rates vary from county to county but range between 4.5 and 6.6 cases per 100,000 population with the exception of Monroe County with no recent utilization. See table below.

**Service Area Resident BMT Use Rates per 100,000 Population
Actual Inpatient and Estimated Outpatient Cases Age 15+
12 Months Ending September 30, 2015**

Resident County	Resident Population 7/1/2015	Resident BMT Cases 12 Months Ending 9/30/2015	Use Rate per 100,00
Broward	1,485,234	98	6.60
Collier	291,887	18	6.17
Miami-Dade	2,174,378	98	4.51
Monroe	64,271	0	0.00
Palm Beach	1,151,683	68	5.90
Service Area Total	5,167,453	282	5.46

Source: CON application #10444, page 61

CCH notes that the comparative calculation shows that the service area use rate is much lower (2.21 points) than the transplant use rate throughout the rest of Florida, 5.46 percent in the service area versus 7.67 transplants per 100,000 adult population in the remainder of the State. The applicant states this data indicates that the service area use rate is suppressed and presents the table below to illustrate the use rates similar to the State when proper access to quality programming is utilized:

**Service Area Resident BMT Use Rates per 100,000 Population
Actual Inpatient and Estimated Outpatient Cases Age 15+
12 Months Ending September 30, 2015**

OTSA 4 Residents	
Population ⁽¹⁾	5,167,453
Adult Resident BMT Cases ⁽²⁾ (inpatient and outpatient)	282
Use Rate per 100,000 Population Ages 15+	5.46
Florida Residents	
Population ⁽¹⁾ Ages 15+	16,404,322
Adult Resident BMT Cases ⁽²⁾ (inpatient and outpatient)	1,144
Use Rate Per 100,000 Population, Ages 15+	6.97
Florida Residents Minus OTSA 4	
Population ⁽¹⁾ Ages 15+	11,236,869
Adult Resident BMT Cases ⁽²⁾ (inpatient and outpatient)	862
Use Rate Per 100,000 Population, Ages 15+	7.67

Source: CON application #10444, pages 61-62

(1) Population as of July 1, 2015

(2) Inpatient volume is actual based on AHCA Inpatient Data Tapes, outpatient volume is adjusted based on adjustments factor presented on page 46 of CON application #10444.

The applicant states that the 7.67 transplants per 100,000 adult population in Florida, outside the service area, not only exceeds the service area's overall use rate of 5.46 transplants per 100,000 population

but also exceeds the use rate of each of the service area's five counties, which according to CCH, further indicates that every one of the five service area counties has suppressed use rates.

CCH anticipates a higher use rate with the establishment of both Baptist Hospital of Miami in Miami-Dade County's adult BMT program and the Cleveland Clinic Hospital's establishment of a program in Broward County, with ready access to Palm Beach County. The applicant contends that the geographic distance between Baptist Hospital of Miami and CCH in Weston, exceeds 32 miles which can be more than 90 minutes in traffic. CCH notes with significant outmigration to elsewhere in Florida and out of state, there is sufficient volume based on current use rates to ameliorate the access problem and implement a successful adult bone marrow program as proposed in CON application #10444.

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.

CCH states it has been awarded a host of program specific achievements that have earned national recognition, including but not limited to the following, as indications of its quality of care:

- "100 Top Hospitals" by Thomson Reuters (the applicant reports this organization as a leading provider of information and solutions to improve the cost and quality of health care;
- US News and World Report, 2015-2016, *Best Hospital Rankings* (Ranked #3 among 66 best hospitals in Miami metro area and #9 in Florida for gastroenterology and GI surgery)
- The Leapfrog Group (naming the applicant as a "top hospital")
- American Heart Association's "Get with the Guidelines" program, Gold Level (for heart failure and stroke).

The applicant states the Cleveland Clinic Florida Maroon Cancer Center has earned three-year approval with commendation from the Commission on Cancer (CoC) of the American College of Surgeons. CCH assures that patients have access to quality care which includes:

- Comprehensive care, including a range of state-of-the art services and equipment
- A multidisciplinary team approach to coordinate the best treatment options
- Information about ongoing clinical trials and new treatment options
- Access to cancer-related information, education and support

Agency complaint records indicate, during the three-year period ending June 7, 2016, Cleveland Clinic Hospital had two substantiated

complaints. A single complaint can encompass multiple complaint categories. One substantiated complaint was in the category “quality of care/treatment” and one substantiated complaint was in the category “emergency access”.

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

Analysis:

The purpose of our analysis for this section is to determine if the applicant has access to the funds necessary to fund this and all capital projects. Our review includes an analysis of the short and long-term position of the applicant, parent, or other related parties who will fund the project. The analysis of the short and long term position is intended to provide some level of objective assurance on the likelihood that funding will be available. The stronger the short term position, the more likely cash on hand or cash flows could be used to fund the project. The stronger the long-term position, the more likely that debt financing could be achieved if necessary to fund the project. We also calculate working capital (current assets less current liabilities) a measure of excess liquidity that could be used to fund capital projects.

Historically we have compared all applicant financial ratios regardless of type to bench marks established from financial ratios collected from Florida acute care hospitals. While not always a perfect match to a particular CON project it is a reasonable proxy for health care related entities. The below is an analysis of the audited financial statements of Hebrew Homes Health network (parent company) and where the two short term and long term measures fall on the scale (highlighted in gray) for the most recent year.

Cleveland Clinic Florida Health System					
	Jun-15		Jun-14		
Current Assets	\$95,924,000		\$122,269,000		
Total Assets	\$221,269,000		\$236,879,000		
Current Liabilities	\$27,038,000		\$26,430,000		
Total Liabilities	\$28,392,000		\$27,780,000		
Net Assets	\$192,877,000		\$209,099,000		
Total Revenues	\$277,807,000		\$276,911,000		
Excess of Revenues Over Expenses	\$53,778,000		\$80,422,000		
Cash Flow from Operations	\$63,524,000		\$54,585,000		
Short-Term Analysis					
Current Ratio (CA/CL)	3.5		4.6		
Cash Flow to Current Liabilities (CFO/CL)	234.94%		206.53%		
Long-Term Analysis					
Long-Term Debt to Net Assets (TL-CL/NA)	0.7%		0.6%		
Total Margin (ER/TR)	19.36%		29.04%		
Measure of Available Funding					
Working Capital	\$68,886,000		\$95,839,000		
Position	Strong	Good	Adequate	Moderately Weak	Weak
Current Ratio	above 3	3 - 2.3	2.3 - 1.7	1.7 – 1.0	< 1.0
Cash Flow to Current Liabilities	>150%	150%-100%	100% - 50%	50% - 0%	< 0%
Debt to Equity	0% - 10%	10%-35%	35%-65%	65%-95%	> 95% or < 0%
Total Margin	> 12%	12% - 8.5%	8.5% - 5.5%	5.5% - 0%	< 0%

Capital Requirements and Funding:

The applicant provided audited financial statements for the years 2014 and 2015. The audit indicates that the applicant has a strong financial position. The applicant indicates on Schedule 2 capital projects totaling \$245,445,750 which includes this project. The applicant also indicates on Schedule 3 of its application that the total funding for this project in the amount of \$2,445,750 will be provided by operating cash flows.

Staffing:

The table below shows CCH’s projected staffing in the year one (ending 2019) and year two (ending in 2020) for the proposed project. The applicant indicates that staffing is limited to the direct care staff of the BMT program as the support staff in other ancillary and overhead departments are already employed at the hospital and no other incremental positions are required. The table below illustrates the FTE’s to be added as a result of the proposed project if approved.

Cleveland Clinic Florida Health System Nonprofit Corporation, d/b/a Cleveland Clinic Hospital, CON application #10444 Adult Inpatient Autologous and Allogeneic Bone Marrow Transplant Program Staffing Patterns		
	Year One Ending 2019	Year One Ending 2020
NURSING		
R.N.s	8.00	9.00
L.P.N.s	1.00	1.00
Tech	1.00	1.00
Nurses Other	--	1.00
Clerical	--	1.00
Other: Agency Nurse, Director, Coordinator, Secretary, Educator	2.00	2.00
OPERATIONS		
Other: Directors, Secretary, Case Manager	1.00	1.00
TOTAL	13.00	16.00

Source: CON application #10444, Schedule 6A

Conclusion:

Funding for this project should be available to the applicant as needed.

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

Analysis:

A comparison of the applicant’s estimates to the control group values provides for an objective evaluation of financial feasibility, (the likelihood that the services can be provided under the parameters and conditions contained in schedules seven and eight) and efficiency (the degree of economies achievable through the management skills of the applicant). In general, projections that approximate the median are the most desirable and balance the opposing forces of feasibility and efficiency. In other words, as estimates approach the highest in the group, it is more likely that the project is feasible because fewer economies must be realized to achieve the desired outcome. Conversely, as estimates approach the lowest in the group, it is less likely that the project is feasible because a much higher level of economies must be realized to achieve the desired outcome. These relationships hold true for a constant intensity of service through the relevant range of outcomes. As these relationships go beyond the relevant range of outcomes, revenues and expenses may go either beyond what the market will tolerate or may decrease to levels where activities are no longer sustainable.

Because the proposed 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 similar acute care hospitals using case mix and geographic location. Per Diem rates are projected to increase by an average of 3.1 percent per year. Inflation adjustments were based on the new CMS Market Basket, 1st Quarter, 2016.

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

			COMPARATIVE GROUP VALUES		
	Total	PPD	PPD		
Net Revenues	440,888,873	6,553	7,239	3,270	2,619
Total Expenses	346,628,056	5,152	6,116	3,157	2,668
Operating Income	94,260,817	1,401	1,311	90	-509
Operating Margin	21.38%		Comparative Group Values		
	Days	Percent			
Occupancy	67,276	89.23%	81.70%	57.22%	39.72%
Medicaid/MDCD HMO	1,100	1.64%	66.40%	14.45%	1.63%
Medicare	30,797	45.78%	69.75%	54.21%	0.42%

The projected NRPD and CPD fall within the group range. Profitability exceeds the highest comparative group value by 6.86%.

Conclusion:

This project appears to be financially feasible based on the projections provided by the applicant. However, profitability appears marginally excessive.

- 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. Since Medicare and Medicaid are the primary payers in the hospital industry, price based competition is limited. With a large portion of the revenue stream essentially fixed on a per patient basis, the available margin to increase quality and offer additional services is limited. In addition, competitive forces truly do not

begin to take shape until existing business' market share is threatened. The existing health care system's barrier to price based competition via fixed price payers limits any significant gains in cost effectiveness and quality that would be generated from competition.

Conclusion:

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

- f. Are the proposed costs and methods of construction reasonable? Do they comply with statutory and rule requirements? ss. 408.035(1)(h), Florida Statutes and Ch. 59A-3, Florida Administrative Code.**

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

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

- g. Does the applicant have a history of and propose the provision of health services to Medicaid patients and the medically indigent? Does the applicant propose to provide health services to Medicaid patients and the medically indigent? ss. 408.035(1)(i), Florida Statutes.**

Below is a chart to account for the applicant's and the district's Medicaid/Medicaid HMO and charity care percentages for fiscal year (FY) 2015 provided by the Agency's Florida Hospital Uniform Reporting System (FHURS).

**Medicaid, Medicaid HMO and Charity Care for
Cleveland Clinic Hospital (CON application #10444)
Compared to the District for FY 2015**

Applicant	Medicaid and Medicaid HMO Days	Charity Percentage Service	Combined Medicaid and Charity Care
Cleveland Clinic Hospital	1.7%	0.36%	2.1%
District 10 Average	19.1%	1.87%	20.97%

Source: Fiscal Year 2015 Agency for Health Care Administration Actual Hospital Budget Data

CCH states it has a long history of providing health services to the medically indigent and notes in FY 2015 ending December 31, CCH provided \$3.9 million in charity care representing 14 percent of its net patient revenue. The applicant reports that during 2015, 3.1 percent of CCH’s 45,449 patient days were Self-Pay and charity care (with charity care being a subset of Self-Pay). CCH asserts it intends to continue to provide the same level of uncompensated care to the community as it has done in the past. The reviewer notes that according to FHURS, CCH’s charity care was 0.36 percent.

According to the applicant’s Schedule 7A, CCH intends to provide 1.6 percent of year one and year two adult bone marrow transplant program patient days to Medicaid and Medicaid HMO patients and 2.2 percent charity care for year one and year two of the proposed program annual total patient days. CCH does not propose to condition approval of the proposed project to provide adult inpatient bone marrow transplants to Medicaid or charity care patients.

The reviewer notes that although the applicant indicates charity care is a subset of Self-Pay, Schedule 7A and the Schedule 7A assumptions do not specifically allocate any patient days to charity care.

The reviewer notes that CCH does not participate in the Disproportionate Share Hospital (DHS) or the Low Income Pool Payment (LIP) programs.

F. SUMMARY

Cleveland Clinic Florida Health System Nonprofit Corporation d/b/a Cleveland Clinic Hospital (CON application #10444) proposes to establish a new adult bone marrow transplant program at Cleveland Clinic Hospital in Weston, Broward County, Florida, District 10, and OTSA 4.

Project costs total \$2,445,000. The project involves 6,860 GSF of new construction with total construction costs of \$1,635,000. Total project costs include building, equipment, project development and start-up costs.

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

Need/Access

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

Presently there are three operational adult inpatient bone marrow transplant programs in Service Area 4, Good Samaritan Medical Center in District 9, Memorial Hospital West in District 10 and University of Miami Hospital and Clinics in District 11. There is also one approved program at Baptist Hospital of Miami.

The applicant states that need for proposed project is based on a series of factors that are not normal circumstances related to geographic and programmatic access factors. Cleveland Clinic Hospital indicates the areas that serve as the foundation of need include the following:

- Outmigration of BMT patients from OTSA 4 to BMT programs in other areas of Florida
- Outmigration of BMT patients from OTSA 4 to BMT programs outside the state of Florida
- Dominance of outpatient BMT programs in South Florida, potentially limiting high acuity patients from receiving BMT transplants
- Low BMT utilization rate in OTSA 4
- Patients currently in treatment at Maroon Cancer Center who may be appropriate candidates for BMT transplants
- External support for the BMT Program including referrals by unrelated area cancer centers

CCH forecasts 16 procedures in year one, 25 in year two and 30 in year three.

The Agency finds that the applicant failed to demonstrate the applicable criteria specified in Section 408.035, F.S. and Rule 59C-1.044 F.A.C. The Agency has determined that within the context of the criteria, neither need for the project nor was the extent to which the proposed services will enhance access to health care for the residents of the services district established by the applicant in order to merit approval of the proposed project. In addition, the Agency did not find that the application provided information that their past and proposed provision of health care services to Medicaid patients and the medically indigent would increase financial accessibility to the 15+ inpatient BMT

population of OTSA 4. Further, the Agency notes that in the previous batching cycle it approved a new adult inpatient BMT program in OTSA 4 that has not yet become licensed and operational and therefore the extent of utilization of existing health care facilities cannot be judged until the program does become licensed and operational.

Quality of Care

The applicant demonstrated quality of care measures through numerous awards and recognitions. Policies and protocols to accommodate the proposed project were discussed as being in place or in development and were stated to be complete prior to initiation of service.

Agency complaint records indicate during the three-year period ending June 7, 2016, Cleveland Clinic Hospital had two substantiated complaints on in each of the following categories: quality of care/treatment and emergency access.

Cleveland Clinic Hospital demonstrated the ability to provide quality care.

Cost/Financial Analysis

- Funding for this project should be available to the applicant as needed.
- This project appears to be financially feasible based on the projections provided by the applicant. However, profitability appears marginally excessive.
- This project is not likely to have a material impact on competition to promote quality and cost effectiveness.

Medicaid/Charity Care Commitment

The Agency's FY 2015 FHURS data indicates Cleveland Clinic Hospital provided 1.7 percent of its total patient days to Medicaid/Medicaid HMO patients and 0.36 percent to charity care.

Cleveland Clinic Hospital projects 1.6 percent of year one and year two's adult bone transplantation patient days will be provided to Medicaid and Medicaid HMO patients (year two ends December 31, 2020). Charity care is not shown in the project's Schedule 7A or notes to this schedule.

Cleveland Clinic Hospital does not propose to condition project approval to serve Medicaid or charity care patients.

Architectural Analysis

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

G. RECOMMENDATION

Deny CON #10444

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