STATE AGENCY ACTION REPORT

ON 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 #10566
3100 Weston Road
Weston, Florida 33331

Authorized Representative: Patti Greenberg
Wael Barsoum, M.D.
(954) 689-5000

2. Service District/Subdistrict

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

B. PUBLIC HEARING

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

Letters of Support

Cleveland Clinic Florida Health System Nonprofit Corporation d/b/a Cleveland Clinic Hospital (CON application #10566) provides letters of support from area health providers, health-affiliated institutions and local businesses. Support for the proposal is provided in expectation of the capacity for the proposal to benefit service area residents, the availability of post-transplant follow-up care in neighboring areas, institutional relationships with the applicant, travel constrains that affect access to bone marrow transplant (BMT) services and the renowned reputation of Cleveland Clinic as a provider.

Letters of support are noted from the following individuals:

- Robert L. Lord, Jr., President and CEO, Martin Health System[1]

[1] Martin Health System and Cleveland Clinic signed a definitive agreement on October 2, 2018 resulting in Martin Health becoming a full member of the Cleveland Clinic Health System.

- Karen Davis, Interim President and CEO, Indian River Medical Center[2]
- Mayra Lopez-Cepero, Ph.D.D. (ABHI), Senior Vice President/Director, LifeLink Transplant Immunology Lab
- George Scholl, President and CEO, OneBlood, Inc.
- Denise Brockington, Area General Manager, Residence Inn Marriott

Letter of Opposition

Representatives of South Broward Hospital District d/b/a Memorial Hospital West (MHW) provided a letter of opposition to the Cleveland Clinic's application to establish a new BMT program in OTSA 4 (Broward County). MHW is an existing provider of adult inpatient BMT services within OTSA 4 that opposes approval of the proposed project for the following reasons:

- There is no evidence of a lack of access to adult BMT services in OTSA 4. Any assertion that the new program will address a problem with access to care (geographic or financial), quality of care or outmigration of BMT patients is erroneous.
- Existing providers are well-positioned to meet increased market demand for BMT services. Although there has been a substantial increase in the number of BMT cases in OTSA 4, more than sufficient capacity still exists at authorized providers to accommodate future growth. Even considering the growth of BMT services in OTSA 4, BMT programs are by nature low volume, with less than 1,000 cases generated by adult Florida residents (treated in Florida BMT centers) in 2017.
- An increasing use rate confirms patient ability to access high quality services in OTSA 4. The OTSA 4 and Broward County resident use rates of BMT per 100,000 population have experienced dramatic growth and have recently surpassed the State of Florida average. The use rate will be even higher when the newly operational program at Baptist Hospital of Miami's (BHM) utilization is taken into account.
- BHM's program in OTSA 4 just became operational in late 2018. Any unmet need for adult BMT services in OTSA 4 was remedied by BHM's project. BHM recently performed its first transplant and over time will increase the volume and use rate of BMTs in OTSA 4. The new program needs time to reach maturity before the need for additional programs can even be considered. The application for a BMT program at Cleveland Clinic Hospital (CCH) has been previously submitted and denied by the Agency based on a lack of need for an additional program in OTSA 4.

[2] Indian River Medical Center and the Indian River County Hospital District Trustees voted to approve a series of agreements on October 3, 2018, which will result in Indian River Medical Center becoming part of the Cleveland Clinic Health System.

- A new program at CCH will adversely impact the MHW adult BMT program. The impact on MHW's program, which is now beginning to mature, will particularly affect its ability to maintain and recruit experienced staff, maintain high quality/services to its patients and its ability to continue to ensure accreditation.

MHW provides a summary of Agency rule criteria and the definition of a tertiary service. Furthermore, MHW notes that as defined by statute, the number of BMT programs should be limited in order to ensure quality, availability and cost-effectiveness of care. Opposition states that CCH's proposed project cannot meet any of the required review criteria because there is no need for an additional adult BMT program in OTSA 4.

There is no evidence of a lack of access to adult BMT services in OTSA 4

MHW explains that adult BMT services are not emergent in nature since patients requiring BMT services are identified and scheduled for procedures weeks to months in advance. Opposition observes that in recent years, OTSA 4 program volume has increased while outmigration has decreased due in part to MHW's innovative clinical affiliation with Moffitt Cancer Center (MCC). MHW states that CCH's proximity to MHW (within eight miles) would not have any positive impact on geographic accessibility of BMT services in OTSA 4.

As it pertains to treating patients aged 15+ within the service area, MHW states that while patients between ages 15 – 21 are classified as adults by rule it is reasonable to expect that they will continue to be treated by their historical pediatric provider. MHW indicates that the ability of pediatric providers to treat "adult" patients means there is actual capacity available in OTSA 4 to provide these services above and beyond the three existing adult programs. From 2015 – 2017, MHW states that there was an average of 10 – 12 OTSA 4 patients aged 15 – 21 treated at pediatric programs in Florida.

MHW describes how, in some cases, BMT procedures can be performed on an outpatient basis, which does not require CON approval. Opposition states that over the past few years the utilization of outpatient BMT procedures has increased, which provides additional availability and capacity to OTSA 4 patients.

Opposition provides the following table summarizing the historical utilization of OTSA 4 adult BMT programs for the years ending June 30 2014 – 2018.

Historical Utilization of OTSA 4 Adult BMT Programs							
FY—ending June 30th							
Hospital Name	**2014**	**2015**	**2016**	**2017**	**2018**	**2014 - 2018 Raw Growth**	**2017 - 2018 Growth**
MHW	16	22	6	11	52	36	41
UM	141	133	201	173	236	95	63
BHM							
OTSA 4 Adult Programs Total	**157**	**155**	**207**	**184**	**288**	**131**	**104**

Source: MHW letter of opposition, page 4

MHW underscores the following points pertaining to the historical BMT volume:

- In just one year (July 1, 2017 – June 30, 2018) MHW's adult BMT volume increased by nearly 375 percent from 11 to 52 cases
- For the 2018 calendar, year-to-date internal data MHW shows that it performed 70 adult BMTs through the end of November, which annualizes out to a projected volume of 75 - 77 cases for 2018

Opposition also discusses administrative changes experienced at MHW after the approval of BHM's adult BMT program. MHW also comments on the increase in volume at University of Miami Hospital and Clinics (UMHC) within the same period.

There is no material geographic access benefit resulting from CCH's proposed project

Opposition discusses the elective non-emergent process of both autologous and allogeneic BMT procedures. MHW describes how patients must meet criteria based on prognostic features of the disease, their response to initial therapy and overall status of the disease in addition to other processes. Opposition notes how the time between the initial consultation and the BMT procedure can span between 2-4 months. A description of the donor matching process and human leukocyte antigen (HLA) typing is provided on pages five and six of the opposition letter. MHW states that a number of processes add time to the BMT procedure and are coordinated with the referring center prior to the procedure being performed.

Opposition states that CCH patients who need to be evaluated may obtain an appointment at MHW either the same or following week to be evaluated for a BMT. MHW determines that this minimal delay does not affect the BMT process, even in the case of acute leukemia where obtaining the patient's HLA typing is critical. In these cases, the opposition asserts that an appointment can be accomplished with a simple blood draw being sent to MHW. Opposition contends that no problems have been identified with CCH patients having timely access to MHW services.

A map of existing OTSA 4 adult BMT providers is included on pages six and seven of the letter of opposition, along with drive times. When examining the location of providers by population density, opposition finds that existing OTSA 4 providers are within heavily populated areas and have available capacity—easily accessible to the majority of residents of the OTSA. MHW states that the proposal will not increase geographic accessibility to services for residents of the area and notes the proximity of Cleveland Clinic to other providers in minutes and miles:

- 8.2 miles or 16 driving minutes from MHW
- 31.2 miles or 38 driving minutes from UMHC
- 34 miles or 40 driving minutes from BHM

OTSA 4 has more resources for adult BMT than the rest of Florida

MHW provides an analysis of the distribution of BMT providers by OTSA and population size—noting that by number and distribution of programs by population per million, OTSA 4 has the highest ratio of operational adult BMT programs per adult population of any OTSA and is higher than the overall state average. See the table below:

Ratio of Florida Adult BMT Programs to Population by OTSA			
OTSA	**Adult BMT Programs**	**15+ 2019 Population**	**Programs per million population**
1	2	3,865,992	0.52
2	1	4,773,251	0.21
3	1	3,687,417	0.27
4	3	5,624,891	0.53
Statewide	**7**	**17,951,551**	**0.39**

Source: MHW letter of opposition, page 9

Outmigration is not an issue in OTSA 4

Opposition describes the outmigration patterns in OTSA 4 and notes that in recent years, outmigration has decreased in Broward County and OTSA 4. From 2013 to 2017, MHW finds that OTSA 4 outmigration has decreased significantly from 43.6 percent in 2013 to just 16.1 percent in 2017. Within the same time period, outmigration among Broward County residents decreased from 45.3 percent in 2013 to just 7.1 percent in 2017 and outmigration in Palm Beach County decreased from 66.7 percent in 2013 to 31.7 percent in 2017.

MHW states that MCC in Tampa has long been a statewide destination for cancer treatment given its wide breadth of specialists, access to research and cutting-edge treatments. Opposition notes that the majority of outmigration from OTSA 4 resulted in care at MCC, see the following table:

OTSA 4 Adult Resident Outmigration to MCC for Bone Marrow Transplant					
	2013	**2014**	**2015**	**2016**	**2017**
Total OTSA 4 Resident Adult BMT Cases	163	152	180	225	280
Total OTSA 4 Resident Adult BMT Outmigration Cases	71	64	52	64	45
Percent	**43.6%**	**42.1%**	**28.9%**	**28.4%**	**16.1%**
OTSA 4 Resident Adult BMT Outmigration to Moffitt	67	62	51	62	43
Percent of OTSA 4 Outmigration to Moffitt	**94.4%**	**96.9%**	**98.1%**	**96.9%**	**95.6%**

Source: MHW, letter of opposition, page 11

Opposition contextualizes the outmigration analysis from Broward County residents, demonstrating that the vast majority of Broward County outmigration cases resulted in outmigration to MCC. From these analyses, MHW concludes that it is evident that in the past Broward County residents relied upon MCC for care when they chose to leave for a BMT, not for lack of resources in the local area, but as a result of patient choice in seeking care at the pre-eminent provider of cancer care in Florida. Opposition maintains that MCC provides cutting edge treatments that are only available at select cancer centers around the county and due to a number of factors some patients may continue to leave the area to seek these services, a pattern that will not change with the approval of the CCH proposal.

MHW comments on the operational relationship between MHW and MCC established on July 1, 2017. Opposition advances that since the operational relationship began, Broward County outmigration has sharply declined and county-wide utilization has increased significantly. MHW contends that its clinical affiliation with MCC has increased access to world-class BMT care for Broward County and OTSA 4 residents in their service area. Opposition asserts that outmigration will continue to markedly decline as BHM's newly operational program matures and its volumes increase.

There is no financial access benefit to the development of an adult BMT program at CCH

MHW states that the South Broward Hospital District/Memorial Healthcare System has a strong commitment to its charitable mission. Opposition states that MHW is "much more" financially accessible than CCH. Based on data reported on the Florida Hospital Uniform Reporting System (FHURS) fiscal years (FY) 2016 and 2017, MHW observes that it outperformed CCH in the provision of bad debt, charity care and service to Medicaid patients. Opposition provided the following chart to illustrate FHURS data between the two hospital systems.

FY 2016 and 2017 Financial Accessibility Comparison		
Charity Care		
Hospital Name	**FY 2016**	**FY 2017**
MHW	$ 52,796,175	$ 56,017,045
Cleveland Clinic	$ 4,793,000	$ 8,479,000
Bad Debt		
MHW	$ 91,553,316	$ 109,304,164
Cleveland Clinic	$ 16,210,000	$ 10,634,000
Medicaid/Medicaid HMO Percent of Total Patient Days		
MHW	14.8%	15.0%
Cleveland Clinic	1.8%	2.3%
Commercial Percent of Total Patient Days		
MHW	29.2%	29.2%
Cleveland Clinic	40.6%	38.4%

Source: MHW letter of opposition, pages 12-13

From the financial analysis provided, MHW provides the following arguments:

- In 2017, MHW provided nearly $50 million more in charity care (seven times the amount provided by CCH) and significantly more of its patient days were covered by Medicaid
- Cleveland Clinic's commercial payor mix of patient days is higher than MHW's meaning that the hospital draws a more favorable overall payor mix than MHW

Opposition maintains that the BMT-specific payer mix information shows MHW provides a very substantial amount of BMT care to the Medicaid population and within the last few years, 18.0 percent of BMT program revenue has been for the Medicaid/Medicaid HMO population. Opposition determines financial access is being provided to all patients, including Medicaid recipients, who traditionally experience more access problems than other groups. MHW contends that it is unlikely that the proposed CCH program would enhance financial access in OTSA 4 as the quantitative analysis provided does not show evidence of an unserved population in need or a lack of accessible BMT resources.

Existing providers are well-positioned to meet increased market demand for BMT services

MHW states that statewide adult BMT cases show modest increases between the years ending June 30, 2014 and 2018, or approximately 20 percent total case growth during the period. The opposition states that MHW and OTSA 4 show the highest percentage growth of adult BMT volumes in the state during the five-year period (MHW volume increased by 225 percent and OTSA 4 provided volume nearly doubled—with all incremental growth absorbed by the existing providers, as BHM was not operational until October 2018). A consolidated reference to the table summarizing this growth is provided below:

Florida Adult BMT Volumes and Growth by Provider and OTSA						
Area	**2014**	**2015**	**2016**	**2017**	**2018**	**2014 - 2018 Growth**
OTSA 1	182	236	238	218	249	36.8%
OTSA 2	421	453	437	427	444	5.5%
OTSA 3	141	148	138	113	98	-30.5%
OTSA 4 Providers Total	**157**	**155**	**207**	**184**	**288**	**83.4%**

Source: MHW letter of opposition, page 13

In analysis of the adult BMT cases generated by OTSA 4, MHW notes that the adult population in OTSA 4 also has the largest and fastest growing market of adult resident inpatient BMT cases of any planning area in the state compared to 2013 when its population generated the smallest number of cases in the state. The table below summarizes the analysis:

Adult BMT Cases and Growth Generated by 15+ Population by OTSA						
Resident OTSA	**2013**	**2014**	**2015**	**2016**	**2017**	**2013 - 2017**
OTSA 1	164	160	218	173	182	11.0%
OTSA 2	201	193	205	217	230	14.4%
OTSA 3	238	206	211	227	197	-17.2%
OTSA 4	**163**	**152**	**180**	**225**	**280**	**71.8%**
Statewide Resident BMT Cases	766	711	814	842	889	16.1%

Source: MHW letter of opposition, page 14

MHW determines that while an increasing "market" of cases and increasing provider utilization could be interpreted as a rationale for increased need for services in a particular area, this is not applicable within the service area or for BMT services. Opposition advances that BMT is not a service that has a standard capacity per program or room.

MHW states that while volume is increasing, the two providers in OTSA 4 that have historical utilization show that there is significant available capacity as compared to other providers in the state. MHW references the volume of cases it experienced for the twelve months ended June 30, 2018 in comparison to UMHC which performed 236 cases during the same period. Opposition notes that BHM recently became operational in October 2018 and has not reported utilization data to AHCA yet. In addition, regarding the availability of children's programs and outpatient procedures, MHW determines that there is significant additional capacity within the existing continuum of adult BMT providers in OTSA 4 and that OTSA 4 providers can more than sufficiently accommodate current and future levels of demand for BMT services.

An increasing use rate confirms patient ability to access high quality services in OTSA 4

MHW provides a summary of the 15+ adult population within OTSA 4 and notes that it consists of the largest population base and performs the

largest number of adult BMT programs within the state. Opposition forecasts that by 2024, residents 15+ within OTSA 4 will account for nearly one-third of the statewide adult population. MHW notes that population growth within OTSA 4 is slightly lower than the statewide average at 7.0 percent in comparison to 7.3 percent statewide. In analysis of the elderly population within OTSA 4, MHW observes that the elderly population within OTSA 4 will increase to more than a quarter of OTSA 4's total 15+ population.

In reference to arguments made in a previous BMT CON application submitted by CCH[3], MHW states that CCH alleges that lower use rates per 100,000 population indicate a lack of access to BMT services in OTSA 4. Opposition contends that inpatient BMT use rates within OTSA 4 and Broward County have increased significantly in recent years and surpassed the statewide average in 2017. A summary of adult inpatient BMT use rate trends is provided below:

15+ BMT Use Rate Per 100,000					
Area	**2013**	**2014**	**2015**	**2016**	**2017**
OTSA 4	3.22	2.97	3.48	4.31	5.30
Florida	4.8	4.4	4.96	5.06	5.26

Source: MHW letter of opposition, page 16

MHW interprets the most recent increase in OTSA 4 BMT use rates relative to the statewide average to mean that residents of the area are accessing care at a slightly greater rate than the rest of Florida residents. In consideration of declining outmigration of OTSA 4 residents alongside increased use rates, opposition determines that residents are accessing BMT services closer to home at greater rates than historically observed. In continuation of this analysis, MHW also trends the adult resident use rate of BMT services in Broward County, which again shows that the 15+ BMT use rate within Broward County per 100,000 (6.58) exceeded the statewide average in 2017 (5.26). Opposition concludes that Broward County residents have more than ample access to adult BMT services in the OTSA. MHW notes that these use rates do not consider the volume at the newly operational program at BHM.

Opposition determines that existing use rates reveal that residents of OTSA 4 and Broward County have better access to care than other parts of the state and that there is no need for an additional adult BMT program in South Florida.

[3] CON application #10444 was submitted during the first "Other Beds and Programs Batch" of 2016 by Cleveland Clinic Hospital to establish a new adult bone marrow transplantation program. The application was denied by the Agency.

Baptist Hospital of Miami's Program in OTSA 4 just became operational in late 2018

MHW discusses BHM's institutional affiliation with Memorial Sloan Kettering's Cancer Alliance, which carries over into the BMT program.

Opposition notes that the program at BHM recently became operational and there is no utilization volume currently available. MHW states that until additional information is generated from the Baptist BMT program, the impact of the Agency's approval on the extent of utilization of existing adult BMT programs in OTSA 4 cannot be fully evaluated. Opposition determines that if BHM's proposal was intended to remedy any purported unmet need that could have existed in the area, the appropriate health planning approach would be to allow the BHM program to be established before any additional programs are approved.

MHW asserts that even prior to BHM's program becoming operational, declining outmigration within the region and increasing resident use rates reveal that any potential barrier to accessing services was remedied partially due to MHW's clinical affiliation with MCC. Opposition asserts that assuming that BHM reaches its projected year three volume of 30 cases (all of which will originate from OTSA 4) and assuming existing cases remain flat, then the use rate for OTSA 4 residents will increase from 5.30 per 100,000 in 2017 to 5.62 per 100,000 in 2021—higher than the current OTSA 4 use rate and higher than the current statewide use rate.

Opposition states that given market conditions in OTSA 4 have improved in the past two years, the notion that there is an unserved market of patients who need but cannot easily access BMT services is false and unsupported by quantitative data.

MHW contends that given the early stages of the BHM program, it is too soon to consider the addition of another adult BMT program in OTSA 4. Opposition argues that the addition of an additional program would be in direct contradiction to 408.032(17), Florida Statutes, especially given that the area already has a higher program to population ratio in comparison to other OTSAs within the state.

A New Program at CCH will adversely impact the BMT program at MHW

MHW provides a historical summary of its operations and its intent to help meet the diverse needs of the community to ensure continued financial viability by generating a payer mix necessary to further the South Broward Hospital District's charitable mission to residents. Opposition provides a narrative description of its existing service offerings, facilities, and institutional affiliations with MCC which serves to provide blood and marrow transplant and malignant hematology

services in addition to molecular diagnostics, personalized medicine and hematopathology. Opposition attributes a decline in outmigration within the service area to this institutional affiliation.

MHW notes that its BMT program is accredited for autologous and allogeneic transplantation by the Foundation for the Accreditation of Cellular Therapy and its Memorial Cancer Institute is accredited with commendation by the American College of Surgeons and participates in a number of research studies. MHW notes that these accreditations require the program to maintain certain levels of participation in research and analytical studies related to cancer and bone marrow disorders. Opposition states that approval of an additional BMT provider in OTSA 4 is unwarranted and existing providers have more than sufficient capacity and expertise to meet the needs of residents of south Florida.

Opposition maintains that approval of an additional provider would result in an unquantifiable loss of cases at MHW, staffing decline and loss of accreditations that require volume thresholds. MHW states that the fixed costs of operating the BMT program at MHW or any other provider are higher because of the clinical staffing and specialized resources required which will not be reduced if MHW loses patient volume as a result of the implementation of the proposed CCH program. Opposition asserts that loss of patient volume as a result of CCH's close proximity to MHW is anticipated. Narratives detailing the specific anticipated mechanisms of these adverse consequences are detailed on pages 23 – 24 of the opposition letter.

In summary, MHW concludes that there are no quantitative or qualitative factors currently supporting need for an additional program in OTSA 4. Opposition summarized the following points for which denial of the application is merited:

- Outmigration from OTSA 4 to other areas of Florida and out of state has decreased
- The adult BMT use rate for OTSA 4 and Broward County residents has increased in recent years and now surpasses the state average
- CCH does not provide the level of overall financial accessibility that MHW provides
- BHM's adult BMT program has been operational for less than two months, thus the extent of utilization of existing healthcare facilities cannot fully be evaluated at this time

C. PROJECT SUMMARY

Cleveland Clinic Florida Health System Nonprofit Corporation d/b/a Cleveland Clinic Hospital is a Florida, not-for-profit corporation that

proposes to establish a new adult inpatient autologous and allogeneic BMT program at CCH in Broward County, Florida (OTSA 4).

CCH is a 206-bed acute care hospital located in Broward County. It is a designated statutory teaching hospital with three adult transplant programs: heart, kidney and liver. It is a Comprehensive Stroke Center and is a Level II provider of adult cardiovascular services.

The applicant states that CCH is seeking CON approval to establish an adult BMT program in order to provide high-quality specialized patient care in a setting of education and research which will ultimately enhance access to BMT services for many patients and residents in and around South Florida.

The cost subject to fee for the proposal is $1,115,692, which includes equipment, project development and start-up costs. The applicant's Schedule 10 forecasts initiation of service in January 2020.

The following Schedule C conditions are included with the proposal:

- The adult bone marrow transplant program will be located on the Cleveland Clinic campus at 3100 Weston Road/Cleveland Clinic Boulevard Weston, Florida 33331.
- 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 physician that will serve as the initial Medical Director has already been designated and is active on staff.
- The applicant will seek FACT accreditation during year two of operation (or sooner) with the intent of becoming FACT Accredited during year three of operation of the BMT program.
- The applicant will develop an apheresis facility on its hospital campus.
- The applicant will develop its cell processing laboratory on its hospital campus.
- The applicant will establish outpatient access points in Palm Beach, Martin, St. Lucie and Indian River Counties to allow for BMT patient follow-up in their home counties. These outpatient sites will be established by the second year of operation of the BMT program.

Should the proposed project be approved, the applicant's conditions would be reported in the annual condition compliance report, as required by Rule 59C-1.013(3), Florida Administrative Code. Section 408.043 (4) Florida Statutes states that "Accreditation by any private organization may not be a requirement for the issuance or maintenance of a certificate of need under ss. 408.031-408.045. Florida Statutes." The Agency will not impose conditions on already mandated reporting requirements.

Issuance of a CON is required prior to licensure of certain health care facilities and services. The review of a CON application and ultimate approval or denial of a proposed project is based upon the applicable statutory criteria in the Health Facility and Services Development Act (408.031-408.045, Florida Statutes) and applicable rule criteria within Chapters 59C-1 and 59C-2, Florida Administrative Code. An approved CON does not guarantee licensure of the proposed project. Meeting the applicable licensure requirements and licensure of the proposed project is the sole responsibility of the applicant.

D. REVIEW PROCEDURE

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

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

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

As part of the fact-finding, the consultant, Bianca Eugene, analyzed the application with consultation from Financial Analyst Eric West, of the Bureau of Central Services, who evaluated the financial data, and Scott Waltz of the Office of Plans and Construction, who reviewed the application for conformance with the architectural criteria.

E. CONFORMITY OF PROJECT WITH REVIEW CRITERIA

The following indicate the level of conformity of the proposed project with the criteria and application content requirements found in Florida Statutes, sections 408.035, and 408.037; applicable rules of the State of Florida, Chapter 59C-1 and 59C-2, Florida Administrative Code.

1. Fixed Need Pool

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

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

There are currently three operational adult inpatient BMT programs in OTSA 4 and no CON approved adult inpatient bone marrow transplantation programs pending licensure in Service Area 4. The operational programs are at MHW (Broward County), UMHC (Miami-Dade County) and BHM (Miami-Dade County). Below is a chart to account for adult inpatient BMTs for the five-year period ending on June 30, 2018.

Adult Inpatient Bone Marrow Transplantation Procedures: July 1, 2013 through June 30, 2018

Facility	OTSA	7/13 – 6/14	7/14 - 6/15	7/15 - 6/16	7/16 - 6/17	7/17 - 6/18	Total
UF Health Shands	1	93	149	143	118	150	653
Mayo Clinic	1	89	87	95	100	99	470
H. Lee Moffitt Cancer Center	2	421	453	437	427	444	2,182
Florida Hospital	3	141	148	138	113	98	638
Good Samaritan Medical Center**	4	0	148	41	25		214
Memorial Hospital West	4	16	22	6	11	52	107
Jackson Memorial Hospital*	4	0	0				0
UM Hospital & Clinics	4	141	133	201	173	236	884
Total		901	1,140	1,061	967	1,079	5,148

Source: *Agency for Health Care Administration Utilization Data for Adult Organ Transplantation Programs*, January 2017 Planning Horizon – January 2021 Planning Horizon
* Jackson Memorial Hospital terminated its program effective 9/27/2013
** Good Samaritan informed the Agency that its program had not performed any inpatient or outpatient BMT procedures since before CY 2016 on June 16, 2017 and that it had been reporting incorrectly since the fourth quarter of CY 2014.

The following is a chart depicting the number of BMT discharges among OTSA 4 Residents aged 15+ for the 12 months ending June 30, 2018:

OTSA 4 15+ Inpatient Transplant Data July 2017 - June 2018		
Facility Name	**Total Discharges**	**Percent**
FLORIDA HOSPITAL	1	0.3%
H LEE MOFFITT CANCER CENTER & RESEARCH INSTITUTE HOSPITAL	34	10.7%
JACKSON MEMORIAL HOSPITAL	6	1.9%
JFK MEDICAL CENTER	1	0.3%
MAYO CLINIC	1	0.3%
MEMORIAL HOSPITAL WEST	53	16.7%
NICKLAUS CHILDREN'S HOSPITAL	5	1.6%
UNIVERSITY OF MIAMI HOSPITAL	2	0.6%
UNIVERSITY OF MIAMI HOSPITAL AND CLINICS	215	67.6%
Total	**318**	**100.0%**

Source: Florida Center for Health Information and Transparency Database, July 2017 – June 2018. MS-DRGs 14, 16, and 17

The next chart summarizes the adult discharges among OTSA 4 providers serving OTSA 4 residents only:

OTSA 4 15+ Inpatient Transplant Data July 2017 - June 2018		
Facility Name	**Total Discharges**	**Percent**
Jackson Memorial Hospital	6	2.1%
Memorial Hospital West	53	18.9%
Nicklaus Children's Hospital	5	1.8%
University of Miami Hospital	2	0.7%
University of Miami Hospital and Clinics	215	76.5%
Total	**281**	**100.0%**

Source: Florida Center for Health Information and Transparency Database, July 2017 – June 2018. MS-DRGs 14, 16, and 17

Based on the data provided, 88.36 percent of OTSA 4 patients remained within the service area for care and 11.64 percent of patients outmigrated for care.

CCH notes that there is no need published for organ transplant programs. The applicant describes conducting its own needs assessment based on the availability and accessibility of adult BMT programming in the region. The applicant observes that there were currently two operators in the defined OTSA and one approved program.[4] CCH states that because of the nature of BMT, BHM's BMT program and the proposed BMT service will not affect each other. The reviewer notes that the applicant does not provide an explanation or demonstrate why the proposed program will not affect the newly operational program at BHM. The applicant contends that the only program in Broward County, at

[4] The adult BMT program at BHM performed its first inpatient autologous BMT procedure on October 24, 2018.

MHW, has been struggling for years and its most recent volume has trailed (53 cases[5]) in the 12 months ending June 30, 2018. CCH notes that the adult BMT program at Good Samaritan Medical Center closed during CY 2017 and performed between 42 and 99 outpatient cases in each of the last three years it operated. The reviewer notes that according to condition compliance reports for CON #7874 (Good Samaritan Hospital's Adult Autologous BMT program), the facility had no inpatient or outpatient activity for CYs 2016 and 2017 while CY 2015 had 111 outpatient visits (not cases) and CY 2014 had 114 outpatient visits.

Service Area

Using Environics/Claritas data CCH provides a population summary of the service area: Broward, Collier, Miami-Dade, Monroe and Palm Beach Counties from 2018 – 2022 and notes the following trends:

- The five-county service area is home to 5.5 million adult residents age 15+
- By 2022, (the third year of the proposal's operations) the service area population will increase by 5.6 percent to nearly 5.9 million adult residents
- Broward and Miami-Dade County represent the two most populated counties in the OTSA—nearly 29.0 percent of the anticipated population growth will be within Broward County and 40 percent will be within Miami-Dade County
- Though Broward and Miami-Dade account for nearly 71 percent of the area's adult population, Collier County's growth rate is the largest in the service area (6.8 percent) with Palm Beach County's population growth rate at 5.7 percent

CCH describes the population density of Broward and Miami-Dade counties and observes that OTSA 4 is the most densely populated region of the state. The applicant notes that Broward County has the second greatest population density within the state while Miami-Dade has the third greatest population density in the state.

The applicant provides a summary of population estimates of OTSA 3, for which CCH states there are no accessible BMT programs. The reviewer notes that the applicant is proposing to establish an adult BMT program in OTSA 4 to serve the residents of OTSA 4 and which requires an examination of the services available to residents of OTSA 4 to make a determination of need for a new program within OTSA 4. CCH states that it is anticipating adding four hospitals to the Florida system and over 30 ambulatory sites within these three counties. In particular, the applicant describes having a comprehensive strategy for providing BMTs

[5] The reviewer notes that MHW increased procedures 472 percent from FY 16/17 to FY 17/18 (from 11 to 52) and is the fastest growing BMT program in the state.

and all necessary follow-up treatments within OTSA 3 counties. The reviewer notes that the applicant is trying to demonstrate an institutional need not a population-based or accessibility-based need for a new adult BMT provider within OTSA 4. CCH outlines the following demographic trend of OTSA 3:

- South OTSA 3 counties (Indian River, Martin and St. Lucie) have 535,000 adult residents and more than 32,000 additional adults are expected within the next few years—an overall 6.0 percent growth rate

Based on the existing array of BMT providers, the applicant identifies a void in BMT services for northern OTSA 4 and southern OTSA 3 residents who are not within an hour of a transplant program for follow-up treatment. Cleveland Clinic expects to fill this void by providing required outpatient follow-up treatments for BMT patients at its newly acquired hospital-based cancer centers. The reviewer notes that there is no CON approval required to set up or maintain outpatient BMT clinics or treatments. Nothing at present prevents CCH from implementing outpatient services and clinics at their newly acquired hospital-based cancer centers.

Historical Utilization

CCH summarizes the volume of BMT transplants performed by existing providers from July 1, 2017 – June 30, 2018 (1,079) and observes that OTSA 4 providers accounted for 288 of 1,079 of the volume of transplants performed. The applicant provides a chart summarizing the change in transplant volume by provider; overall the chart reveals that the total volume of transplants has increased by 1.7 percent across all providers and 16.1 percent within OTSA 4. The reviewer did not reproduce the table due to discrepancies in the reported time periods included in the applicant's analysis (CON application 10566, Page 44).

CCH describes the following trends across providers:

- Good Samaritan Hospital terminated its BMT program[6] during 2017 but MHW grew by a similar amount
- MHW has the lowest volume program in the state[7]
- Florida Hospital Orlando transplanted 29 percent fewer patients during the most recent 12 months than it did in FY 15/16 and 16/17

The applicant provides an analysis of the resident use rate of BMT services which is reproduced below:

[6] According to Agency records, Good Samaritan Hospital has not performed any inpatient adult BMTs (those regulated by CON) since before CY 2014.
[7] The reviewer notes that MHW is the fastest growing BMT program in the state.

15+ Resident Use Rates by OTSA 12 Months Ending March 31, 2018			
OTSA	**Inpatient BMT Cases**	**Population Age 15+**	**Use Rate/100,000**
OTSA 1	192	3,816,112	5.03
OTSA 2	230	4,673,260	4.92
OTSA 3	193	3,605,270	5.35
OTSA 4	304	5,536,634	5.49
Florida	**919**	**17,631,276**	**5.21**

Source: CON application #10566, page 45

From the analysis provided, the applicant determines that on an inpatient basis there is not a significant disparity amongst adult BMT use rates by OTSA. The applicant does contend that there is significant outmigration, therefore the use rate of OTSA 4 is the result of this phenomenon, not access within the service area[8] The reviewer notes based on Agency data, there is not significant outmigration for adult BMT services from OTSA 4—only 11.36 percent for FY 17/18. CCH states that there are significant disparities at the county level which will be addressed with the approval of the proposal. The applicant notes that the above data does not include outpatient procedures, which are not performed in OTSA 4. The reviewer notes that this statement by the applicant is incorrect as BHM has been performing outpatient BMT services since April 18, 2018.

The applicant details six "not normal" circumstances for which approval of the proposal is merited:

- BMT should be deregulated from CON as it no longer falls within the "tertiary health services" definition
- Excessive outmigration of BMT patients from OTSA 4
- Northern OTSA 4 and contiguous areas in southern OTSA 3 do not have reasonably accessible or programmatically accessible BMT programs resulting in lower use rates
- South OTSA 3 counties are not geographically accessible to any BMT program and therefore there is 100.0 percent outmigration for transplant and post-transplant treatment
- Incidence and prevalence of diseases requiring adult BMT and internal demand
- Internal demand for BMT based on new cases diagnoses at CCH

BMT should be deregulated from CON as it no longer falls within the "tertiary health services" definition

In explanation of this not normal circumstance, CCH states that Cleveland Clinic Maroone Center is nationally recognized for providing

[8] The reviewer notes that if you calculate the use rate utilizing the applicant's number of procedures (288), the use rate for OTSA 4 is 5.20, on par with the state average and second only to OTSA 3 which the applicant claims does not have reasonable access to adult BMT services.

world class care to patients with cancer, at the forefront of new and emerging cancer research and is not approved to perform adult BMTs. The applicant states that these services are an essential component of cancer treatment and the inability to deliver these services in Florida results in fragmented care for patients. CCH states that as a teaching hospital, the inability to provide BMT services limits CCH's ability to educate the next generation of physicians in cancer treatment and innovate better ways to provide cancer care.

CCH maintains that the ability to provide BMT services to international patients would be an important economic opportunity for Florida and would increase the continuity of cancer care provided by CCH. The reviewer notes that there is nothing in place at present to limit international patients from accessing BMT services from any of the other three adult BMT providers in OTSA 4.

The applicant asserts that the current tertiary health services definition should exclude BMT services. Descriptions of bone marrow, the purpose of bone marrow transplantation and illnesses treated with BMT are outlined in length on pages 47 – 48.

The reviewer notes that the statutory definition of a tertiary health services, pursuant to 408.032 (17), F.S., is "a health service which, due to its high level of intensity, complexity, specialized or limited applicability, and cost, should be limited to, and concentrated in, a limited number of hospitals to ensure the quality, availability, and cost-effectiveness of such service". The Agency notes that according the applicant's data points in the chart on page 45 of CON application #10566, there were 919 total inpatient BMT procedures for a population of 17,631,276. According to the applicant's Schedule 1, the equipment cost for the proposed project is $950,692 and the proposed staffing for year three of the program is estimated to be 13.00 FTEs with total operating expenses of $3,668,370 for 922 total patient days. According to FloridaHealthFinder.gov, compare site for the category of cancer and the condition/procedure of BMT for all adults 18+ from April 2017 to March 2018, there were 955 hospitalizations in the state with an average length of stay (ALOS) for an inpatient BMT of 21.7 with the charges ranging from $229,762 to $523,197 per procedure on average.

CCH observes that the volume of autologous and allogeneic bone marrow transplants performed in the United States has increased substantially

over the past 30 years and cites nearly 26,000 BMTs performed in the U.S. in 2016[9]. In comparison the applicant observes 1,079 transplants performed in Florida from July 2017 – June 2018 (CON application #10566).

Of note, the applicant comments on the widespread performance of peripheral blood stem cell transplantation since its introduction in 1986. The applicant states that peripheral blood stem cells have replaced bone marrow as a stem-cell source by approximately 100.0 percent in autologous transplants and 75.0 percent in allogeneic transplants, a table summarizing the volume of transplants by cell source for adult recipients from "Be The Match" is provided by the applicant to demonstrate the change in this procedural trend since 1990 (CON application #10566, Page 50).

CCH states that currently, less than 5.0 percent of the total number of BMTs involve the extraction of blood stem cells by aspiration. As a result of significant advancements in the BMT process and substantial growth in the number of BMTs performed on an annual basis, CCH concludes that these changes merit the removal of BMT services from definition of "tertiary health services" due to the health service no longer being an intense, complex, specialized or costly service that warrants the tertiary health service classification.

Cleveland Clinic asserts that the removal of BMT services from the "tertiary health services" definition would also prompt removal of the service from the Organ Transplantation Rule, 59C-1.044, Florida Administrative Code. According to the applicant BMT is not a transplant of an organ. The applicant maintains that while the transplant involves the infusion of extracted stem cells performed on an inpatient basis, this is largely due to the need to isolate the patient to avoid infections or other vulnerabilities and allow for continuous monitoring. CCH states that BMT is not a surgical process, not performed in an operating room, but rather occurs in the patient's room or bedside. The reviewer notes that other CON-regulated programs classified as tertiary services, such as CMR, are not surgical processes.

Excessive outmigration of BMT patients from OTSA 4

CCH states that for each of the past three years, between 13 and 35 percent of OTSA 4 residents annually outmigrated for BMTs within the State of Florida. A table provided on page 53 of the application reveals that outmigration within the service area decreased from 35.2 percent in the 12 months ending March 31, 2016 to 12.8 percent in the 12 months ending March 31, 2018. Overall, the applicant states that outmigration

[9] The reviewer notes that this averages to 520 BMTs per state, not including Washington D.C. and Puerto Rico.

varies across each county and that CCH will be the closest and most accessible provider to residents of Collier and Palm Beach Counties (with MHW approximately eight miles from CCH) which the applicant states experienced 100.0 percent outmigration. The reviewer notes that if measuring on a county basis, 62 out of 67 counties in Florida have 100 percent outmigration for inpatient adult BMT procedures.

The applicant indicates that the analysis provided reflects an overall outmigration decrease in the past three years from 35 to 13 percent, which CCH largely attributes to Broward and Miami-Dade Counties. CCH maintains that Palm-Beach and Collier Counties still experience significant out-migration as a result of nearly 30 persons "out-migrating" elsewhere in Florida for BMT services. In total, the applicant finds that there were 304 total BMTs from OTSA 4 residents during the 12 months ending March 31, 2018. The applicant additionally itemizes the percentage of outmigration by county for the 304 BMT patients for the 12 months ending March 31, 2018—noting that all Collier County residents outmigrated from OTSA 4 and that 23 percent of Palm Beach County residents outmigrated for a total of 28 residents from these counties that outmigrated (CON application #10566, Page 54).

The applicant observes that the inpatient database does not account for patients who left the state of Florida to receive a transplant. Using MedPar data to evaluate the number of the number of patients receiving care within and outside of the State of Florida for the 12 months ending March 31, 2018, CCH finds that 50 of the 304 BMT patients found in the previous analysis were Medicare Fee For Service (FFS) Payers and only 25 of those cases were treated at OTSA 4 BMT programs. Of the 25 Medicare FFS OTSA 4 cases identified, eight cases went to hospitals within Florida but outside of OTSA 4 and 17 left Florida, a summary of these cases by county is provided on page 55 of the application.

Based on this analysis of BMTs and outmigration of OTSA 4 residents to other programs in Florida and outside of the state, the applicant estimates that if twice as many patients of all payers left Florida "as left" for other programs in Florida, this would increase out-migration by 78 additional BMT cases during the 12 months ending March 31, 2018. The reviewer notes that the applicant does not provide any data points to support the supposition above. This applicant's ultimate outmigration analyses are reproduced below:

OTSA 4 Outmigration	
Transplant Location	**BMT Cases**
Licensed BMT in OTSA 4	265
Outside OTSA 4, in Florida	**39**
Total within Florida	304
Medicare FFS Out of State	**17**
All Other Payors out of State	Unknown
Total without Other Payers out of State	321
Outmigration including Medicare FFS Out of State	56
Outmigration including Medicare FFS Out of State (%)	**17.4%**

Source: CON application #10566, page 56

OTSA 4 BMT Transplants Total Outmigration, All Payors 12 Months Ending March 31, 2018		
	All Payors	**Percent of Total**
Outside OTSA 4 Within Florida	39	10.2%
Outside Florida (Factor of 2)	78	20.4%
Total Outmigration	117	30.6%
Cases in OTSA 4	265	69.4%
Total BMT Cases	382	100.0%

Source: CON application #10566, page 56

Overall, the applicant determines that there are an estimated 78 BMT cases originating in OTSA 4 who travel out of state and 117 cases leaving OTSA 4 each year for programs elsewhere in Florida or out of the state. CCH expects for the proposal to remedy this level of outmigration. The reviewer notes the applicant does not show any quantifiable data points to illustrate how it will remedy the outmigration it is forecasting since the proposed project will be located within a contiguous Zip Code to the existing provider MHW in Zip Code 33028.

Northern OTSA 4 and contiguous areas in southern OTSA 3 do not have reasonably accessible or programmatically accessible BMT programs resulting in lower use rates

The applicant states that data confirms that Palm Beach County adult BMT use rates are markedly lower than the rest of OTSA 4 and OTSA 3 counties. See the table below:

Adult BMT Use Rates 12 Months Ending March 31, 2018	
OTSA 4	5.49
OTSA 3	5.35
South OTSA 3	4.11
Palm Beach County	3.8
Palm Beach County is Less than OTSA 4 by	31.0%
South OTSA 3 is less than OTSA 4 by	25.0%
South OTSA 3 is less than OTSA 3 by	23.0%

Source: CON application #10566, page 58

Based on the calculated use rate, the applicant determines that it is evident that Palm Beach County access to BMT services is minimized as a result of programmatic and geographic access. The reviewer notes that tertiary services are examined on a district basis for some hospital services and on a regional basis for transplant services—they are not examined on a county basis. Additionally, the reviewer notes that the proposed program will not be located in Palm Beach County, it will be located in Broward County, proximate to the existing Broward County adult BMT provider.

Continuing with this analysis, the applicant states that the south OTSA 3 use rate is effectively at 75 percent of the OTSA 4 use rate, again underscoring programmatic and geographic access. The applicant states that it is evident that these counties' access to BMT is minimized as a result of the programmatic and geographic access.

CCH references its Schedule C condition to establish outpatient programs for BMT follow-up in northern Palm Beach County and each of the counties in OTSA 3. The applicant expects the establishment of these outpatient programs to create the necessary access points for residents of these areas to be in compliance with the patient protocol in terms of time and distance for follow-up treatment. The reviewer notes that this condition can be accomplished at present and without the approval of the proposed project.

South OTSA 3 counties are not geographically accessible to any BMT program and therefore there is 100.0 percent outmigration for transplant and post-transplant treatment

CCH describes how Martin Memorial Health System and Indian River Medical Center are two health systems that are anticipated to join the applicant in January 2019. The applicant states that its expansion into Indian River, Martin and St. Lucie Counties will include four acute care hospitals and a host of outpatient programs: Martin Medical Center, Martin Hospital South, Tradition Medical Center and Indian River Medical Center. CCH states that more than 30 ambulatory sites will be added to serve CCH patients.

The applicant maintains that three OTSA 3 counties do not have access, geographically nor programmatically to BMT programs. The reviewer notes that CCH is not proposing to add an access point within OTSA 3. The reviewer also notes that Indian River Medical Center is closer to Florida Hospital Orlando than CCH according to driving directions from Mapquest. CCH states that there is one BMT program within OTSA 3, Florida Hospital Orlando, which is in excess of one hour away and therefore not geographically accessible due to the requirement/industry standard of having follow-up care within a 60-minute drive. The applicant describes the access standard policy practiced by Dr. Wesam

Ahmed, who transitioned from Florida Hospital Orlando to Cleveland Clinic. The applicant notes that Dr. Wesam Ahmed and his team of hematologists would not transplant any patients who did not reside, either permanently or temporarily, within a one-hour drive of Florida Hospital Orlando during their follow-up treatment, as long as six months. The applicant states that very few patients from Indian River, Martin, and St. Lucie Counties receive transplants at Florida Hospital Orlando. The applicant advances the argument that because relocation is not an option for many patients, they often forego the option to transplant which results in lower use rates. A map of 60-minute drive time contours surrounding Florida Hospital Orlando is provided on page 61 of CON application #10566.

CCH intends to provide inpatient transplantation in Weston, Florida and then provide multiple weekly follow-up BMT appointments at three different sites within OTSA 3. The applicant intends to establish sites at Martin Memorial Medical Center, Indian River Medical Center and at a third ambulatory site in St. Lucie County which will allow for patients to receive inpatient BMT services at CCH and return home for follow-up care. CCH expects to enhance access to BMT services for more than six million residents in eight counties. Maps of 60-minute drive contours from CCH and its proposed outpatient locations are provided on pages 62 – 64 of the application.

The applicant trends the outmigration patterns within OTSA 3, noting that in each of the past three years the level of outmigration for the three noted counties (St. Lucie, Martin and Indian River) has increased from 82.1 percent during the twelve months ending March 31, 2016 to 95.5 percent for the 12 months ending March 31, 2018 (CON application #10566, page 65). CCH itemizes the volume of outmigration by the three-county area identified from OTSA 3 for each year on page 66 of the application. The reviewer notes that while the applicant presents large outmigration percentages from these areas, 95.5 percent, that this percentage represents a relatively small number of adult BMTs (21 procedures or seven percent of the total of OTSA 4 BMT procedures for the same time period. In addition, the Agency can make no determination regarding outmigration for these 21 procedures since the applicant does not provide information on where these 21 case outmigrated to—if, for example, they are already outmigrating from OTSA 3 to OTSA 4 then that would show that OTSA 4 is already an access point utilized by residents, if these residents are outmigrating to Mayo Clinic, then traffic patterns and freeway access (1-95) might be an explanation. The reviewer also notes that by the applicant's own data (see table on page 45) OTSA 3 has the second highest adult resident use rate for BMTs in the state, surpassed only by OTSA 4.

In review of MedPar data from this area (south OTSA 3), the applicant finds that there were 14 BMT patients from the selected OTSA 3 area. Of the 14 BMTs, none were performed within OTSA 3 or at Florida Hospital's program. Nine of the 14 patients migrated to other Florida BMT programs and the remaining five left Florida to receive a BMT. The applicant provides the following analysis to trend the overall outmigration pattern for BMT services within this area:

OTSA 3 Medicare FFS Bone Marrow Transplants 12 Months Ending March 31, 2018				
	Indian River	**Martin**	**St. Lucie**	**Total**
Licensed BMT in OTSA 3	0	0	0	0
Outside OTSA 3, in Florida	3	3	3	9
Out of State	3	1	1	5
Total	6	4	4	14
Outmigration:	**Indian River**	**Martin**	**St. Lucie**	**Total**
Outside OTSA 3, in Florida	50%	75.0%	75.0%	64.3%
Out of State	50%	25.0%	25.0%	35.7%
Total Outmigration	100%	100%	100%	100%

Source: CON application #10566, page 67

CCH observes that based on Medicare data, half of the number of these three counties' transplants were transplanted outside the State of Florida. Combined, the applicant finds that those who left OTSA 3 for a hospital in Florida and those who left the state results in 33+ annual BMT patients who reside within Indian River, Martin and St. Lucie Counties who were not served within their home OTSA. The applicant's analysis of these outmigration patterns within OTSA 3 based on the assumption that 55.0 percent of outmigration cases were treated out of state is included below:

OTSA 3 BMT Transplants Total Outmigration, All Payors 12 Months Ending March 31, 2018		
	All Payors	**Percent of Total**
Outside OTSA 3 Within Florida	21	61.8%
Outside Florida (Multiplied by 55%)	12	35.3%
Total Outmigration	33	97.1%
Cases in OTSA 3	1	2.9%
Total BMT Cases	34	100.0%

Source: CON application #10566, page 67

Overall, the applicant expects for nearly all BMTs to occur outside of the OTSA because there is a lack of programmatic and geographic access to BMT programs in OTSA 3. CCH states there is significant underutilization and suppression of BMT services in OTSA 3. The reviewer notes that the applicant is presenting an argument encouraging nearly 100 percent outmigration from a number of OTSA 3 counties to justify adding another access point to adult BMT services within OTSA 4. The reviewer notes that typically outmigration within the realm of health

care planning is utilized as justification to approve a program in the area where patients are outmigrating from not where they are outmigrating to receive health care services.

Incidence and prevalence of diseases requiring adult BMT and internal demand

CCH provides a summary of the most common diseases affecting patients requiring a BMT. The applicant states that the majority of patients requiring BMTs are affected by myeloma, leukemia and/or lymphoma. Nationally, CCH references American Cancer Society data to estimate that 174,250 people in the U.S. are expected to be diagnosed with one of these disorders in 2018. The applicant states that new cases of these blood diseases are expected to account for 10.0 percent of new cancer cases diagnosed in the U.S. in 2018. CCH trends the prevalence of the estimated number of people who had a diagnosis of the previously mentioned diseases to be 1,345,123 people. Based on the Leukemia and Lymphoma Society's projections of 174,000 new cases of blood diseases and cancers that can require BMT, the applicant forecasts an additional 17,000 new cases of other diseases that could result in a BMT.

The applicant uses two approaches to quantify numerical need for the proposal. The first method calculates the projected number of BMTs expected in the service area based on the historical incidence of new blood diseases in the United States and historical BMTs by disease as a percent of total new cases (CON application #10566, page 71). CCH provides analyses of the incidence rate of BMTs by blood disease to forecast the number of new blood diseases expected within the service area by year one of the proposed project. The applicant next applied U.S. incidence rates by disease to the 2020 forecasted populations 15+ at the county level (CON application #10566, pages 72 - 76). The following tables reveal the applicant's forecasted BMTs from 2020 – 2022 and the estimated incremental demand.

Forecasted Bone Marrow Transplants Originating From Service Area 2020 - 2022			
	2020	**2021**	**2022**
Broward	109	111	112
Collier	22	22	23
Miami-Dade	158	160	162
Monroe	5	5	5
Palm Beach	85	86	87
OTSA 4	**379**	**384**	**389**
OTSA 3			
Indian River	9	9	9
Martin	10	10	10
St. Lucie	18	18	18
South OTSA 3	37	37	*37*
Total	**416**	**421**	**427**

Source: CON application #10566, page 77.

OTSA 4 Resident Bone Marrow Transplants, Demand Minus Supply 2020	
OTSA 4 Forecasted Market - Year 1 Demand	379
University of Miami Hospital, Actual 3/31/18	213
Memorial West, Actual 3/31/18	40
Baptist Hospital Miami, Forecasted 2020	30
Total, Existing and Planned BMT Programs (Supply)	283
Incremental Unserved Patients (Unmet Need)	96

Source: CON application #10566, page 78

The applicant states that the unmet need for 96 cases in just OTSA 4 counties is a result of a suppressed use rate and out-migration.

Internal demand for BMT based on new cases diagnoses at CCH
The applicant next quantifies volume for the proposed service by applying a conversion rate to the average annual volume of CCH historical cases for these blood diseases during the last three years. CCH states that the Cleveland Clinic Maroone Center currently has internal demand for an adult BMT program. The applicant observes that on average for the past three years, there have been 169 new blood disease cases that ultimately require a BMT. In 2018, CCH identified 193 of such cases, which exceeds the three-year average. The applicant describes how its Taussig Cancer Center (Cleveland) has a longstanding and renowned BMT program and determined specific "conversion rates" of these newly diagnosed cases of blood diseases that would result in a BMT. The reviewer notes that CCH did not relate where the identified 193 cases were referred to receive BMT services within Florida—whether they received inpatient or outpatient BMT, whether they outmigrated from OTSA 4 or if they were not referred to any CON-authorized BMT program. The reviewer cannot tell what proportion of the BMTs that occurred in OTSA 4 were a result of CCH's identified 193 probable cases in 2018—if 55 occurred as forecasted by the applicant, it would represent approximately one-fifth of the cases that occurred and redirecting them to a new program could significantly adversely affect the three existing providers in OTSA 4.

The applicant also provides analyses of various blood disorder patients seen at the Maroone Center, from 2014 to 2018 (annualized) for new and established patients by disease and by geographic region within OTSA 4 and select OTSA 3 counties (CON application #10566, pages 80 – 83).

CCH describes how internally determined conversion rates (20 to 50 percent) results in an internal demand forecast of 50 transplants that could be performed at CCH each year or 55 transplants based on the 193 case value. Overall, the applicant intends to capture 86.0 percent of this projected demand by year three.

Forecasted Bone Marrow Utilization
Based on all the quantification methods described in the previous section, the applicant provides the following utilization forecast:

Forecasted BMT Patient Volumes, Ages 15+			
	Year 1 (2020)	**Year 2 (2021)**	**Year 3 (2022)**
Allogeneic Transplants	10	10	16
Autologous Transplants	14	16	17
Total Bone Marrow Transplants	24	26	33
Length of Stay	21.7	21.4	21.3
Patient Days	512	553	922
Average Daily Census	1.4	1.5	2.5
Occupancy Rate (10 Beds)	14.0%	15.2%	25.3%

Source: CON application #10566, page 85

The applicant states that the forecasted volumes meet the minimum requirement for autologous and allogeneic transplants as defined by Rule Criteria. CCH indicates that the program will be developed with the goal of obtaining FACT accreditation as soon as possible and will maintain staff to meet all FACT requirements. The applicant notes that while it awaits FACT accreditation it will only transplant Medicare and Medicaid patients. CCH expects for the volume of transplants to increase as the program develops.

No Adverse Impact on Existing or Planned Adult BMT Providers
Given the market dynamics, market profile and incremental demand, the applicant does not expect any adverse impact on any existing licensed or planned adult BMT program. Due to suppressed levels of utilization, the applicant determines that there is sufficient volume in the area to allow existing BMT programs to grow well into the future while allowing the proposed program to flourish. CCH states that the program will primarily rely on residents of the northern OTSA 4 region to support its program and indicates that the proposal is intended to serve southern OTSA 3 residents who do not have an accessible BMT program. The applicant underscores that the outpatient centers that will be established within the service area will also serve as access points within select OTSA 3 areas. The reviewer notes that the BHM BMT program just began inpatient services on October 24, 2018 and has not had time to mature—nor can adequate health planning be analyzed on the program until maturation occurs and use rates can be analyzed. In addition, the applicant provides no statistical data that demonstrates that existing providers will not be adversely affected by approval of the proposed program—since need was not established and no discernable increase in access to BMT services to residents of OTSA 4 was demonstrated.

CCH also details letters of support and reproduces excerpts from area providers noted in the "Letters of Support" section of this report on pages 87 – 93 of the proposal. The reviewer notes that the applicant submitted

six total letters of support, were of a form template for the three hospital administrators (two from OTSA 3) and that none of these letters were from residents or discharge planners of OTSA 4. The reviewer indicates that none of the letters of support cite any examples of OTSA 4 residents not being able to access BMT services within OTSA 4.

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 a statutory teaching hospital as defined in Section 408.07(45), Florida Statutes. The applicant describes itself as one of the largest non-university based physician-graduate training centers. CCH considers education an integral component of its mission since its inception in 1921. The applicant notes that as a part of its overall commitment to education, the importance and value of graduate medical education are recognized. CCH currently offers training for residents and fellows in 18 medical and surgical disciplines and specialties. The applicant provides a list of the number of people currently training in different disciplines:

- 63 clinical residents
- 44 fellows
- Two pharmacy residents
- 30 visiting residents
- 495 medical students
- 30 observers
- 35 visiting researchers
- 48 research fellows
- 102 high school and college students in its “Summer Scholar” program

CCH discusses having formal affiliations with Herbert Wertheim College of Medicine at Florida International University and Charles E. Schmidt College of Medicine at Florida Atlantic University to provide training for medical students and other healthcare professionals from both universities. Details of training, accreditation and education programs are provided on pages 34 – 37 of CON application #10566.

The applicant states that the Division of Research and Education maintains a high degree of international acclaim for the number and quality of research protocols. The applicant indicates that these significant research advancements enable CCH to provide the best possible patient care and that research involves a spectrum of efforts. CCH states that clinical research is second nature to its physicians who have conducted nearly 1,500 clinical trials comparing the effectiveness of various treatment methods on patients. CCH notes that currently there are more than 160 active clinical studies underway at the hospital. The applicant states that close to 1,000 research studies have been successfully undertaken in Florida and have resulted in over 500 peer reviewed publications which serve as a resource to health care providers around the globe.

CCH states that the applicant currently has 17 research fellows whose sole focus is conducting clinical studies and publishing findings across various fields including but not limited to hematology/oncology. An index of the applicant's active clinical studies and a listing of current research fellows by department is provided in the Supporting Documents section of the application. Details of cancer research activities are provided on pages 32 – 33 of the application.

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

The applicant indicates that in year one it will perform 10 allogeneic transplants, 10 in year two and 16 in the third year. For autologous patient volumes, the applicant forecasts 14 transplants in year one, 16 in year two and 27 in year three or: 24 transplants in year one, 26 in year two and 43 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 Wesam Ahmed, MD, PhD, has been appointed as head of Leukemia and BMT in the Maroone Cancer Center and will assume the leadership role of the BMT program if approved. The applicant states that Dr. Ahmed has dually served as the Medical

Director of Cellular Therapy and the Stem Cell Laboratory at Florida Hospital's Cancer Institute and in 2017 was appointed to CCH's medical staff as Staff Hematologist. A summary of Dr. Ahmed's education and training is provided on pages 112 – 113 of CON application #10566.

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

The applicant states that CCH has a robust, highly-credentialed and proficient nursing staff that provides quality care to very critically-ill patients. CCH maintains over 100 nurses with experience and competencies of caring for critically-ill immunosuppressed patients. The applicant provides a list of these staff on pages 113 – 114 of CON application #10566. CCH notes that the referenced nurses helped the hospital ICU earn its American Association of Critical-Care Nurses' Beacon Award for Excellence, which signifies exceptional care achieved through improved patient outcomes and greater overall patient satisfaction.

CCH asserts that the proposed BMT program will be staffed with a dedicated nursing team expert in providing care to critically immunosuppressed patients. The applicant indicates that nurses for the proposed 10-bed BMT unit are in place and incremental staffing for additional BMT patient days is provided in Schedule 6 of CON application #10566.

The applicant notes that the "BMT Nurse Training and Competency Standard Operating Procedure Manual" is in place at Cleveland Clinic's main campus in Ohio. CCH states that the standard operating procedures outline the initial orientation, competency requirements and documentation to ensure the competency of the BMT nursing staff to provide an appropriate level of care. According to the applicant, the standard operating procedures provide 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.

CCH maintains that the BMT team will be specially trained in meeting the needs of transplant patients. The applicant states that the team will include 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

The applicant indicates having 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 that the interdisciplinary team will guide the patient through the entire process from evaluation, outpatient work-up, transplantation and immediate and long-term follow-up care. CCH discusses its current staff of 11 hematologists and oncologists and a pending addition of one transplant hematologist prior to the program's inception. A listing of the current hematologists and oncologists on-staff is provided including descriptions of interdisciplinary team members (CON application #10566 pages 116 – 119).

(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 states that during the hospital stay for a BMT, patients will stay in the 10-bed BMT unit within the broader third floor, 26 room hematology/oncology unit that opened October 2018. The applicant states that all patient rooms in the BMT unit are equipped with Protective Environment systems because acute patients are immunocompromised and the BMT unit will also 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 that one of the patient rooms has a combination of Airborne Infection Isolation/Protective Environment and has the required anteroom. The applicant states that the 10 patient rooms are 230 square feet with private bathrooms. CCH states that the unit also has a patient lounge, family lounge, separate clean supply/soiled utilities rooms, medication room, nourishment and an environmental services space. A table of the schematics is provided on page 120 of CON application #10566.

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

The applicant indicates that the Department of Radiation-Oncology at the Maroone Cancer Center is led by a board-certified physician, Dr. John Greskovich, Jr., who is the Medical Director of the Department of Radiation-Oncology. The applicant states that the Department of Radiation – Oncology also includes four other board-certified physicians and physicists.

CCH states that the Department of Radiation-Oncology at the 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 with more accuracy and speed. The applicant notes that CCH is one of only a few centers around the world to offer a Varian Edge radiosurgical suite[10].

CCH notes that the Maroone Cancer Center has earned three-year approval with Commendation from the Commission on Cancer 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

[10] According to Cleveland Clinic's website (https://my.clevelandclinic.org/health/treatments/17601-varian-edge), "The Edge is a state-of-the-art linear accelerator coupled with real-time motion management to ensure fast, precise delivery of treatment. The six degree couch allows for accurate patient positioning."

- 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 that its laboratory and pathology center is qualified to handle the studies identified. To the extent that a study is identified that is outside their capabilities, the applicant intends to have a contract in place to provide it, although such is not known at this time.

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

The applicant asserts it is developing a cell processing laboratory on the hospital campus in collaboration with the Department of Pathology. The applicant describes how 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 it is developing its own apheresis facility on the third floor of the hospital in the current dialysis space which will be relocated.

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

The applicant notes that the hallmark of CCH is innovation and patient care with clinical research and medical education intertwined and interdependent. The applicant describes the aspects of its Center of Research and Education and cancer research and provides a listing of ongoing trials and studies at CCH. The applicant states that it will continue to pave the way in clinical research (especially cancer research) and as the proposed BMT program develops there will be related ongoing research.

(k) An established research-oriented oncology program.

CCH maintains that its cancer research staff is dedicated to providing patients innovative therapies through clinical research trials including new targeted agents and therapies. The applicant discusses its research activities at the main campus in Ohio and provides a summary of research conducted on pages 126 – 132 of CON application #10566.

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

The applicant describes its current collaborations with a number of local hotels to ensure that patients and their families have accessible housing during extended hospital stays. CCH references its professional relationship with the Marriott Residence Inn Weston which is located across the street from the hospital. The applicant indicates that Marriott's regional management has relayed its willingness to partner with CCH to provide temporary residential listing for patients and/or family members during their long lengths of inpatient stay, follow-up treatment and post-hospitalization. A letter of support from the Residence Inn is referenced in support of this collaboration. CCH describes how social workers provide a resource and assistance to patients and 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 at Maroone Cancer Center, where patients are referred, evaluated and treated pre- and post-transplant on an outpatient basis. The applicant also states that four locations distant from the Weston campus will be added to enable follow-up treatments for patients who reside in Palm Beach, Martin, St. Lucie and Indian River Counties. CCH states that these access points will be located within existing ambulatory sites, including cancer centers in Martin and Indian River Counties which are being acquired by CCH, effective January 2019.

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

a. <u>Coordination of Services</u>. 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 attests to having sufficient staff and other resources to care for BMT 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 states that prior to transplantation, BMT candidates will be seen in the office by physicians for all of their outpatient testing/workup and will meet with physicians in their offices on the Weston campus. The applicant indicates that stem cell collection in the apheresis facility will be performed on an outpatient basis.

CCH notes that team members will include an assigned nurse, social worker and others who will schedule appointments to meet with the transplant candidate as needed. The applicant states that during the hospital stay for transplants, the patient will stay in the 10-bed BMT unit. CCH states that team members will stay current on the candidate's case throughout the whole pre-transplant process, including if/when the patient must be hospitalized prior to BMT. In order to assure the highest quality and outcomes, CCH states that BMT will occur on an inpatient basis. The applicant indicates that the BMT unit will have HVAC and HEPA filtration systems in place for the protection of acute immunocompromised patients. The applicant states that all follow-up care will be provided on an outpatient basis.

The applicant states that it has 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 including pathology, pharmacy, radiology, infectious diseases, cardiology, pulmonary/critical care, nephrology, endocrinology, internal medicine and nursing for

both inpatient and outpatient care. CCH states 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 BMT recipients will be cared for in a 10-bed BMT unit within the hematology/oncology acute care unit of the new bed tower that opened in October 2018. CCH describes how 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 patients at risk. The applicant states that the unit's staff will also be specially trained.

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

   CCH indicates that a clinical review committee will be established to evaluate all potential patients in order to determine their suitability for a BMT. CCH indicates that the committee will be organized and directed by the program's medical director and that 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 staff
   - Social worker

- Program manager (nursing)
- Financial counselor
- Pharmacist
- Dietician

The applicant details that the committee will meet on a weekly basis with new potential BMT patients presented by the physician who initially received the patient referral and performed the initial consult. CCH states that patients who are identified as appropriate candidates 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 that the proposed program will adopt protocols similar to the ones in place at the Cleveland Clinic Main Campus in Ohio. CCH discusses having similar protocols in place for its other existing transplant programs. The applicant states that the main Cleveland Clinic campus adheres to the Taussig Cancer Center's "BMT Standard Operating Procedure Manual" for patient selection criteria, for patient management/evaluation during the pre-hospital, in-hospital, immediate post discharge and long-term follow up phases of autologous and allogeneic BMT programs. Copies of the Standard Operating Procedures of the BMT program are provided in the Supporting Documents of CON application #10566.

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 because it will perform 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.**

   The applicant asserts that it has a contract with LifeLink of Florida which is 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 tissues for transplantation therapy. CCH notes that LifeLink is one of four organ procurement organizations in the State of Florida and among 58 within the country.

   CCH references a letter of support from Jean Aiken Davis, Executive VP and COO at Lifelink, endorsing support of the proposal and a copy of the agreement between CCH and Lifelink.

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

   The applicant states that CCH's Division of Pathology and Laboratory processes and interprets approximately 20,000 surgical and cytology specimens annually. CCH maintains that 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 to study and promptly report BMT patient responses to

transplant and analyze appropriate biopsy material. The Center of Pathology and Laboratory Medicine at Weston is part of the Cleveland Clinic main campus (Ohio) which is also licensed in Florida.

10. Blood banking facilities.

CCH indicates that its existing blood bank has the physical capacity to accommodate the additional needs of the BMT program. The applicant states that its blood inventory will be increased as needed to accommodate BMT programming needs and ensure that a sufficient inventory of blood is maintained at all times to accommodate all of its transplant programs. The applicant notes that OneBlood will have the blood supply and blood product resources available at all times for CCH as back up, if needed. The applicant states that 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. A letter referencing OneBlood's intent to collaborate with CCH in this capacity is cited by the applicant (CON application #10566, Page 101 – 102).

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

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

The applicant discusses its transplant team members and how they will be aware of and adhere to the Cleveland Clinic Taussig Cancer Institute's "Bone Marrow Transplant Standard Operating Procedure Manual". Components of the standard operating procedure are provided on pages 102 – 103 of CON application #10566.

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

CCH states that the Main Ohio Campus has designed an extensive teaching program to help patients and their families learn about the BMT process, individual health needs and medical care before/during/after transplant. The applicant describes how notebooks which provide detailed instruction, explanations, expectations, and coping mechanisms are provided to each patient as a reference tool for patients to review while awaiting a BMT.

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

- Introduction to the BMT program
- Pre-transplant/central line care
- Social work
- The transplant
- Transplant medicines
- Follow-up care after your BMT
- Graft-versus host diseases (allogeneic patients only)
- Keeping healthy

CCH states that these guides are comprehensive and include information about different types of autologous and allogeneic transplants. The applicant states that individualized treatment plans will also be provided. CCH details the instruction and education provided by the nurse coordinator subsequent to transplantation and the support groups available to patients.

b. <u>Staffing Requirements</u>. 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 currently maintains a team of 11 hematologists/ oncologists who are appointed to the medical staff, including Dr. Ahmed, who will serve as Medical Director of the proposed BMT program. The applicant intends to hire an additional hematologist/oncologist with BMT experience prior to the initiation of service. The applicant states that Dr. Ahmed will assist with recruiting and training other physicians to work in the program as volume increases.

2. **A program director who shall have a minimum one year formal training and one year of experience at a transplantation program for the same type of organ transplantation program proposed.**

   The applicant provides a biography of Dr. Wesam Ahmed who will serve as the Medical Director of the proposed BMT program. Dr. Ahmed completed fellowship training in hematology/oncology at Tufts Medical Center in Boston and began his career as a BMT hematologist in 2013 at Tufts Medical Center, relocating to Florida Hospital's Cancer Institute in 2014 where he served as the Medical Director of Cellular Therapy and Stem Cell Laboratory. In 2017, Dr. Ahmed was appointed as Staff Hematologist at CCH. A profile of Dr. Ahmed is included in the Supporting Documents section of CON application #10566.

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 states that its current nursing staff are highly credentialed, proficient and provide quality care to critically-ill patients. The applicant notes that it currently employs more than 65 nurses with experience and competencies in the care of critically-ill, immunosuppressed patients. The applicant states that these nurses have the credentials to treat BMT patients and have earned the Hospital's American Association of Critical Care Nurse's Beacon Award for Excellence, which signifies 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 who are well-versed in blood banking and capable of meeting the unique long-term needs of transplant patients. The applicant describes its contract with OneBlood to supplement any gaps in service should they 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 BMT patients are members of the multidisciplinary team that will care for adult BMT patients and provide transplant patients with medical nutrition therapy using current scientific principles supported by reliable research to optimize patient care. The applicant indicates that it will make nutritional assessments and diet counseling services furnished by a qualified dietician available to all transplant patients and donors. CCH refers to the American Dietetic Association's definition of a qualified dietitian and indicates that Lori Drummond, RD, who currently works with the hospital's solid organ transplant patients, meets the criteria above.

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

CCH asserts that the proposed program will provide respiratory therapists who have expertise in the needs of transplant patients and specifically the needs of BMT patients. The applicant states that respiratory therapists are

involved in the transplant patient's care during their inpatient stay, most commonly in the ICU but also in the BMT unit. CCH notes that respiratory therapists with expertise in the needs of transplant and hematology/ oncology patients are well-versed with providing care to the immunosuppressed. The applicant further details the scope of the responsibilities of respiratory therapists on page 110 of CON application #10566. CCH states that it currently has a staff of 28 respiratory therapists who have expertise in the needs of transplant patients and indicates that this criteria is consistent with the Conditions of Participation required by CMS.

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.**

   The applicant states that it will have social workers, psychologists, psychiatrists and other individuals skilled in performing comprehensive psychological assessments, counseling for patients and family members, providing assistance with financial arrangements and making arrangements for the use of community resources. CCH notes that it has social workers, psychiatrists and psychologists on staff that will be part of the patient's multidisciplinary team who also evaluate certain patient populations including solid organ transplant candidates. CCH outlines the role of financial counselors in its transplant programs.

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 expresses the intent to comply with this criteria.

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 all other OTSA 4 Florida adult inpatient BMT providers from the proposed location for CON application #10566

Cleveland Clinic and OTSA 4 Provider Proximity Map				
Facility	**CCH**	**MHW**	**BHM**	**UMHC**
Cleveland Clinic		18 min (8.1 miles)	38 min (30.6 miles)	43 min (34.6 miles)
Memorial Hospital West	18 min (8.1 miles)		37 min (27.4 miles)	31 min (21.8 miles)
Baptist Hospital of Miami	38 min (30.6 miles)	37 min (27.4 miles)		26 min (15.7 miles)
University of Miami Hospital and Clinics	43 min (34.6 miles)	31 min (21.8 miles)	26 min (15.7 miles)	

Source: Mapquest

Data reported to the Agency for the most recent reporting period, July 1, 2017 through June 30, 2018 show the following adult inpatient BMT utilization data:

Florida Adult Bone Marrow Transplantation Program Utilization: July 2017 – June 2018			
Hospital	**OTSA**	**District**	**Total Procedures**
UF Health Shands Hospital	1	3	150
Mayo Clinic	1	4	99
H. Lee Moffitt Cancer Center	2	6	444
Florida Hospital-Orlando	3	7	98
Memorial Hospital West	4	10	52
Univ. of Miami Hosp. & Clinics	4	11	236
		Total	**1,079**

Source: *Agency for Health Care Administration Utilization Data for Adult Organ Transplantation Programs*, published October 28, 2018**.**

The applicant states that the proposed project will allow south Florida residents to remain within their home region while accessing treatment at CCH. CCH maintains the proposed program will allow service area residents to remain close to home throughout the entire transplant process, from evaluation to transplantation and follow-up care rather than relocating to another unfamiliar place outside of South Florida to seek care. The applicant maintains that the proposed program will afford patients of Palm Beach, Martin, St. Lucie and Indian River

Counties the benefit of follow-up and post-transplant treatment on an outpatient basis in their own communities.

CCH summarizes the existing providers of adult BMT services and the volume of BMTs performed from July 1, 2017 – June 30, 2018 as provided in the Agency's publication. The applicant stresses that need for the proposal is demonstrated within the application based on a series of factors that evidence not normal circumstances related to geographic and programmatic access factors as well as internal demand for the project (institutional need). CCH contends that data, research, analysis and operational characteristics identified and presented herein provide substantive support for the proposed BMT program's need for development.

The applicant details six "not normal" circumstances for which approval of the proposal is merited:

- BMT should be deregulated from CON as it no longer falls within the "tertiary health services" definition
- Excessive outmigration of BMT patients from OTSA 4
- Northern OTSA 4 and contiguous areas in southern OTSA 3 do not have reasonably accessible or programmatically accessible BMT programs resulting in lower use rates
- South OTSA 3 counties are not geographically accessible to any bone marrow transplant program and therefore there is 100 percent outmigration for transplant and post-transplant treatment
- Incidence and prevalence of diseases requiring adult BMT and internal demand
- Internal demand for bone marrow transplant based on new case diagnoses at Cleveland Clinic Florida

In conclusion, CCH intends to address what it purports is the limited access to BMT programming for residents in northern OTSA 4 and southern OTSA 3 and seeks to mitigate the geographic and programmatic access barriers. The applicant states that the proposal will address the growing internal demand within its own hospital (institutional need). The applicant contends that CCH is uniquely positioned to fill the gap in service, given its recent expansion into Indian River, Martin, and St. Lucie Counties and the experience of its main campus.

The applicant offers narrative descriptions of external support for the program as evidenced in letters of support provided by neighboring hospitals and describes Cleveland Clinic's capacity to offer quality as explanations for need for the proposal on pages 155 – 157 of CON application #10566.

The reviewer notes that CCH failed to demonstrate that residents in OTSA 4 are unable to obtain adult BMT services. CCH also fails to demonstrate that OTSA 4 residents are experiencing now or are likely to experience in the foreseeable future, poor, substantially delayed or clinically undesired health care outcomes as a result of the landscape of the existing adult inpatient BMT services in OTSA 4.

b. Does the applicant have a history of providing quality of care? Has the applicant demonstrated the ability to provide quality care? ss. 408.035(1)(c), Florida Statutes.

The applicant states that the CCH system shares a mission, vision, values and commitment to principles, which is to provide better care to the sick, investigation into their problems and further education of those they serve. In order to carry out its mission and foster the group practice of medicine, the applicant states that CCH:

- Excels in specialized medical care supported by comprehensive research and education
- Develops, applies, evaluates and shares new technology
- Attracts the best qualified medical, scientific and support staff
- Excels in service
- Provides efficient access to affordable medical care
- Ensures that Cleveland Clinic quality underlies every decision

CCH stresses that it strives to be the world's leader in patient experience, clinical outcomes, research and education. The applicant lists its six fundamental values as follows:

- Quality: We maintain the highest standards and achieve them by continually measuring and improving our outcomes
- Innovation: We welcome change, encourage invention and continually seek better, more efficient ways to achieve our goals
- Teamwork: We collaborate and share knowledge to benefit patients and fellow caregivers for the advancement of our mission
- Service: We strive to exceed our patients' and/or fellow caregivers' expectations for comfort and convenience
- Integrity: We adhere to high moral principles and professional standards by a commitment to honesty, confidentiality, trust, respect, and transparency
- Compassion: We demonstrate our commitment to world-class care by providing a caring and supportive environment for our patients, patients' families and caregivers

The applicant states that it is committed to principles as presented in the United Nations Global Compact.

CCH further details program specific achievements that have earned its programs national recognition as indications of its quality of care on pages 163 – 167 of CON application #10566.

Agency complaint records indicate that the applicant had one substantiated complaints within the three period ending on January 25, 2019 in the resident/patient/client rights category.

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 Cleveland Clinic Florida Health System, where the short term and long term measures fall on the scale (highlighted in gray) for the most recent year. All figures except ratios are in thousands.

Cleveland Clinic Florida Health System (In Thousands)		
	Dec-17	**Dec-16**
Current Assets	$66,033	$123,107
Total Assets	$290,642	$273,377
Current Liabilities	$43,693	$36,342
Total Liabilities	$44,809	$37,509
Net Assets	$245,833	$235,868
Total Revenues	$325,970	$312,743
Excess of Revenues Over Expenses	$64,857	$72,900
Cash Flow from Operations	$86,052	$93,708
Short-Term Analysis		
Current Ratio (CA/CL)	1.5	3.4
Cash Flow to Current Liabilities (CFO/CL)	196.95%	257.85%
Long-Term Analysis		
Long-Term Debt to Net Assets (TL-CL/NA)	0.5%	0.5%
Total Margin (ER/TR)	19.90%	23.31%
Measure of Available Funding		
Working Capital	$22,340	$86,765

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

Capital Requirements and Funding:

The applicant indicates on Schedule 2 capital projects totaling $67,142,442 which includes remaining FY 2018 Routine Capital Expenditures, FY 2019-22 Capital Expenditures, and the CON currently under review ($1,142,442). The applicant provided a copy of its December 31, 2016 and December 31, 2017 audited financial statements. These statements were analyzed for the purpose of evaluating the applicant's ability to provide the capital and operational funding necessary to implement the project. The applicant noted on Schedule 3 that the funds will be provided by cash flow from operations.

Staffing:

Cleveland Clinic Florida CON application #10566 Proposed Staffing Pattern			
	Year One	**Year Two**	**Year Three**
FTEs			
Physician	1.00	1.00	1.00
APP	-	-	1.00
Outpatient Nurse Coord.	1.00	1.00	2.00
Social Work	1.00	1.00	1.00
Quality Manager	1.00	1.00	1.00
Research Coordinator	0.5	1.00	1.00
IP Floor Nurses	5.00	5.00	5.00
OP RN	-	1.00	1.00
Total	**9.5**	**11.0**	**13.0**

Source: CON application #10566, Schedule 6A

Conclusion:
The applicant states on Schedule 3 that funding will be provided by operating cash flows. With $86,052,000 in cash flows from operations, funding for the entire capital budget should be available as needed.

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

Analysis:
Our comparison is of the applicant's estimates to its latest FHURs report.

Because the proposed adult bone marrow transplant program cannot operate without the support of the hospital, we have evaluated the reasonableness of the projections of the entire hospital including the project. The applicant will be compared to its latest AHCA filing which was December 31, 2017. Inflation adjustments were based on the new CMS Market Basket, 3rd Quarter, 2018.

	PROJECTIONS PER APPLICANT		Actual Data Inflated to
	Total	**PPD**	**2021**
Net Revenues	478,636,211	6,248	7,577
Total Expenses	382,048,584	4,987	6,085
Operating Income	96,587,627	1,261	1,146
Operating Margin	20.18%		
	Days	**Percent**	**2017**
Occupancy	76,606	101.88%	85.49%
Medicaid/MDCD HMO	1,520	1.98%	2.32%
Medicare	45,894	59.91%	56.42%

The bone marrow transplant unit represents .5 percent of the hospital's total revenue and .6 percent of the hospital's expenses. Projections indicate a $95,738,608 profit margin at the end of year two. Because the bone marrow transplant unit is such a minor part of the hospital's overall operations, the hospital could easily support the bone marrow transplant unit even if extended losses were projected. The applicant is showing a significant difference between the projected per patient day data and the actual data from the facility's most recent fiscal year. While the use of estimates and shifts in patient mix may account for some of the discrepancy, the projected per patient data (6,248) appears to be lower than even the most recent fiscal results (6,723). This suggests that normal economic forces (e.g. inflation) may not being taken into proper consideration.

Additionally, the applicant is showing an occupancy above 100 percent. The applicant may be overstating patient days or understating available beds. The assumptions for Schedule 7 do not make any reference to how the applicant intends to accommodate patient levels that exceed capacity.

Conclusion:
Given the very small impact the project will have on the hospital, the project appears financially feasible. However, the projections provided by the applicant are questionable especially in light of the 2021 net revenue per patient day projection of $6,248 vs the actual 2017 net revenue per patient day of $6,723. Because of the discrepancies highlighted, the project may not be as profitable as expected.

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

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

Conclusion:

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

f. Are the proposed costs and methods of construction reasonable? Do they comply with statutory and rule requirements? ss. 408.035(1)(h), Florida Statues 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. The new program will be located in a new bed tower addition currently under construction as approved by Plans and Construction. 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.

The following is a chart that summarizes the provision of Medicaid/ Medicaid HMO and charity care at Cleveland Clinic Hospital and District 10:

Medicaid, Medicaid HMO, Charity Provision FY 2017			
	Medicaid/Medicaid HMO (%)	**Charity (%)**	**Total (%)**
Cleveland Clinic Hospital	2.31	0.71	3.02
District 10 Average	21.13	2.51	23.64

Source: Fiscal Year 2017 Agency for Health Care Administration, FHURS Data

CCH attests to having a long history of providing health services to the medically indigent. In FY 2017 ending December 31st, CCH discusses providing $8.5 million in charity care, for the YTD 2018 (11 months) the applicant states that it provided $8.9 million in charity care. The applicant states that it intends to continue to provide the same level of uncompensated care to the community as it has done in the past. The applicant states that given the low number of BMT patients in initial years the applicant does not expect to initially treat indigent patients and predicts that maintaining follow-up protocols and the ability to afford ongoing maintenance could be challenging for this subpopulation group, thus the conservative estimates in the applicant's Schedule 7.

Per the applicant's Schedule 7, CCH forecasts that self-pay will account for 0.04 percent of patient days and Medicaid will account for 1.15 percent of patient days in year one. In year two self-pay is expected to account for 0.07 percent of patient days and Medicaid is expected to account for 1.06 percent of patient days. In year three self-pay is expected to account for 0.21 percent of patient days and Medicaid is expected to account for 0.66 percent of patient days.

The applicant did not participate in the disproportionate share hospital (DSH) or LIP programs for SFY 2018-2019.

CCH does not condition approval of the proposal to the minimum provision of any level of care to any payer group. The reviewer notes that CCH, according to the latest FHURS data, is the fifth lowest hospital provider in the State of Florida (by percentage in comparison to total revenue) for combined Medicaid and charity care. For the latest reporting period Cleveland Clinic reported total patient revenue of $1,188,011,000 and total Medicaid revenue/charity care (shown as deductions from revenue) of $34,687,000 (2.92 percent). During the

same reporting period, BHM provided 15.74 percent ($664,492,687), UMHC (a class III specialty hospital) provided 9.70 percent ($259,126,937), MHW provided 14.56 percent ($433,316,340), of total revenue.

F. SUMMARY

Cleveland Clinic Florida Health System Nonprofit Corporation d/b/a Cleveland Clinic Hospital (CON application #10566) proposes to establish a new adult inpatient autologous and allogeneic BMT program in Broward County, Florida (OTSA 4).

The applicant states that Cleveland Clinic Hospital is seeking CON approval to establish an adult BMT program in order to provide high-quality specialized patient care in a setting of education and research which will ultimately enhance access to BMT services for many patients and residents in and around South Florida.

The cost subject to fee for the proposal is $1,115,692, which includes equipment, project development and start-up costs. The applicant's Schedule 10 forecasts initiation of service in January 2020.

Cleveland Clinic conditions approval of the proposal to six Schedule C conditions.

Need/Access
There is no fixed need pool publication for adult BMT programs. It is the applicant's responsibility to demonstrate the need for the project.

There are presently three operational adult inpatient BMT programs in OTSA 4 with no CON approved adult inpatient BMT programs. These three operational programs are at the following locations: BHM, (Miami-Dade County), MHW (Broward County) and UMHC (Miami-Dade County). Currently, OTSA 4 is the only service area statewide with more than one adult inpatient BMT provider.

Cleveland Clinic offers six "not normal" circumstances for which they contend approval of the proposal is merited:

- BMT should be deregulated from CON as it no longer falls within the "tertiary health services" definition
- Excessive outmigration of BMT patients from OTSA 4
- Northern OTSA 4 and contiguous areas in southern OTSA 3 do not have reasonably accessible or programmatically accessible BMT programs resulting in lower use rates

- South OTSA 3 Counties are not geographically accessible to any BMT program and therefore there is 100.0 percent outmigration for transplant and post-transplant treatment
- Incidence and prevalence of diseases requiring adult BMT and internal demand
- Internal demand for BMT based on new cases diagnoses at Cleveland Clinic Florida

Overall, the applicant expects for nearly all BMTs in the southern counties of OTSA 3 to occur outside of OTSA 3 because CCH contends there is a lack of programmatic and geographic access to BMT programs in OTSA 3. CCH states there is significant underutilization and suppression of BMT services in OTSA 3. The applicant presented an argument encouraging nearly 100 outmigration from a number of OTSA 3 counties to justify adding another access point to adult BMT services within OTSA 4. The reviewer notes that typically outmigration within the realm of health care planning is utilized as justification to approve a program in the area where patients are outmigrating from not where they are outmigrating to receive health care services. In addition, tertiary services are examined on a regional basis for transplant services—they are not examined on a county basis, nor do they contemplate a service area designated by an applicant.

The Agency notes that the statutory definition of a tertiary health services, pursuant to 408.032 (17), Florida Statutes, is "a health service which, due to its high level of intensity, complexity, specialized or limited applicability, and cost, should be limited to, and concentrated in, a limited number of hospitals to ensure the quality, availability, and cost-effectiveness of such service". According to the applicant's data points in the chart on page 45 of CON application #10566, there were 919 total inpatient BMT procedures for a population of 17,631,276. According to the applicant's Schedule 1, the equipment cost for the proposed project is $950,692 and the proposed staffing for year three of the program is estimated to be 13.00 FTEs with total operating expenses of $3,668,370 for 922 total patient days. According to FloridaHealthFinder.gov, compare site for the category of cancer and the condition/procedure of BMT for all adults 18+ from April 2017 to March 2018, there were 955 hospitalizations in the state with an ALOS for an inpatient BMT of 21.7 days with the charges ranging from $229,762 to $523,197 per procedure on average.

There is no CON approval required to set up or maintain outpatient BMT clinics or treatments. Nothing at present prevents CCH from implementing outpatient services and clinics at their newly acquired hospital-based cancer centers.

The BHM BMT program just began inpatient services on October 24, 2018 and has not had time to mature—nor can adequate health planning be analyzed on the program until maturation occurs and use rates can be analyzed. In addition, the applicant provides no statistical data that demonstrates that existing providers will not be adversely affected by approval of the proposed program—since need was not established and no discernable increase in access to BMT services to residents of OTSA 4 was demonstrated.

The reviewer notes that CCH failed to demonstrate that residents in OTSA 4 are unable to obtain adult BMT services. CCH also fails to demonstrate that OTSA 4 residents are experiencing now or likely to experience in the foreseeable future, poor, substantially delayed or clinically undesired health care outcomes as a result of the landscape of the existing adult inpatient BMT services in OTSA 4.

The Agency determined that in weighing and balancing the rule and statutory criteria, need for an additional adult inpatient BMT program was not established by the applicant. CCH did not establish that residents of OTSA 4 are not able to access BMT services or that BMT services are not available, either geographically or financially, to OTSA 4 residents. The applicant did not illustrate the enhancement to health care access to BMT services approval of the proposed tertiary service will bring to residents, especially in light that the proposed program will be located less than ten miles away (in a contiguous Zip Code) from an existing provider and that the newest provider of adult BMT services in OTSA 4 has only been providing services for two months prior to submission of the omissions for CON application #10566.

Quality of Care
The applicant states that the CCH System shares a mission, vision, values and commitment to principles. CCH states that the mission of the Cleveland Clinic is to provide better care of the sick, investigation into their problems and further education of those they serve.

The applicant demonstrated its ability to provide quality care.

Agency complaint records indicate that the applicant had one substantiated complaints within the three period ending on January 25, 2019.

Cost/Financial Analysis
The applicant states on Schedule 3 that funding will be provided by operating cash flows. With $86,052,000 in cash flows from operations, funding for the entire capital budget should be available as needed.

Given the very small impact the project will have on the hospital, the project appears financially feasible. However, the projections provided by the applicant are questionable especially in light of the 2021 net revenue per patient day projection of $6,248 vs the actual 2017 net revenue per patient day of $6,723. Because of the discrepancies highlighted, the project may not be as profitable as expected.

Strictly from a financial perspective, this project is not likely to have a material impact on competition to promote quality and cost-effectiveness.

Medicaid/Charity Care Commitment
In FY 2017 Cleveland Clinic provided 0.71 percent of patient days to charity care and 2.31 percent of patient days to Medicaid/Medicaid HMO.

CCH attests to having a long history of providing health services to the medically indigent.

Per the applicant's Schedule 7, CCH forecasts that self-pay will account for 0.04 percent of patient days and Medicaid will account for 1.15 percent of patient days in year one. In year two self-pay is expected to account for 0.07 percent of patient days and Medicaid is expected to account for 1.06 percent of patient days. In year three self-pay is expected to account for 0.21 percent of patient days and Medicaid is expected to account for 0.66 percent of patient days.

The applicant did/did not participate in the disproportionate share hospital (DSH) program for FY 2017-2016.

The applicant does not condition approval of the proposal to the minimum provision of any level of care to any payer group.

The reviewer notes that CCH, according to FHURS data for FY 2017, is the fifth lowest hospital provider in the State of Florida (by percentage in comparison to total revenue) for combined Medicaid and charity care. For the latest reporting period Cleveland Clinic reported total patient revenue of $1,188,011,000 and total Medicaid revenue/charity care (shown as deductions from revenue) of $34,687,000 (2.92 percent). During the same reporting period, BHM provided 15.74 percent ($664,492,687), UMHC (a class III specialty hospital) provided 9.70 percent ($259,126,937), MHW provided 14.56 percent ($433,316,340), of total revenue.

Architectural Analysis

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.

G. RECOMMENDATION

Deny CON #10566.

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