

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

A. PROJECT IDENTIFICATION

1. Applicant/CON Action Number

Largo Medical Center, Inc.
d/b/a Largo Medical Center/CON #10383
201 14th Street, SW
Largo, Florida 33770

Authorized Representative: Mr. Anthony M. Degina, Jr., CEO
(727) 588-5200

2. Service District/Subdistrict

Organ Transplantation Service Area 2 which includes: District 5 (Pinellas and Pasco Counties), District 6 (Hardee Highlands, Hillsborough, Manatee and Polk Counties), and District 8 (Charlotte, DeSoto, Glades, Hendry, Lee and Sarasota Counties only)

B. PUBLIC HEARING

A public hearing was not held or requested regarding the proposed project to establish an adult liver transplantation program at Largo Medical Center.

Letters of Support

The applicant submitted 17 letters of support and the Agency received one support letter independently, totaling 18 support letters. The support letters promoted both of the applicant's current co-batched proposals (CON application #10383 and CON application #10384). These support letters were of a form letter variety, indicating origination as follows: 14 from Pinellas County, one from Hillsborough County and three from out-of-state.

The primary theme in these support letters indicates that Largo Medical Center continues to deliver leading-edge care, research and medical education within the community, including the recent addition of kidney transplant services and that Largo Medical Center provides superior quality health care to all patients whom they serve.

Some of the support letters were from the following:

- Larry Ahern, State Representative, District 66, and Chris Latvala, State Representative, District 67, Florida House of Representatives
- The chief executive officer from each of the following area sister Hospital Corporation of America, Inc. (HCA) affiliated hospitals:
 - Northside Hospital
 - Palms of Pasadena Hospital
 - St. Petersburg General Hospital
- Two area physicians
- Tom Morrissette, President, Central Pinellas Chamber of Commerce

C. PROJECT SUMMARY

Largo Medical Center, Inc. d/b/a Largo Medical Center (CON application #10383), also referenced as LMC or the applicant, an affiliate of HCA, parented by HCA Holdings, Inc., seeks approval to establish an adult liver transplantation program in Organ Transplantation Service Area (OTSA or TSA) 2, which includes District 5, District 6, and District 8 excluding Collier County. The applicant is also seeking approval in this batching cycle to establish an adult pancreas transplantation program. The applicant is also approved to provide adult kidney transplantation through CON application #10205.

The proposed project's anticipated issuance of licensure is in November 2016, with initiation of service projected for January 2017.

Largo Medical Center has two sites sharing one hospital license (Largo Medical Center and Largo Medical Center-Indian Rocks) both located in Largo, Florida (District 5). LMC is located at 201 14th Street SW and is the site for the proposed project, which is to be integrated with the applicant's CON approved adult kidney transplantation program.

LMC currently holds a class 1 general hospital licensed for 256 acute care beds, Level II adult cardiovascular services and is a primary stroke center. Also, the applicant is CON approved to provide adult kidney transplantation (CON application #10205). Largo Medical Center-Indian Rocks is a class 1 general hospital located at 2025 Indian Rocks Road, and is licensed for 68 acute beds, 71 adult psychiatric beds, and 30 comprehensive medical rehabilitation beds (169 beds in total).

LMC is a statutory designated teaching hospital, affiliated with Nova Southeastern University (NSU) and the University of South Florida (USF). LMC states being the West Coast Academic Center of NSU, an

osteopathic medical school located in Broward County, Florida. LMC indicates that at the applicant's facility, over 120 interns, residents and fellows are in training.

The total project cost is \$1,869,683 and involves 2,884 gross square feet (GSF) of renovation, with no new construction. The total renovation cost is \$260,000. Total project costs include building, equipment, project development and start-up.

Schedule C includes the following condition:

- Largo Medical Center is a statutory teaching hospital, and will uphold the requirements to maintain that designation

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

As part of the fact-finding, the consultant, Steve Love analyzed the applications in its entirety with consultation from the financial analyst Eric West of the Bureau of Central Services, who evaluated the financial data, and Said Baniahmad 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 liver transplant programs. Therefore, it is the applicant’s responsibility to demonstrate the need for the project, including a projection of the expected number of adult liver transplants that will be performed in the first years of operation.

TSA 2 includes District 5, District 6, and District 8 (excluding Collier County) for adult liver transplantation. The service area currently has one operational adult liver transplant program located at Tampa General Hospital in District 6 (Hillsborough County).

There are seven operational adult liver transplantation programs in Florida, two in Service Area 1, one each in Service Areas 2 and 3 and three in Service Area 4. Cleveland Clinic Hospital’s (Service Area 4) program was not operational until July 11, 2013. The utilization chart below shows all adult liver transplantations performed during the five-year period ending December 31, 2014.

Florida Adult Liver Transplantation Utilization								
12-Month Reporting Periods Ending December 31, 2010 to December 31, 2014								
Service Area			12-Month Reporting Periods January 1 – December 31					
	County	Facility	2010	2011	2012	2013	2014	Total
1	Alachua	UF Health Shands Hospital	35	22	21	31	47	156
1	Duval	Mayo Clinic	166	164	165	146	157	798
2	Hillsborough	Tampa General Hospital	92	116	103	76	63	450
3	Orange	Florida Hospital	82	66	71	54	56	326
4	Broward	Broward Health Medical Center	26	28	25	14	17	110
4	Broward	Cleveland Clinic Hospital				9	21	30
4	Miami-Dade	Jackson Memorial Hospital	95	101	88	93	102	479
		Total	496	497	473	423	463	2,352

Source: Florida Need Projections Utilization Data for Adult and Pediatric Transplant Programs issued April 2011 - April 2015

During the five-year period shown above, Mayo Clinic in Duval County (Service Area 1) performed the most adult liver transplants in Florida at 33.93 percent (798/2,352), followed by Jackson Memorial Hospital (Service Area 4) with 20.37 percent (479/2,352), followed by Tampa

General Hospital (Service Area 2) with 19.13 percent (450/2,352), then Florida Hospital (Service Area 3) with 13.99 percent (329/2,352), next UF Health Shands Hospital (Service Area 1) with 6.63 percent (156/2,352), followed by Broward Health Medical Center (Service Area 4) with 4.68 percent (110/2,352) and finally Cleveland Clinic Hospital (Service Area 4) with 1.28 percent (30/2,352).

Unlike other hospital programs, transplant services are reliant upon donors, and patients are often placed on waiting lists. Utilization data, whether current or historic, is primarily an indication of the number of donors. Although wait lists are an indicator of need, without available donors, they are not by themselves a predictor of utilization.

The reviewer notes that the Organ Procurement Transplantation Network (OPTN), the national database of patient waiting lists for organ transplantation in the United States, shows 503 adults in Florida currently registered on the liver transplantation waiting list¹. See the organ by waiting time table below.

**OPTN Current Florida Wait List Registrants
Based on OPTN Data as of May 13, 2015**

	Liver
Total	503
< 30 Days	55
30 to < 90 Days	66
90 Days to < 6 Months	86
6 Months to < 1 Year	95
1 Year to < 2 Years	107
2 Years to < 3 Years	46
3 Years to < 5 Years	34
5 or More Years	14

Source: <http://optn.transplant.hrsa.gov/latestData/rptData.asp>, May 13, 2015

Donor/patient matches are also a factor in transplant services. The chart below contains the most recent five-year volume of liver donations by Florida residents.

**Florida Liver Donors Recovered
January 1, 2009 - December 31, 2014
Based on OPTN Data as of May 13, 2015**

	2014	2013	2012	2011	2010	2009
All Donor Types	496	470	480	478	465	437
Deceased Donor	496	470	478	478	465	436
Living Donor	0	0	2	0	0	1

Source: <http://optn.transplant.hrsa.gov/latestData/rptData.asp>, May 13, 2015

¹ As of May 13, 2015 per the OPTN website @ <http://optn.transplant.hrsa.gov>.

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As shown above, there were 496 Florida liver donors in 2014. The Florida Center for Health Information and Policy Analysis data indicates there were a total of 443 adult liver transplants performed at Florida hospitals in calendar year (CY) 2014. Therefore, the total procedures (443) were less than the total donors (496) by 53 in CY 2014. This data indicates that a surplus of livers was available for transplantation in CY 2014.

Agency data indicates that 358 of 443 (or 80.81 percent) of the adult patients (15 years of age or older) receiving liver transplants performed in Florida in CY 2014 were Florida residents². The remaining 85 adult patients had an unknown residence. Service Area 2 residents accounted for 77 of the 443 procedures, or 17.38 percent. Below is a chart to account for these totals.

**Adult Liver Transplants at Florida Hospitals
by Patient Residence
CY 2014**

Service Area	Transplants Performed	Percent of Total
1	88	19.86%
2	77	17.38%
3	87	19.64%
4	106	23.93%
Unknown	85	19.19%
Total	443	100.00%

Source: Florida Center for Health Information and Policy Analysis CY 2014 database, MS-DRGs 005 and 006

Service Area 2 residents generally do not migrate outside their home service area for adult liver transplantation, though there are some exceptions. Below is a chart to account for these procedures.

**Service Area 2 Resident Facility Selection
Adult Liver Transplantation Procedures
CY 2014**

Facility/Organ Transplant Service Area	Patient Total	Patient Percent
Tampa General Hospital (Service Area 2)	50	64.94%
Mayo Clinic (Service Area 1)	11	14.29%
Florida Hospital-Orlando (Service Area 3)	5	6.49%
Jackson Memorial Hospital (Service Area 4)	4	5.19%
UF Health Shands Hospital (Service Area 1)	4	5.19%
Cleveland Clinic Hospital (Service Area 4)	3	3.90%
Service Area 2 Total	77	100.00%

Source: Florida Center for Health Information and Policy Analysis CY 2014 database, DRGs 005 and 006

The above chart indicates that in calendar year 2014, 50 of the 77 (or 64.94 percent) of Service Area 2 residents/patients who had adult liver transplants remained in Service Area 2 for the procedure (with Tampa General Hospital being the sole adult liver transplant provider in the service area). Tampa General Hospital's service to Service Area 2

² DRGs 005 and 006 as reported in the Florida Center for Health Information and Policy Analysis database for CY 2014. There were 463 total adult liver transplant procedures reported to the local health councils for CY 2014. Some variation in the patient data is to be expected.

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residents consisted of applicable procedures for 23 Hillsborough County residents, 11 Pinellas County residents, 10 Lee County residents, nine Polk County residents, six Pasco and six Sarasota County residents (each), five Highlands and five Manatee County residents (each) and one Charlotte and one Hendry County resident (each).

Of Mayo Clinic's 11 patients from OTSA 2, three were residents of Manatee County, two were residents of Hillsborough County and Pinellas County (each) and one each were residents of the following counties: Charlotte, Highlands, Pasco and Sarasota. Of Florida Hospital-Orlando's five residents from OTSA 2, two were residents of Polk County and one each were residents of the following counties: Highlands, Lee and Pasco. Of Jackson Memorial Hospital's four residents from OTSA 2, two were residents of Lee County and one (each) was a resident of Highlands County and Polk County. Of UF Health Shands Hospital's four residents from OTSA 2, two were residents of Hillsborough County and Pinellas County (each). Finally, of Cleveland Clinic Hospital's three residents from OTSA 2, two were residents of Lee County and one was a resident of Highlands County.

In summary, in CY 2014, most OTSA 2 residents (50) who sought and received an adult liver transplant received it within OTSA 2 (at Tampa General Hospital). Of the 27 remaining OTSA 2 residents that migrated to a non-OTSA 2 authorized provider, migration occurred (most to least) as follows: Lee County (five residents), Highlands, Hillsborough and Pinellas Counties (four residents each), Manatee and Polk Counties (three residents each), Pasco County (two residents) and Charlotte and Sarasota Counties (one each).³

LMC asserts that CON application #10383 and CON application #10384 will be integrated with the adult kidney transplantation program recently approved and that this is prudent, as the adult kidney transplantation program recently received United Network for Organ Sharing (UNOS) approval. The applicant offers a copy of the UNOS adult kidney transplantation approval for LMC (Exhibit 1-1 of the application).

According to the applicant, the total adult population aged 18 years and older for July 2014 was 4,043,483 persons, ranking it second after TSA 4 in size (4,863,653) for the same population cohort and time frame. The applicant indicates that using Agency publications of reported liver transplantations in CY 2014, TSA 2 had the lowest rate--1.6 per 100,000 adults (age 18+) who received this procedure. See the table below.

³ This outmigration pattern summary is relatively consistent with that reported in the opposition letter submitted by Jackson Memorial Hospital, Jackson Health System.

**Number of Adult Liver Transplantation Programs,
Number of Transplants Performed, Number of Persons Aged 18 Years and Older
and the Rate per 100,000 Persons**

Reported Liver Transplants in CY 2014	Number of Transplant Programs	Number Performed	Adult Population 18+	Rate Per 100,000 18+	Number per Program
TSA 1	2	204	3,374,723	6.0	102
TSA 2	1	63	4,043,483	1.6	63
TSA 3	1	56	3,083,761	1.8	56
TSA 4	3	140	4,863,653	2.9	47
State	7	463	15,365,620	3.0	66

Source: CON application #10383, page 1-5, Table 1-1

The reviewer notes that the above adult population 18+ column differs from the corresponding co-batched CON application #10384, page 1-5, Table 1-1.

LMC contends that what is striking in the table above is that TSAs with more than one program performed better--that is, performed at a higher rate and more adult liver transplants than the two TSAs with only one program.

LMC asserts that the benefits of the proposed program are these:

- Greater public education and advocacy for adult liver transplantation
- Increase donors and organ donations within the area as education and information enhances awareness and creates positive associations to donate, particularly for cadaveric organs
- Higher likelihood of reduced wait times as those on the waiting list can list at more than one center that is proximate to home
- Enhanced physician education and training, particularly within a teaching hospital

b. Applications for the establishment of new adult liver transplantation program shall not normally be approved in a service planning area unless the following additional criteria are met:

- 1. The applicant is a teaching or research hospital with training programs relevant to the type of organ transplantation program proposed to be established preceding the application deadline, and no additional program has been approved for the same service planning area. (Rule 59C-1.044(10)(a) Florida Administrative Code).**

Largo Medical Center is a statutory teach hospital, as defined by section 408.07(45) Florida Statutes.

- 2. Applicants have established interactive programs of basic and applied research in organ failure, transplantation, immunoregulatory responses, and related biology.**

The applicant does not directly respond to this criterion.

- (b) Coordination of Services. The following services shall be available in the hospital, or through contractual arrangements:**

- 1. A department of gastroenterology, including clinics, and adequately equipped procedure rooms.**
- 2. Radiology services to provide complex biliary procedures, including transhepatic cholangiography, portal venography and arteriography.**
- 3. A laboratory with the capability of performing and promptly reporting the results of liver function tests as well as required chemistry, hematology, and virology tests.**
- 4. A patient convalescent unit for further monitoring of patient progress for approximately one month post-hospital discharge following liver transplantation.**

Largo Medical Center states having the required services as reflected in the application (Exhibit 2-1/Additional Equipment, Exhibit 2-2/Required and Conforming Laboratory Licenses, Exhibit 2-3/Transplant Immunology Service Agreement between Largo Medical Center and LifeLink, the Organ Procurement Organization (OPO), Exhibit 2-4/Largo Medical Center's Licenses and Designations and Exhibit 2-5/Resumes of Key Personnel in the Transplant Program).

- (c) Staffing Requirements. In addition to the general staffing requirements for all transplantation programs, program staff for liver transplantation programs shall be trained in the care of patients with hepatic diseases, and liver transplantation.**

The applicant states that both continuing education units (CEUs) and continuing medical educations (CMEs) will be provided to assure professional competencies and skill levels of personnel within the transplant center. According to LMC, appropriate and adequate personnel currently exist with the advent of the UNOS approval of the adult kidney transplantation program.

(d) Need Determination.

- 1. The application includes documentation that a minimum of five liver transplants will be performed within two years of certificate of need approval. Such evidence shall include, at a minimum, the number of livers procured in the state during the most recent calendar year, and an estimate of the number of patients in the service delivery area who would meet commonly-accepted criteria identifying potential liver transplant recipients. The caseload estimate shall be based on the number of persons with end-stage hepatic diseases in the service planning area, for which death due to the disease is likely to occur within one year without the transplantation.**

In years one through four, ending December 31, 2020, the applicant expects 13, 19, 23 and 30 procedures, respectively.

LMC states that according to the Scientific Registry of Transplant Recipients (SRTR), a total of 49 patients, age 18 years and older, were candidates on the adult liver transplant waiting list for Tampa General Hospital, as of June 30, 2014 (page 1-12, Table 1-3 of the application). The applicant also states that Tampa General Hospital reported that for CY 2014, 63 adult liver transplants were performed. LMC further contends that the ratio between transplants and waiting list numbers can be stated as 63:49 or one to 1.29 and that this means that for every transplant there is 1.29 persons on the waiting list in TSA 2. According to LMC, TSA 2 could benefit from the proposed project by potentially increasing access and reducing the wait list to approach a ratio of one to one.

The applicant discusses specific disorders that lead to liver transplantation (pages 1-13 to 1-17 of the application). LMC briefly discusses contraindications for transplants (pages 1-17 and 1-18 of the application) and the role of immunosuppression (pages 1-18 and 1-19 of the application). Additionally, the applicant discusses costs, charges and payers for liver transplantation (pages 1-19 to 1-23 of the application).

LMC maintains that of the 63 liver transplants performed and reported during CY 2014 at Tampa General Hospital, 47 were TSA 2 residents while 16 (or 25 percent) had in-migrated. LMC indicates patterns of urgency where people

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will list at more than one center to improve a match coming from the OPO serving the TSA that serves the transplant centers. The applicant contends that this practice echoes the policy where recovered organs are first used locally within the Donor Service Area.

Below is the applicant's forecasting for adult liver transplants to be performed within TSA 2, for the period 2017 to 2020, using baseline Tampa General Hospital data and in-migration to TSA 2.

Procedure for Forecasting the Numbers of Adult Liver Transplants by Year

Baseline Tampa General	Number	Percent		
Number of TSA Transplant Residents	48	80.0%		
Number of Transplants in migrated	9	15.8%		
Number performed Unknown County/ZIP Code	3	5.0%		
Total Performed Quarter 3, 2013 to Quarter 2, 2014	60	100.0%		
Number & Percent Market Share of State	403	14.9%		
Forecasting Adult Liver Transplants				
	2017	2018	2019	2020
TSA Population 18 Years and Older	4,273,253	4,339,296	4,406,479	4,468,742
State Population 18 Years and Older	16,192,559	16,464,384	16,673,239	16,906,794
TSA 2 rate @ 0.0181 per 1,000				
State Rate @ 0.030 per 1,000				
State Forecasted Number of Liver Transplants	486	494	500	507
TSA 2 use State Rate @ 0.030 Forecasted	72	74	74	76
Tampa General @ MS 57.8%	42	43	43	44
Largo Livers	12	18	22	28
Total Transplanted from TSA 2	54	61	65	72
Largo MS of TSA	16.6%	24.5%	29.5%	37.1%
Number TSA 2 Residents Outmigration	18	13	9	4
INMIGRATION TO TSA 2				
To Largo Medical Center @ 5.4% (third of Tampa Gen Rate)	1	1	1	2
To Tampa General Hospital @ 15.8% of TSA 2	11	12	12	12
Total Adult Liver Transplants Performed within TSA 2				
Largo Medical Center	13	19	23	30
Tampa General Hospital	53	54	55	56
Total Number of Transplants at TSA 2 Centers	66	73	78	85
Baseline TSA 2 Livers Transplanted all Centers	57	57	57	57
Increase over baseline	9	16	21	28

Source: CON application #10383, page 1-24, Table 1-8

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According to the applicant, the forecast presented above considers the current statewide experience by TSA, which summarized below in the table. The reviewer notes that the applicant's table narrative title indicates adult kidney transplantation. The reviewer confirms that MS-DRGs 005 and 006 apply to liver transplantation. See the table below.

**Number of Adult Kidney Transplants Performed within Each TSA by Patient
TSA for Quarter 3, 2013 to Quarter 2, 2014,
Agency Hospital Discharge Data File (DRGs 005 and 006)
Patient**

Hospital	TSA 1	TSA 2	TSA 3	TSA 4	Unknown County/ ZIP Code	Total
TSA 1	64	24	27	4	60	179
TSA 2	5	48	3	1	3	60
TSA 3	0	6	44	0	0	50
TSA 4	2	5	7	87	13	114
Total	71	83	81	92	76	403

Hospital	TSA 1	TSA 2	TSA 3	TSA 4	Total Unknown
TSA 1	64	24	27	4	119
TSA 2	5	48	3	1	57
TSA 3	0	6	44	0	50
TSA 4	2	5	7	87	101
Total	71	83	81	92	327

Out-migration by TSA		
TSA 1	7	9.9%
TSA 2	35	42.2%
TSA 3	37	45.7%
TSA 4	5	5.4%

In-migration by TSA		
TSA 1	55	46.2%
TSA 2	9	15.8%
TSA 3	6	12.0%
TSA 4	14	13.9%

Source: CON application #10383, page 1-25, Table 1-9

The applicant summarizes by indicating that for years one through four at LMC, it forecasts adult liver transplantation procedures of 13, 19, 23 and 30, respectively. Further, of these, in-migration represents, respectively by year, one, one, one and two. The total procedures at both the proposed project and Tampa General Hospital (TSA 2) is estimated by year respectively of 66, 73, 78 and 85. Finally, the applicant projects an increase over the baseline, by year respectively, of nine, 16, 21 and 28. The applicant contends that by year four, the estimated 85 adult liver transplants to be well within the number of livers procured and used during July 1, 2013 to June 30, 2014.

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LMC maintains that the proposed program would increase the numbers of patients listed and by doing so, increase the likelihood of a match within the service area. The applicant indicates that approval of the proposed program would assure that organs are retrieved and transplanted locally-- assuring better graft survival. The applicant contends that the fact that donated organs are leaving the service area is of concern and produces a map on page 1-8 of programs around the United States transplanting livers recovered by LifeLink which includes nine states other than Florida for July 1, 2013 to June 30, 2014.

2. The application includes documentation that the new liver transplantation program improves patient access.

LMC contends that the proposed project is particularly important, given that the placement of organs outside of the transplantation service area occurs.

The reviewer provides a mileage chart below, indicating the driving distances between current Florida adult liver transplant providers and the proposed location for CON application #10383.

Driving Distances in Miles - CON application #10383 and Florida Adult Liver Transplantation Providers								
Facility	Largo Medical Center	Tampa General Hospital	Florida Hospital-Orlando	UF Health Shands Hospital	Mayo Clinic	Cleveland Clinic Hospital	Broward Health Medical Center	Jackson Memorial Hospital
Largo Medical Center		24.58	109.99	152.60	245.88	251.71	262.24	279.09
Tampa General Hospital	24.58		88.29	131.14	224.41	251.68	262.21	279.06
Florida Hospital-Orlando	109.88	88.29		115.03	137.32	222.83	216.24	235.74
UF Health Shands Hospital	152.60	131.14	115.03		89.82	321.58	314.99	334.48
Mayo Clinic	245.88	224.41	137.32	89.82		330.04	327.17	342.94
Cleveland Clinic Hospital	251.71	251.68	222.83	321.58	330.04		17.93	30.84
Broward Health Medical Center	262.24	262.21	216.24	314.99	327.17	17.93		26.03
Jackson Memorial Hospital	279.09	279.06	235.74	334.48	342.94	30.84	26.03	

Source: www.Mapquest.com

The chart above illustrates that from the proposed project, the nearest adult liver transplant provider is Tampa General Hospital (at 24.58 miles distant), followed by Florida Hospital-Orlando (at 109.88 miles distant) followed by UF Health Shands (at 152.60 miles distant), with all other providers being 245.88 miles distant or further. Agency data has also previously shown that TSA 2 adult liver transplant recipients, in CY 2014, generally did not migrate outside of their home service area for this procedure. In fact, 50 or 77 (or 64.94 percent) of TSA 2's adult liver transplant patients remained in TSA 2 for transplant services (at Tampa General Hospital). As indicated, the remaining 27 TSA 2 residents seeking and obtaining this procedure received it outside of TSA 2.

2. Agency Rule Criteria

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

- a. Coordination of Services. Chapter 59C-1.044(3), Florida Administrative Code. Applicants for transplantation programs, regardless of the type of transplantation program, shall have:**
 - 1. Staff and other resources necessary to care for the patient's chronic illness prior to transplantation, during transplantation, and in the post-operative period. Services and facilities for inpatient and outpatient care shall be available on a 24-hour basis.**

The applicant notes that it has developed an adult kidney transplantation program that has already received UNOS approval to begin services. Largo Medical Center indicates that the proposed program along with the adult pancreas program will be integrated with the existing staff. In addition, the applicant maintains that the key leadership for the liver transplantation program is in place.

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Largo Medical Center indicates that it has the staff and resources necessary to provide both inpatient and outpatient care on a 24-hour basis. Also, LMC indicates having necessary staff and resources for patients prior to, during and in the post-operative period of transplantation.

The applicant provides a description for each of following services and program resources:

- Laboratory
- Radiology services
- Operating suites
- Intensive care unit
- Outpatient clinic pre and post-transplant follow-up
- Staff
- Transplant clinical coordinators for the transplantation programs
- Transplant social worker
- Transplant case manager
- Clerical personnel
- 24/7 intensivist coverage
- Rapid response team
- Medical intensive care unit (MICU)

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

The applicant states that LifeLink of Florida, located at 409 Bayshore Boulevard, Tampa, Florida 33606, is the federally assigned designated OPO for TSA 2 and a written agreement will be executed between LMC and LifeLink of Florida.

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

The applicant states that existing intensive care units at LMC include facilities for prolonged reverse isolation.

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

According to the applicant, the hospital has a clinical review committee whose duties and responsibilities shall include the systematic review of candidates for the adult liver transplantation program. The committee will consist of one or more of the following: vascular and thoracic surgeon, psychiatrist, nephrologist, social worker, cardiologist, pathologist and general medicine.

The duties of the committee will include application of the criteria developed by the Patient Care and Education Committee of the American Society of Transplant Physicians, document contraindications to liver transplantation, answer questions and explain the procedure, risks, and outcomes to candidates so they can arrive at a personal decision and determine candidate suitability.

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.

LMC states the written protocol for adult liver transplantation will be developed based on UNOS guidelines and hospital operating procedures, and will include input from LifeLink of Florida. The applicant offers an in-depth candidate evaluation and selection process (pages 2-8 to 2-21 of the application). Some of these topics include the following:

- If the patient is diabetic, additional testing
- Cardiac testing for all patients
- Pulmonary, imaging and endoscopic studies
- Consultants/evaluations
- Liver evaluation treatment orders
- Recipient admission work-up and preoperative management
- Postoperative orders and postoperative management
- Immunosuppression protocols
- Acute rejection and steroid treatment of acute rejection

- 6. Detailed therapeutic and evaluative procedures for the acute and long-term management of each transplant program patient, including the management of commonly encountered complications.**

The applicant includes details of therapeutic and evaluative procedures for the acute long-term management of patients in previous sections, providing a thorough overview of the resources and protocol for patient management.

- 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.**

LMC states that some of the supportive equipment is provided by LifeLink of Florida. However, the applicant further states the acquisition of two devices: a CardioQuip modular heater cooler (at a cost of \$17,750) and a liver by-pass machine (at a cost of \$49,483). Documentation is referenced in Exhibit 2-1 (Additional Equipment) in the application.

- 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.**

According to the applicant, LifeLink of Florida will provide such services prior to the expansion of LMC's clinical laboratory functions. LMC states that the contract appears in Exhibit 2-2 of the application. The reviewer notes that the signed and dated contract between Largo Medical Center, Inc. and LifeLink Foundation, Inc., d/b/a LifeLink Transplantation Immunology Laboratory, is found in Exhibit 2-3 of the application.

- 9. Pathology services with the capability of studying and promptly reporting the patient's response to the organ transplantation surgery.**

The applicant states that LMC's laboratory is accredited and includes corroborative information in Exhibit 2-3 of the application. The pathology services necessary for the

transplantation programs will have the capability to study and promptly report the patient's response to transplantation and analyze appropriate biopsy material.

The reviewer notes the following information found in Exhibit 2-2 of the application: curriculum vitae of Ricardo L. Munoz, MD, FCAP, (Laboratory Medical Director) with a Florida Department of Health licensure expiration of January 31, 2014, a Centers for Medicare and Medicaid Services (CMS).

Clinical Laboratory Improvement Amendments Certificate of Accreditation expiration of February 27, 2015 and an Agency clinical laboratory license expiration of June 30, 2015. The reviewer notes that according to FloridaHealthFinder.gov that the current license is effective July 1, 2015 to June 30, 2017.

10. Blood banking facilities.

LMC states that blood and blood products are provided by OneBlood located in St. Petersburg, Florida. LMC states having a blood bank as well as the hospital laboratory that assists in providing complex antibody identification.

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

LMC states a variety of printed materials for families and patients being available from UNOS and that this is important for providing information and procedures about risks, outcomes and maintenance of the transplant. According to the applicant, an educational curriculum will be developed that includes printed material, participation in groups and video/audio tapes for patients and their families. Topics listed in the application are as follows:

- Donors
- Histocompatibility testing
- Medications used in transplantation
- Biology
- Management of complications
- Outpatient strategies for long-term graft survival
- Patient management and reporting
- Nutritional support
- Ethical issues in transplantation
- Religious issues in donation/transplantation
- Current topics in transplantation
- Reimbursement and financial issues in transplantation

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

The applicant states that printed materials for patients and families are available from UNOS. LMC states that common areas where training is necessary is to promote long-term survival of the graft. LMC notes that communication with the patients' community physicians will be viewed as an ongoing effort, requiring the exchange of information and participation from the center, the patient and the community physician.

b. Staffing Requirements.

Applicants for transplantation programs, regardless of the type of transplantation program, shall meet the following staffing requirements. Chapter 59C-1.044(4), Florida Administrative Code.

- 1. A staff of physicians with expertise in caring for patients with end-stage disease requiring transplantation. The staff shall have medical specialties or sub-specialties appropriate for the type of transplantation program to be established. The program shall employ a transplant physician, and a transplant surgeon, if applicable, as defined by the United Network for Organ Sharing (UNOS) June 1994. A physician with one year experience in the management of infectious diseases in the transplant patient shall be a member of the transplant team.**

The applicant provides names and/or curriculum vitae for seven physicians that the applicant states have agreed to support the organ transplant program. Many of the listed physicians are stated to be on staff at LMC. A separate list states that 25 anesthesiologists are credentialed at LMC (page 2-26, Table 2-1 of the application). According to LMC, the program will benefit from these anesthesiologists who contract with LMC and who also provide anesthesiology services at Tampa General Hospital. According to LMC, the anesthesiologist group is TEAMHealth Anesthesia. The transplant surgeon, Hussein K. Osman-Mohamed, MD, PhD, FACS is mentioned along with other transplant and allied health staff (page 2-27 of the application). Also, see in the application, Exhibit 2-5/Resumes of Key Personnel in the Transplant Program.

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

LMC states the position is filled by Dr. Osman-Mohamed mentioned above. LMC indicates that Dr. Osman-Mohamed recently came to LMC to lead the transplantation team, coming from Tampa General Hospital where he practiced from 2010 to 2014. The reviewer notes that Dr. Osman-Mohamed's curriculum vitae confirms that he was in the Tampa General Medical Group (12/2010-11/2014) where his title was Transplant and Hepatobiliary Pancreatic Surgeon.

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

The applicant provides a table outlining the five types of nursing personnel available to the liver transplant program patients and families at LMC: critical care nurse educator, infection control practitioner, critical care medicine, pulmonary medicine and cardiology.

- 4. 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.**

LMC acknowledges that the complex needs of adult liver transplantation may, in addition to the full-time regular staff, require consultants with expertise in blood banking. LMC and OneBlood provide blood and blood products and assistance providing complex antibody identification is provided by the blood bank. The present scope of the hospital's laboratory is stated to include capabilities to provide cross-match, antibody screening, typing and Rh identification.

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

LMC states that the nutritionist will be responsible for: nutritional assessment/monitoring, documentation/quality assurance, patient counseling and education of staff/patient/family. The applicant provides names and profiles for three LMC registered dietitians capable of performing these functions.

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

LMC states that respiratory therapy staff will receive in-service training and participate in cross training with staff in the Transplant Center so that a broad understanding is achieved to supplement the technical requirements of their duties. According to LMC, it is a provider of full service respiratory therapy and has available required personnel to perform the functions. Ms. Darya Muraveynik, RRT, BS is mentioned.

7. 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.

LMC states that it is currently well staffed with personnel appropriate to this criterion, including case managers, social workers, psychologists and psychiatrists. The applicant previously provided names and additional resume profiles to support this statement.

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

The applicant states that it will comply with organ transplant data reporting requirements of the Agency.

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.

Availability

LMC states and the reviewer confirms that Tampa General Hospital is the sole adult liver transplantation provider in TSA 2. The reviewer also notes there are no CON approved adult liver transplant programs in TSA 2.

The applicant contends that the proposed project will enhance the capability to perform transplantation, as it will be integrated with the existing kidney transplantation program. LMC further contends that this integration will increase collaboration among hospitals as well as focus more emphasis on all organ transplantation donations.

Access

LMC states that components of access include geography, impediments, distance, time of travel, and eligibility criteria for qualifying for the service. Additionally, LMC states considerations such as financial cost and methods of reimbursement from third parties. LMC also states that another overlapping factor is utilization, because a full bed is not accessible if a person must be placed.

LMC contends that the limited supply of organs as well as the prognosis of the outcomes based on the health status of each candidate determines the accessibility of the service. LMC notes that candidates may list at more than one TSA in order to increase the likelihood that a retrieved organ from that TSA would match.

Extent of Utilization

The reviewer notes that as demonstrated in the five-year utilization data chart (see Item E.1.a.) in this report, historical utilization trends of adult liver transplantation in Florida fluctuate over time. The numbers of total adult liver transplants in Florida statewide have generally declined during the five-year period with 496 procedures reported (CY 2010) to 463 procedures reported (CY 2014). Over the same period (CY 2010 to CY 2014), these procedures in TSA 2 have also declined, from 92 to 63, respectively. Additionally (see Item E.1.a) in this report, the total adult liver procedures statewide in CY 2014 (443 procedures) were less than the total donors (496) by 53, CY 2014. This data indicates that a surplus of livers statewide was available for transplantation in CY 2014.

- 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.**

Largo Medical Center offers accreditation by The Joint Commission, holds Joint Commission advanced certification as a Primary Stroke Center, has Society of Cardiovascular Patient Care designation of Accredited Chest Pain Center with PCI and Agency licensure (Exhibit 2-4 of the application). The reviewer notes that the Agency licensure for LMC that was provided expired June 30, 2015 but that Agency records indicate that the licensed was renewed and is effective July 1, 2015 until June 20, 2017. The applicant mentions having the Gold Seal of Approval with The Joint Commission and that LMC is in the commission's list of *Top Performers on Key Quality Measures*. The applicant offers related recognitions under Focus on Quality (page 4-1 of the application).

The applicant notes that CMS Conditions of Participation must be met in order to serve Medicare and Medicaid subscribers and further notes that, for transplant programs, several provisions apply and for initial approval. The applicant provides these conditions, including requirements as specified in the survey for participation (pages 4-2 through 4-4 of the application). LMC provides numerous resumes of key staff in the transplant team, including the curriculum vitae of Hussein K. Osman-Mohamed, MD, PhD, FACS, other physicians, nursing staff and others (Exhibit 2-5 of the application).

Agency complaint records indicate, for the three-year period ending June 1, 2015, Largo Medical Center had four substantiated complaints. A single complaint can encompass multiple complaint categories. The substantiated complaint categories included--quality of care/treatment (two), resident/patient/client assessment (two) and one each for admission/transfer and discharge rights, emergency access, EMTALA and nursing services.

HCA, Inc., the parent company of Largo Medical Center, operates 49 Florida hospitals with 11,523 beds. Agency complaint records indicate, for the three-year period ending June 1, 2015, HCA had 213 substantiated complaints in the following complaint categories:

HCA Substantiated Complaint Categories for the 36 months Ending June 1, 2015	
Quality of Care/Treatment	74
Nursing Services	49
Emergency Access	34
EMTALA	27
Resident/Patient/Client Assessment	27
Resident/Patient/Client Rights	24
Administration/Personnel	17
Admission/Transfer & Discharge Rights	14
Physician Services	9
Physical Environment	7
Resident/Patient/Client Abuse	7
State Licensure	7
Infection Control	6
Unqualified Personnel	5
Dietary Services	3
Life Safety Code	3
Restraints/Seclusion General	3
Falsification of Records/Reports	2

Source: Florida Agency for Health Care Administration Complaint Records

- c. What resources, including health personnel, 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.

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Below is an analysis of the audited financial statements of HCA Holdings, Inc., the parent company pledging to fund this project, where the short-term and long-term measures fall on the scale (highlighted in gray) for the most recent year.

HCA HOLDINGS, INC.		
	Dec-14	Dec-13
Current Assets	\$8,930,000,000	\$8,037,000,000
Total Assets	\$31,199,000,000	\$28,831,000,000
Current Liabilities	\$5,480,000,000	\$5,695,000,000
Total Liabilities	\$37,697,000,000	\$35,759,000,000
Net Assets	(\$6,498,000,000)	(\$6,928,000,000)
Total Revenues	\$40,087,000,000	\$38,040,000,000
Excess of Revenues Over Expenses	\$2,373,000,000	\$1,996,000,000
Cash Flow from Operations	\$4,448,000,000	\$3,680,000,000
Short-Term Analysis		
Current Ratio (CA/CL)	1.6	1.4
Cash Flow to Current Liabilities (CFO/CL)	81.17%	64.62%
Long-Term Analysis		
Long-Term Debt to Net Assets (TL-CL/NA)	-495.8%	-433.9%
Total Margin (ER/TR)	5.92%	5.25%
Measure of Available Funding		
Working Capital	\$3,450,000,000	\$2,342,000,000

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

Capital Requirements and Funding:

The applicant lists \$14,880,968 for capital projects which include estimated capital budgets for years 2015, 2016, this CON application, and CON application #10384 which is being reviewed concurrently. The project will be funded by related company financing. A letter from HCA signed by the Vice President – Finance & Treasurer was provided pledging support.

Staffing:

The applicant’s Schedule 6A indicates no FTEs added for the proposed project, at least for the four year period of proposed service ending December 30, 2020 (December 30, 2020 is shown on page 4 of 4 on

Schedule 6A, with all other year ending dates on this schedule indicating December 31). In the Schedule 6A notes, LMC estimates two pancreas transplants in the first year of operation and four such transplants in its fourth year, indicating that half of the transplants will be done in connection with kidney transplantations. The notes further indicate that due to the small volume of cases, the applicant does not anticipate hiring any additional FTEs in order to operate the proposed program. The reviewer notes that CON application #10383 is for approval to establish an adult liver transplantation program. CON application #10384, submitted in this same batch cycle, is submitted by the same applicant, to establish an adult pancreas transplantation program.

Conclusion:

Funding for this project should be available as needed.

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

The immediate and long-term financial feasibility of the project is tied to expected profitability. The purpose of our analysis for this section is to evaluate the reasonableness of the applicant's profitability projections and, ultimately, whether profitability is achievable for this project. Our analysis includes an evaluation of net revenue per patient day (NRPD), cost per patient day (CPD), and profitability. We compared the NRPD, CPD, and profitability to actual operating results from teaching hospitals as reported on Florida Hospital Uniform Reporting System reports. For our comparison group, we selected hospitals from the same group (Group 8: Major Teaching Group) to the utilization projected by the applicant on a per patient day basis (PPD). Comparison group data was adjusted for inflation to match the second year projection (inflation factor was based on the New CMS Market Basket Price Index as published in the 1st Quarter 2015, Health Care Cost Review).

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

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	PROJECTIONS PER APPLICANT		COMPARATIVE GROUP VALUES PPD		
	Total	PPD	Highest	Median	Lowest
Net Revenues	310,313,195	3,353	3,766	2,300	1,914
Total Expenses	285,374,194	3,083	3,742	2,379	1,911
Operating Income	24,939,001	269	260	66	-433
Operating Margin	8.04%		Comparative Group Values		
	Days	Percent	Highest	Median	Lowest
Occupancy	92,555	59.7%	77.6%	61.3%	51.8%
Medicaid	4,808	5.2%	35.8%	17.6%	9.1%
Medicare	43,775	47.3%	45.1%	27.8%	16.5%

NRPD and CPD both fall within their respective ranges, but the operating margin falls slightly above its range. The project appears profitable, but likely not at the levels projected.

Conclusion:

The projections appear reasonable.

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

Analysis:

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

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

Price-Based Competition is Limited - Medicare and Medicaid account for 64.0 percent of hospital charges in Florida, while HMO/PPOs account for approximately 22.5 percent of charges. While HMO/PPOs negotiate prices, fixed price government payers like Medicare and Medicaid do not. Therefore price-based competition is limited to non-government payers. Price-based competition is further restricted as Medicare reimbursement in many cases is seen as the starting point for price negotiation among non-government payers. In this case 52.5 percent of patient days are expected to come from Medicare and Medicaid with 14.5 percent from HMO/PPOs.

The User and Purchaser of Health Care are Often Different – Roughly 86.5 percent of hospital charges in Florida are from Medicare, Medicaid, and HMO/PPOs. The individuals covered by these payers pay little to none of the costs for the services received. Since the user is not paying the full cost directly for service, there is no incentive to shop around for the best deal. This further makes price based competition irrelevant.

Information Gap for Consumers – Price is not the only way to compete for patients, quality of care is another area in which hospitals can compete. However, there is a lack of information for consumers and a lack of consensus when it comes to quality measures. In recent years there have been new tools made available to consumers to close this gap.

However, transparency alone will not be sufficient to shrink the information gap. The consumer information must be presented in a manner that the consumer can easily interpret and understand. The beneficial effects of economic competition are the result of informed choices by consumers.

In addition to the above barriers to competition, a study presented in The Dartmouth Atlas of Health Care 2008 suggests that the primary cost driver in Medicare payments is availability of medical resources. The study found that excess supply of medical resources (beds, doctors, equipment, specialist, etc.) was highly correlated with higher cost per patient. Despite the higher costs, the study also found slightly lower quality outcomes. This is contrary to the economic theory of supply and demand in which excess supply leads to lower price in a competitive market. The study illustrates the weakness in the link between supply and demand and suggests that more choices lead to higher utilization in the health care industry as consumers explore all alternatives without regard to the overall cost per treatment or the quality of outcomes.

Conclusion:

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

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

The applicant has submitted all information and documentation necessary to demonstrate compliance with the architectural review criteria. The cost estimate for the proposed project provided in Schedule 9, Table A and the project completion forecast provided in Schedule 10 appear to be reasonable. A review of the architectural plans, narratives

and other supporting documents did not reveal any deficiencies that are likely to have a significant impact on either construction costs or the proposed completion schedule.

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

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

Below is a chart to account for the applicant's and the district's Medicaid and charity care percentages for fiscal year (FY) 2013 provided by the Agency's Florida Hospital Uniform Reporting System (FHURS).

**Medicaid and Charity Care for
Largo Medical Center, Inc. (CON application #10383)
Compared to the District for Fiscal Year (FY) 2013**

Applicant	Medicaid and Medicaid HMO Days	Charity Percentage Service	Combined Medicaid and Charity Care
Largo Medical Center*	8.29%	2.28%	10.57%
District 5 Average	16.55%	3.97%	20.52

Source: FY 2013 Florida Agency for Health Care Administration Actual Hospital Budget Data

Note: *For this review, Largo Medical Center's fiscal year ended 12/31/2013

The table below illustrates Largo Medical Center's FY 2014-2015 low-income pool (LIP) and disproportionate share hospital (DSH) program participation, as of May 21, 2015.

Largo Medical Center, Inc. (CON application #10383) LIP and DSH Program Participation FY 2014-2015		
Applicant/Program	Annual Total Allocation	Year-to-Date Total Allocation As of May 21, 2015
Largo Medical Center/LIP	535,676	267,839
Largo Medical Center/DSH	1,523,262	1,142,447

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

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The applicant states that charity care under the revised reporting requirements for hospitals is included in the category “Self-Pay”. Largo Medical Center offers patient days and percentages by payer for what the applicant calls its recent published experienced. See the table below.

Largo Medical Center’s Patient Days by Payer

Payer	Patient Days	Percent
Self-Pay	3,830	4.2%
Medicare	43,298	47.3%
Medicare HMO	19,339	21.1%
Medicaid	8,365	9.1%
Other Governmental Payers	1,832	2.0%
Insurance/Charge Based	0	0.0%
Other Charge Based	0	0.0%
Commercial HMO/PPO	14,149	15.4%
Other Discounted	772	0.8%
Total	91,585	100.0%

Source: CON application #10383, Volume 2, page 9-2, Table 9-1

Largo Medical Center shows the program and impact on Largo Medical Center for the forecast period.

Patient Days by Payer with the Transplant Program

Payer	Year One Days	Year Two Days	Year Three Days	Year Four Days	Percent Year Four
Self-Pay	4,103	4,106	4,108	4,110	4.4%
Medicare	43,849	43,926	43,986	44,072	47.4%
Medicare HMO	20,608	20,620	20,632	20,644	22.2%
Medicaid	7,671	7,677	7,684	7,691	8.3%
Other Governmental Payers					0.0%
Insurance/Charge Based	64	93	113	147	0.2%
Other Charge Based	2,922	2,924	2,925	2,927	3.1%
Commercial HMO/PPO	13,446	13,454	13,461	13,469	14.5%
Other Discounted					0.0%
Total	92,663	92,800	92,909	93,060	100.0%

Source: CON application #10383, Volume 2, page 9-2, Table 9-2

According to the applicant, LMC will continue its mission to be both a teaching hospital and a community resource and the addition of the transplantation program does not impede its mission.

In the two tables above, LMC states that the Medicaid percentage for the current experience was 9.1 percent of patient days and that this percentage decreases to 8.3 percent by the fourth year of the forecast with the inclusion of the adult liver program. LMC asserts that this is because the numbers of Medicare and insurance rise. The applicant states that in the table above, Medicaid and Medicaid HMO is included together as “Medicaid”. The applicant notes that in the baseline experience, charity care is 4.2 percent of total patient days, rising to 4.4 percent at the end of the fourth year of the forecast period.

Schedule 7A indicates zero percent Medicaid/Medicaid HMO/charity care patient days for years one through four the proposed project. Notes to Schedule 7A indicate that the payer mix is based on the service area's historical adult pancreas transplant payer mix. The reviewer notes that CON application #10383 seeks approval to establish an adult liver transplantation program.

The reviewer notes that statewide during CY 2014, there were 47 Medicaid patients that received adult liver transplantation.⁴

Largo Medical Center offers no Medicaid or charity care conditions associated with the proposed project. However, the application states that it would accept any and all conditions that would support the donation and transplantation programs within the state. The applicant further states that whatever conditions would enhance public policy to promote organ donation and transplantation as an option would be accepted.

F. SUMMARY

Largo Medical Center, Inc. d/b/a Largo Medical Center (CON application #10383), parented by HCA Holdings, Inc., seeks approval to establish an adult liver transplantation program in Organ Transplantation Service Area (OTSA or TSA) 2, which includes District 5, District 6, and District 8 excluding Collier County. Largo Medical Center has two sites sharing one hospital license (Largo Medical Center (LMC) and Largo Medical Center-Indian Rocks) both located in Largo, Florida (District 5 – Pinellas County). The applicant is also seeking in this batching cycle approval to establishing an adult pancreas transplantation program. The applicant is CON approved to provide adult kidney transplantation through CON application #10205.

The proposed project's anticipated issuance of licensure is in November 2016, with initiation of service projected for January 2017.

The total project cost is \$1,869,683 and involves 2,884 GSF of renovation, with no new construction. The total renovation cost is \$260,000. Total project costs include building, equipment, project development and start-up.

Schedule C includes the following condition:

- Largo Medical Center is a statutory teaching hospital, and will uphold the requirements to maintain that designation

⁴ Based on the Agency's Florida Center for Health Information and Policy Analysis hospital discharge data

Need:

Need is not published by the Agency for liver transplants. It is the applicant's responsibility to demonstrate need. The planning for organ transplantation programs in Florida is done on a regionalized basis covering four regions defined by rule.

TSA 2 currently has one operational adult liver transplant program located at Tampa General Hospital in District 6 (Hillsborough County).

The reviewer notes that during the most recent calendar year (CY 2014) for which Agency publication data is available, TGH performed 63 adult liver transplants.

Largo Medical Center projects that it will perform 13 adult liver transplants in year one (CY 2017) and 19 in year two (CY 2018).

The Agency's hospital inpatient discharge data indicates that of TSA 2's 77 residents that received an adult liver transplant in CY 2014, 50 (or 64.94 percent) received the procedure at Tampa General Hospital. Therefore, TSA 2 residents generally did not migrate for this procedure in CY 2014. Also, over the past five years (CY 2010 to CY 2014), Tampa General Hospital realized a relative decline in adult liver transplants, from 92 to 63, respectively. Additionally, statewide, there was a surplus of livers available for transplantation in CY 2014.

The applicant contends that in CY 2014, TSA 2 adult residents 18 years of age or older experienced the lowest rate of adult liver transplantations (1.6 per 100,000 adults age 18+) of any TSA, with the average rate being 3.0 statewide (per 100,000 adults age 18+). LMC also contends that TSAs with more than one program performed at a higher rate and more adult liver transplants than the two TSAs with only one program.

LMC asserts that the benefits of the proposed program are these:

- Greater public education and advocacy for adult liver transplantation
- Increase donors and organ donations within the area as education and information enhances awareness and creates positive associations to donate, particularly for cadaveric organs
- Higher likelihood of reduced wait times as those on the waiting list can list at more than one center that is proximate to home
- Enhanced physician education and training, particularly within a teaching hospital

Quality of Care:

Largo Medical Center is accreditation by The Joint Commission, has The Joint Commission advanced certification as a Primary Stroke Center, has Society of Cardiovascular Patient Care designation of Accredited Chest Pain Center with PCI and Agency licensure. The applicant mentions having the Gold Seal of Approval with The Joint Commission and that LMC is in the commission's list of *Top Performers on Key Quality Measures*.

Agency complaint records indicate, for the three-year period ending June 1, 2015, Largo Medical Center had four substantiated complaints.

HCA, the parent company of Largo Medical Center, operates 49 Florida hospitals with 11,523 beds. Agency complaint records indicate, for the three-year period ending June 1, 2015, HCA had 213 substantiated complaints.

The applicant demonstrated the ability to provide quality care and provided a good description of the quality of care it plans for the proposed project.

Financial/Cost:

Funding for this project should be available as needed.

The projections appear reasonable.

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

Architectural:

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

Medicaid/Indigent Care:

The Agency's FY 2013 FHURS data indicates that Largo Medical Center provided 8.29 percent of its total patient days to Medicaid/Medicaid HMO patients and 2.28 percent to charity care.

The applicant participates in both the LIP and DSH programs.

The applicant's Schedule 7A shows no provision of Medicaid or charity care during year one through year four of operations.

The applicant does not propose to condition project approval to serve Medicaid or charity care patients. However, the application states that it would accept any and all conditions that would support the donation and transplantation programs within the state. The applicant further states that whatever conditions would enhance public policy to promote organ donation and transplantation as an option would be accepted.

G. RECOMMENDATION

Approve CON #10383 to establish an adult liver transplantation program in Pinellas County, District 5, Organ Transplantation Service Area 2. The total project cost is \$1,869,683. The project involves 2,884 GSF of renovation and a renovation cost of \$260,000.

CONDITION: Largo Medical Center is a statutory teaching hospital and will uphold the requirements to maintain that designation.

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 Services and Facilities Consultant Supervisor
Certificate of Need