

**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 #10384**  
201 14<sup>th</sup> 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 pancreas 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 #10384 and CON application #10383). 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 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 #10384)** also referenced as LMC or the applicant, an affiliate of Hospital Corporation of America, Inc. (HCA), seeks approval to establish an adult pancreas transplantation program in Organ Transplantation Service Area (TSA) 2, which includes District 5, District 6, and District 8 excluding Collier County. The applicant is also seeking approval in this batching cycle approval to establish an adult liver transplantation program. The applicant is approved to provide adult kidney transplantation through CON application #10205 and the proposed project is designed to complement the approved program.

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 14<sup>th</sup> 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, is a primary stroke center and has an approved kidney transplant program. 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 pancreas transplant programs. Therefore, it is the applicant's responsibility to demonstrate need for the project, including a projection of the expected number of adult pancreas 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 pancreas transplantation. The service area currently has one operational adult pancreas transplant program located at Tampa General Hospital in District 6 (Hillsborough County).

The applicant states that the major reason for pancreas transplantation is diabetes mellitus which also leads to renal failure. The applicant further states increased simultaneous transplantation of both organs (kidney and pancreas). The applicant anticipates that some portion of the patients that they expect to serve in this proposed program will have either had a kidney transplant or need to have both a kidney and a pancreas transplant.

Below are tables to account for both adult kidney and adult pancreas transplantations, statewide, over the five-year period ending December 31, 2014. Tables regarding both organ transplant programs are provided due to the applicant's contention that the organs may often be transplanted simultaneously.

There are nine operational adult kidney transplantation programs in Florida, three in TSA 1 and two each in TSAs 2, 3 and 4. The utilization chart below shows all adult kidney transplantations performed during the five-year period ending December 31, 2014.

Florida Adult Kidney Transplantation Utilization Calendar Year (CY) 2010–2014								
Service Area	County	Facility	2010	2011	2012	2013	2014	Total
1	Alachua	UF Health Shands Hospital	146	154	86	90	82	<b>558</b>
1	Duval	Mayo Clinic	117	139	161	160	147	<b>724</b>
1	Duval	UF Health Jacksonville*	29	1				<b>30</b>
2	Hillsborough	Tampa General Hospital	197	223	191	206	204	<b>1,021</b>
2	Lee	Gulf Coast Medical Center Lee Memorial Health System	35	28	29	37	55	<b>184</b>
3	Orange	Florida Hospital	176	148	171	161	124	<b>780</b>
3	Volusia	Halifax Health Medical Center	14	14	19	13	4	<b>64</b>
4	Broward	Cleveland Clinic Hospital**				7	31	<b>38</b>
4	Miami-Dade	Jackson Memorial Hospital	238	280	286	299	345	<b>1,448</b>
		<b>Total</b>	<b>952</b>	<b>987</b>	<b>943</b>	<b>973</b>	<b>992</b>	<b>4,847</b>

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

Notes: \* UF Health Jacksonville’s program was terminated effective 1/12/2011

\*\* Cleveland Clinic Hospital’s program was effective 7/29/2013

There are five operational adult pancreas transplantation programs in Florida, two in TSA 1 and one each in TSAs 2, 3 and 4. The utilization chart below shows all adult pancreas transplantations performed during the five-year period ending December 31, 2014.

Florida Adult Pancreas Transplantation Utilization CY 2010–2014								
Service Area	County	Facility	12-Month Reporting Periods January 1 – December 31					Total
			2010	2011	2012	2013	2014	
1	Alachua	UF Health Shands Hospital	16	10	0	2	4	<b>32</b>
1	Duval	Mayo Clinic	10	11	5	13	17	<b>56</b>
2	Hillsborough	Tampa General Hospital	17	14	2	0	0	<b>33</b>
3	Orange	Florida Hospital	7	9	10	7	10	<b>43</b>
4	Miami-Dade	Jackson Memorial Hospital	9	22	22	27	26	<b>106</b>
		<b>Total</b>	<b>59</b>	<b>66</b>	<b>39</b>	<b>49</b>	<b>57</b>	<b>270</b>

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

Data reported to the Agency show that significantly fewer adult pancreas transplants are performed annually than adult kidney transplants. All adult pancreas transplant providers are also adult kidney transplant providers, but not all adult kidney transplant providers perform adult pancreas transplantations.

During the five-year period shown above, Jackson Memorial Hospital in Miami-Dade County in TSA 4 performed the most adult pancreas transplants in Florida (39.26 percent), followed by Mayo Clinic in Duval County in TSA 1 (20.74 percent), followed by Florida Hospital in TSA (15.93 percent), then Tampa General Hospital in TSA 2 (12.22 percent) and then UF Health Shands Hospital in TSA 1 (11.85 percent).

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 4,797 adults in Florida are currently registered on the kidney transplantation waiting list, 23 adults in Florida on the pancreas transplantation waiting list and 112 adults in Florida are on the kidney/pancreas transplantation waiting list. See the organ by waiting time table below.

**Organ Procurement and Transplantation Network (OPTN)  
Current Florida Wait List Registrants  
Based on OPTN Data as of May 15, 2015**

	<b>Kidney</b>	<b>Pancreas</b>	<b>Kidney/Pancreas</b>
Total	4,797	23	112
< 30 Days	167	1	6
30 to < 90 Days	317	4	13
90 Days to < 6 Months	309	0	14
6 Months to < 1 Year	765	3	19
1 Year to < 2 Years	1,299	8	37
2 Years to < 3 Years	972	3	11
3 Years to < 5 Years	620	2	7
5 or More Years	348	2	5

Source: <http://optn.transplant.hrsa.gov/latestData/rptData.asp>, as of May 19, 2015 (Kidney and Pancreas and June 17, 2015 (Kidney/Pancreas))

As shown in the chart above, although a large percentage of kidney transplant patients do not also need a pancreas transplant, more patients need a kidney/pancreas transplant than pancreas alone.

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

**Florida Pancreas Donors Recovered  
January 1, 2009 - December 31, 2014  
Based on OPTN Data as of May 14, 2015**

	<b>2014</b>	<b>2013</b>	<b>2012</b>	<b>2011</b>	<b>2010</b>	<b>2009</b>
All Donor Types	85	78	91	100	84	115
Deceased Donor	85	78	91	100	84	115
Living Donor	0	0	0	0	0	0

Source: <http://optn.transplant.hrsa.gov/latestData/rptData.asp>, May 14, 2015.

As shown above, there were 85 Florida pancreas donors in 2014. Florida Center for Health Information and Policy Analysis data indicates there were a total of five adult pancreas transplants performed at Florida

**CON Action Number: 10384**

hospitals in CY 2014 Florida residents<sup>1</sup>. Local Health council data shows that there were 57 adult pancreas transplant procedures for CY 2014. Therefore, with either data set that is used, the total procedures (five or 57) fell short of the donors (85) in CY 2014.

Agency data indicates that all (five of five or 100 percent) of the adult patients (15 years of age or older) receiving pancreas transplants under MS-DRG 010 performed in Florida in CY 2014 were Florida residents.

Agency data indicates that 47 of 52 (or 90.38 percent) of the adult patients (15 years of age or older) receiving simultaneous kidney/pancreas transplants performed in Florida in CY 2014 were Florida residents<sup>2</sup>. The remaining five adult patients had an unknown residence. TSA 2 residents accounted for six of the 52 procedures, or 11.54 percent. Below is a chart to account for these totals.

**Simultaneous Adult Kidney/Pancreas Transplants at Florida Hospitals  
by Patient Residence  
CY 2014**

Service Area	Transplants Performed	Percent of Total
1	14	26.92%
2	6	11.54%
3	12	23.08%
4	15	28.85%
Unknown	5	9.62%
<b>Total</b>	<b>52</b>	<b>100.00%</b>

Source: Florida Center for Health Information and Policy Analysis CY 2014 database, MS-DRG 008

TSA 2 residents generally do not migrate outside their home service area for simultaneous adult kidney/pancreas transplantation--with 83.33 percent remaining in the TSA.

LMC asserts that CON application #10384 and CON application #10383 will be integrated with the adult kidney transplantation program recently approved and that with the same transplant team members, this provides greater access to Floridians and will ensure program approval at the national level within a reduced time frame. The applicant provides a copy of the United Network for Organ Sharing (UNOS) approval for the UNOS adult kidney transplantation approval for LMC (Exhibit 1-1 of the application).

<sup>1</sup> MS-DRG 010 (pancreas transplant only) as reported in the Florida Center for Health Information and Policy Analysis database for CY 2014. There were 57 total adult pancreas transplant procedures reported to the local health councils for CY 2014. Some variation in the patient data is to be expected. The reviewer notes that this discrepancy in reported procedures may be due to differences in coding.

<sup>2</sup> MS-DRG 008 (simultaneous kidney/pancreas) as reported in the Florida Center for Health Information and Policy Analysis database for CY 2014. There were 57 total adult pancreas transplant procedures reported to the local health councils for CY 2014. Some variation in the patient data is to be expected. The reviewer notes that this discrepancy in reported procedures may be due to differences in coding.

According to the applicant, TSA 2 total adult population aged 18 years and older for July 2014 was 4,043,483 persons, ranking it second after TSA 4 in size (4,888,782) for the same population cohort and time frame. The applicant indicates that using Agency publications of reported pancreas transplantations in CY 2014, TSA 2 had the lowest rate (0.0) per 100,000 adults (age 18+) who received this procedure. See the table below.

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

<b>Reported Pancreas Transplants in CY 2014</b>	<b>Number of Transplant Programs</b>	<b>Number Performed</b>	<b>Adult Population 18+ *</b>	<b>Rate Per 100,000 18+</b>	<b>Number per Program</b>
TSA 1	2	21	3,369,453	<b>0.6</b>	11
<b>TSA 2</b>	<b>1</b>	<b>0</b>	<b>4,073,627</b>	<b>0.0</b>	<b>0</b>
TSA 3	1	10	3,110,938	<b>0.3</b>	10
TSA 4	1	26	4,888,782	<b>0.5</b>	26
<b>State</b>	<b>5</b>	<b>57</b>	<b>15,442,800</b>	<b>0.6</b>	<b>11</b>

CON application #10384, page 1-5, Table 1-1

The reviewer notes that the above adult population 18+ column differs from the corresponding co-batched CON application #10383, page 1-5, Table 1-1 and from the population narrative (4,043,483) found of page 1-4 of the application.

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 performed more adult pancreas transplants than those TSAs with only one program, though TSA 4's rate approaches that of TSA 1. Per LMC, TSA 2 with zero adult pancreas transplants reported, demonstrates a lack of availability and access.

The applicant offers a brief discussion on Tampa General's CY 2009 to CY 2014 pancreas reported totals and kidney reported totals (page 1-6 of the application). LMC notes that there has been a significant decline in pancreas transplant procedures over the six year period (from 16 transplants in CY 2009 to zero transplants in CY 2014). The applicant indicates that whatever the reasons that underlie the decline in reported adult pancreas transplants, LMC will be able to increase access and retain retrieved organs within TSA 2.

LMC asserts that the benefits of the proposed program are:

- Greater public education and advocacy for adult pancreas transplantation as well as kidney 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

In years one through four, the applicant expects one, two, two and two procedures, respectively.

LMC states that according to the Scientific Registry of Transplant Recipients (SRTR), a total of four patients, age 18+ were candidates on the adult pancreas transplant waiting list for Tampa General Hospital, as of June 30, 2014 (page 1-13, Table 1-3 of the application). LMC further states that during that period, two were transplanted with a ratio of two on the waiting list for each person transplanted. LMC contends that TSA 2 could benefit by having another program that would potentially increase access and reduce the numbers of persons on the waiting list to approach a ratio of one-to-one.

The applicant discusses specific disorders that lead to pancreas transplantation (pages 1-14 to 1-18 of the application). According to LMC, pancreas transplantation is the only known therapy that achieves completely normal blood sugar levels.

LMC maintains on page 1-17, Table 1-4 of the application, that according to Agency hospital discharge data from the third quarter of 2013 to the second quarter of 2014, statewide 59 adult pancreas transplantations were performed of which Tampa General Hospital performed 11--of which five were residents from the TSA or from an unknown ZIP code. LMC asserts that the goal of the proposed program is to retain more residents of the service area and utilize the pancreata that are being sent out of Florida. Also LMC contends that the proposed site will provide another site for listing, as well as increase the likelihood that recovered pancreata will be used. 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 1-9 of programs around the United States transplanting pancreata recovered by LifeLink which includes four states other than Florida for July 1, 2013 to June 30, 2014.

LMC briefly discusses contraindications for transplants, stating that this is somewhat dictated by the calculated panel reactive antibodies (CPRA) results as to whether or not to proceed. LMC maintains that selection requires a detailed evaluation to determine the prognosis for each person who may undergo the procedure. LMC further discusses the role of

**CON Action Number: 10384**

immunosuppression (page 1-18 of the application) and a detailed review of costs, charges and payers for pancreas transplantation (pages 1-19 to 1-22 of the application).

The applicant indicates that since the proposed project addresses the complexity where simultaneous kidney and pancreas transplantation will occur, estimates were made on that basis. Below is the applicant’s forecasting for adult pancreas transplants to be performed within TSA 2, for the period 2017 to 2020, using a baseline pancreas and pancreas/kidney data (simultaneous) for the 12-month period ending June 30, 2014.

**Forecast of the Numbers of Adult Pancreas Transplantations  
To Be Performed in TSA 2**

<b>Baseline Pancreas and Pancreas/Kidney</b>					
Number performed at Florida Centers	59				
Number performed at Tampa General	11				
Statewide population 18+	15,442,800				
Statewide rate per 100,000	0.382				
Percent at Tampa General	18.6%				
Statewide percent of pancreas only to pancreas kidney	5.36%				
<b>Forecast</b>		<b>2017</b>	<b>2018</b>	<b>2019</b>	<b>2020</b>
<b>Largo Kidneys (from prior CON)</b>	<b>23</b>	<b>31</b>	<b>40</b>	<b>52</b>	
Estimated pancreas only	1	2	2	2	
TSA Population 18 Years and Old	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	
Forecast of Kidney Statewide @ rate 0.06424/1000	1,040	1,058	1,071	1,086	
Forecast of Pancreas/Pancreas/Kidney	56	57	57	58	
Tampa General	10	11	11	11	
Include Largo Medical Center Pancreas Component	1	2	2	2	
<b>Total pancreas performed in TSA 2</b>	<b>12</b>	<b>12</b>	<b>13</b>	<b>13</b>	
<b>Expected pancreas/pancreas kidney statewide</b>	<b>62</b>	<b>63</b>	<b>64</b>	<b>65</b>	
<b>Percent expected to be performed at TSA 2</b>	<b>18.8%</b>	<b>19.5%</b>	<b>20.2%</b>	<b>19.9%</b>	

Source: CON application #10834, page 1-23, Table 1-10

The applicant summarizes by indicating that for years one through four at Largo Medical Center, adult pancreas transplantation procedures of one, two, two and two, respectively. Overall, the total numbers of transplanted adult pancreas within TSA 2 at both Centers are stated to be by year respectively, 12, 12, 13 and 13. LMC expects the proposed project to be accommodated without staffing increases or program changes within the current transplantation center.

**b. Applications for the establishment of new adult pancreas and islet cell 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 previously discussed being the West Coast Academic Center of NSU and also being a site of teaching for USF College of Medicine. LMC also states that it offers residency and fellowship programs relevant to the program transplantation programs. LMC maintains that it will offer a nephrology residency program in conjunction with the adult kidney transplantation program.

## **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.**

**CON Action Number: 10384**

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 pancreas transplantation program is in place.

LMC 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. According to the applicant, the team and related staff will be used for the pancreas transplantation program and therefore time to quality is reduced.

LMC contends that key leadership for the pancreas transplantation program is in place. 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 organ procurement organization (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 pancreas 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, documenting contraindications to pancreas transplantation, answering questions and explaining 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 pancreas 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 2-12 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
- 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 more 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 2-17, 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 (pages 2-17 to 2-18 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 that 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 pancreas 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 pancreas 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.

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 pancreas transplantation provider in TSA 2. The reviewer notes there are no CON approved adult pancreas 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

As demonstrated in the five-year utilization data chart (see Item E.1.a.) in this report, historical utilization trends of adult pancreas transplantation in Florida fluctuate over time. The numbers of total adult pancreas transplants in Florida statewide have been relatively stable overall, during the five-year period with 59 procedures reported (CY 2010) to 57 procedures reported (CY 2014). Over the same period (CY 2010 to CY 2014), these procedures in TSA 2 have substantially declined, from 17 to zero, respectively. Additionally (see Item E.1.a) in this report, the total adult pancreas procedures statewide in CY 2014 (57) were less than the total donors (85) by 28, CY 2014. This data indicates that a surplus of pancreata 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).

**CON Action Number: 10384**

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:

<b>HCA Substantiated Complaint Categories for the 36 months Ending June 1, 2015</b>	
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.

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.

<b>HCA HOLDINGS, INC.</b>		
	<b>Dec-14</b>	<b>Dec-13</b>
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
<b>Short-Term Analysis</b>		
Current Ratio (CA/CL)	1.6	1.4
Cash Flow to Current Liabilities (CFO/CL)	81.17%	64.62%
<b>Long-Term Analysis</b>		
Long-Term Debt to Net Assets (TL-CL/NA)	-495.8%	-433.9%
Total Margin (ER/TR)	5.92%	5.25%
<b>Measure of Available Funding</b>		
Working Capital	\$3,450,000,000	\$2,342,000,000

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

**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 #10383 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 ending 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.

**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.

	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%		<b>Comparative Group Values</b>		
	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 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 #10384)  
Compared to the District for FY 2013**

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

Source: Fiscal Year 2013 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.

<b>Largo Medical Center, Inc. (CON application #10384) LIP and DSH Program Participation FY 2014-2015</b>		
<b>Applicant/Program</b>	<b>Annual Total Allocation</b>	<b>Year-to-Date Total Allocation As of May 21, 2015</b>
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

The Agency has previously noted that all adult pancreas transplant providers are also adult kidney transplant providers, as an adult pancreas transplantation alone is relatively rare and is more often aligned with kidney transplantation. In this context, most patients who receive a kidney transplant or kidney/pancreas transplant qualify for Medicare coverage as a result of being disabled due to their End Stage Renal Disease (ESRD) status, therefore few adult kidney transplants are provided to Medicaid or charity care patients. The reviewer notes that statewide during CY 2014, there were no Medicaid patients that received adult pancreas transplantation<sup>3</sup>.

<sup>3</sup> Based on the Agency’s Florida Center for Health Information & Policy Analysis hospital discharge data

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**

<b>Payer</b>	<b>Patient Days</b>	<b>Percent</b>
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%
<b>Total</b>	<b>91,585</b>	<b>100.0%</b>

Source: CON application #10384, 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**

<b>Payer</b>	<b>Year One Days</b>	<b>Year Two Days</b>	<b>Year Three Days</b>	<b>Year Four Days</b>	<b>Percent Year Four</b>
Self-Pay	4,103	4,106	4,108	4,110	4.4%
Medicare	43,745	43,775	43,804	43,829	47.3%
Medicare HMO	20,608	20,620	20,632	20,644	22.3%
Medicaid	<b>7,666</b>	<b>7,669</b>	<b>7,674</b>	<b>7,679</b>	8.3%
Other Governmental Payers					0.0%
Insurance/Charge Based	5	7	10	10	0.0%
Other Charge Based	<b>2,922</b>	<b>2,924</b>	<b>2,925</b>	<b>2,927</b>	3.2%
Commercial HMO/PPO	13,446	13,454	13,461	13,469	14.5%
Other Discounted					0.0%
<b>Total</b>	<b>92,495</b>	<b>92,555</b>	<b>92,614</b>	<b>92,668</b>	<b>100.0%</b>

Source: CON application #10384, 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. The reviewer notes that CON application #10384 seeks to establish an adult pancreas transplantation program.

LMC asserts that the percentage decrease 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 statewide during CY 2014, there were zero Medicaid patients that received adult pancreas transplantation.<sup>4</sup>

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 #10384)** seeks approval to establish an adult pancreas transplantation program in 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 and Largo Medical Center-Indian Rocks) both located in Largo, Florida (District 5-- Pinellas County). The applicant is also seeking approval in this batching cycle to establish an adult liver transplantation program. The applicant is CON approved to provide adult kidney transplantation through CON application #10205 and the proposed project is designed to complement the applicant's existing approved adult kidney program.

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.

<sup>4</sup> Based on the Agency's Florida Center for Health Information & Policy Analysis hospital discharge data

Schedule C includes the following condition:

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

**Need:**

Need is not published by the Agency for pancreas 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 pancreas 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 zero adult pancreas transplants. Over the past five years (CY 2010 to CY 2014), Tampa General Hospital realized a substantial decline in adult pancreas transplants, from 17 to zero, respectively. Additionally, statewide, there was a surplus of pancreata available for transplantation in CY 2014.

Largo Medical Center projects that it will perform one adult pancreas transplant in year one (CY 2017) and two in year two (CY 2018).

The applicant contends that in CY 2014, TSA 2 adult residents 18 years of age or older experienced the lowest rate of adult pancreas transplantations (0.0 per 100,000 adults age 18+) of any TSA, with the average rate being 3.0 statewide (per 100,000 adults age 18+). Agency publication data shows that regardless of whether a given TSA has one or two adult pancreas programs, for CY 2014, TSA 2 was the sole TSA that reported no adult pancreas transplants.

LMC asserts that the benefits of the proposed program are:

- Greater public education and advocacy for adult pancreas 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:**

LMC 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.

Most patients who receive a kidney or kidney/pancreas transplant qualify for Medicare coverage as a result of being disabled due to their ESRD status, therefore few adult kidney transplants are provided to Medicaid or charity care patients and an adult pancreas transplantation alone is relatively rare in comparison to kidney or kidney/pancreas transplants.

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 #10384 to establish an adult pancreas 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 total 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**