

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

A. PROJECT IDENTIFICATION

1. Applicant/CON Action Number

Delray Medical Center, Inc.
d/b/a Delray Medical Center/CON #10385
5352 Linton Boulevard
Delray Beach, Florida 33484

Authorized Representative: Mark H. Bryan
Chief Executive Officer
(561) 495-3100

2. Service District/Subdistrict

Organ Transplantation Service Area (TSA) 4 which includes: District 10 (Broward County), District 11 (Miami-Dade and Monroe Counties), District 8 (Collier County only), and District 9 (Palm Beach County only)

B. PUBLIC HEARING

A public hearing was not held or requested regarding the proposed adult heart transplantation program at Delray Medical Center.

Letters of Support

The applicant submitted many letters of support and the Agency received a few support letters independently. Appreciably, all of these support letters had a TSA 4 origin, the vast majority originating from Palm Beach County. Most of the support letters were from physicians affiliated with the applicant (including but not exclusively from the Tenet Florida Physicians Services Heart and Vascular Network [also referenced as the Tenet Heart and Vascular Network or THVN], the Center for Advanced Heart Therapies-Delray Medical Center and the South Florida Heart Institute) or otherwise affiliated with the applicant or its parent (Tenet Healthcare Corporation). There were 53 physician letters of support, with an additional support letter signed by six physicians of Infectious Disease Associates. This totaled 59 physician signatures in all. Many of

the support letters were of form letter varieties, though often including similar themes, either in total or in part. Some of these themes include:

- THVN is already providing more than 1,300 cardiac catheterizations and 300 open heart surgeries annually
- THVN routinely discharges 20,000 patients whose diagnosis fall within the category of a major cardiovascular disorder with 5,000 patients having a diagnosis of heart failure
- Delray Medical Center routinely receives referrals for cardiac care from other hospitals within and outside the Tenet Network
- Delivery of Transcatheter Aorta Valve Replacement (TAVR), Ventricular Assist Device (VAD) and Left Ventricular Assist Device (LVAD) within the Tenet Network and at Delray Medical Center, with is provided to patients with end stage heart failure which may be a bridge to heart transplantation
- The proposed project is the natural and next logical step to complete the continuum of care for these patients
- While median survival for VAD recipients is four years, median survival for heart transplant recipients is 13.6 years and 40 percent of patients undergoing transplants are bridged with a VAD
- Delray Medical Center has the only VAD program in Palm Beach County and already has much of the infrastructure and skilled nursing and clinical staff to transition to the provision of heart transplantation
- The number of patients in South Florida who are wait listed to receive a heart transplant continues to grow
- The nearest heart transplantation provider is 40 miles away from Delray Medical Center and the commute can be a deterrent to Palm Beach County residents
- Travel time to the nearest heart transplantation provider can be in excess of one hour, often in heavy traffic and this is an unnecessary burden on patients and families for the many pre- and post-transplantation visits that must be made
- When traveling outside of the Palm Beach County area for heart transplantation, the patient and family must develop a relationship with new physicians and this extends beyond the cardiologist, including primary care and multiple other specialists
- The proposed project would promote a continuity of care and bring an ease of access for patients and families in need of this service, reducing travel time, travel expense and the anxiety of transition to other outside area physicians and facilities

CON Action Number: 10385

- Palm Beach County is the most populated county in the state without a heart transplantation program
- The service area is in excess of 20,000,000 residents and a fourth adult heart transplantation program would be supported, given the current number of residents and expected growth in the area

The reviewer confirms that according to population estimates for July 1, 2015 from the Agency's Florida Population Estimates and Projections by AHCA District 2010 to 2013 publication, issued February 2015, Palm Beach County is the most populated county in Florida without a heart transplantation program. However, from the same source for the same period, TSA 4's total population is estimated at 6,246,180 residents and the statewide population is estimated at 19,816,176 residents.

Some of the support letters were from the following:

- Mary Lou Berger, Vice-Mayor, Palm Beach County Commission, District 5
- The chief executive officer from each of the following sister Tenet Healthcare Corporation affiliated hospitals
 - Coral Gables Hospital
 - Delray Medical Center
 - Florida Medical Center a campus of North Shore Medical Center
 - Good Samaritan Medical Center
 - Hialeah Hospital
 - North Shore Medical Center
 - Palm Beach Gardens Medical Center
 - St. Mary's Medical Center
 - West Boca Medical Center

One support letter, from the Dean and Executive Director of Medical Affairs, Charles E. Schmidt, College of Medicine, Florida Atlantic University, indicates that the proposed project would add an important learning opportunity for his school's medical students and residents. One support letter was from the Chief, Division Chief of EMS, Delray Beach Fire Rescue, one from the Battalion Chief and one from the Deputy Chief of Operations (ret.), Palm Beach County Fire Rescue. Regarding area media support, one support letter was from an announcer from Legends Radio 100.3 FM/WLML-FM and another from a news anchor with ABC 25 WPBF, Hearst Television, Inc. There were also a few letters from patients and families of Delray Medical Center who received heart transplantation services at Jackson Memorial Hospital.

Letter of Opposition

The Agency received a letter of opposition to this proposed project from Wael K. Sarsoum, MD, President, Cleveland Clinic Florida. Dr. Sarsoum notes the existing three adult heart transplant providers in TSA 4 and the adult heart transplantation utilization of each of these providers for calendar year (CY) 2014. The reviewer notes that these utilization totals are shown in Item E.1.a. of this report. Dr. Sarsoum indicates that Cleveland Clinic Florida and Memorial Regional Hospital have yet to be certified by the Centers for Medicare and Medicaid Services (CMS), that this certification may only be sought after performing 10 adult heart transplants within a trailing 12-month period and that until this CMS certification is received, new programs cannot seek payment from Medicare for its patients. Dr. Sarsoum maintains that certification is a significant milestone for new programs.

Dr. Sarsoum asserts that most importantly is the existing competitive landscape and their volume of heart transplants. Dr. Sarsoum contends that there is a corollary between the number of cases and quality and proficiency of an institution and its transplant team. Dr. Sarsoum further contends and the reviewer confirms that, by rule, an application for a certificate of need to establish a new heart transplantation program shall not normally be approved in a service area unless each existing heart transplantation provider in the applicable service area performed a minimum of 24 heart transplants in the most recent calendar year preceding the application deadline for new programs, and no other heart transplantation program has been approved for the same service planning area (see Item E.2.(b) and E.2.(b)(1) of this report).

Dr. Sarsoum emphasizes that the minimum volume criteria (24 adult heart transplantations) is per provider within the service area, not in total. The reviewer confirms that none of the existing adult heart transplantation providers in TSA 4 in CY 2014 met the 24 adult heart transplantation minimum volume criteria, with the adult heart transplant volume of each provider being as follows: six procedures (each) at Jackson Memorial Hospital and Memorial Regional Hospital and four procedures at Cleveland Clinic Florida (also see Item E.1.a. of this report). The reviewer notes that to meet the rule criterion, the three existing adult heart transplantation providers in TSA 4 would have had to have performed 72 procedures, cumulatively, in CY 2014. However, local health council data confirms that only 16 such procedures were performed in TSA 4 for CY 2014.

Dr. Sarsoum asserts that Cleveland Clinic Florida and Memorial Regional Hospital are in their infancy in terms of the development cycle for new programs and that their ultimate success is dependent on continuation of program development, their impact on mitigating out-migration from the service area and developing a quality program with great outcomes. Dr. Sarsoum additionally asserts that approval of the proposed project would have a detrimental effect on the two new providers which have yet to receive CMS certification, demonstrate their effectiveness, program outcomes and successes and impacts on outmigration.

C. PROJECT SUMMARY

Delray Medical Center, Inc., d/b/a Delray Medical Center (CON application #10385), also referenced as DMC or the applicant, a for-profit Class 1 hospital and an affiliate of Tenet Healthcare Corporation (Tenet), proposes to establish an adult heart transplantation program at Delray Medical Center, in Delray Beach, Palm Beach County, Florida, District 9, TSA 4. Tenet operates a total of 10 hospitals in Florida--Palm Beach Gardens Medical Center, St. Mary's Medical Center, Good Samaritan Medical Center, Delray Medical Center, West Boca Medical Center, Florida Medical Center (a campus of North Shore), Palmetto General Hospital, North Shore Medical Center, Hialeah Hospital and Coral Gables Hospital. All these facilities are located in TSA 4.

Delray Medical Center is a 493-bed general hospital, licensed for 350 acute care, 48 adult psychiatric, five adult substance abuse and 90 comprehensive medical rehabilitation beds. DMC offers non-CON regulated Level II adult cardiovascular services and is a comprehensive stroke center. DMC is also a Level I Trauma Center¹. The applicant does not currently provide and is not CON-approved to provide any transplantation services.

The applicant indicates that the proposed project service area is based on parts of TSA 4, primarily Palm Beach County, with the assumption that there will be immigration volume generated by other counties close to Palm Beach County, specifically Martin and St. Lucie, served by the Tenet Florida Heart and Vascular Network.

¹ This is confirmed, per the Florida Department of Health, Office of Trauma website at <http://www.floridahealth.gov/licensing-and-regulation/trauma-system/documents/traumacenterlisting20151.pdf>.

Project costs total \$329,725. These costs include equipment, project development and start-up costs. There is no reported construction or renovation associated with the project.

The applicant's adult heart transplant program, if approved, anticipates to be both licensed for and to initiate service effective January 1, 2016.

Schedule C of the application includes the following conditions:

1. Video Conferencing. The applicant will perform the transplant with a live video conferencing feed to Florida Atlantic University Charles E. Schmidt College of Medicine for training and education of its residents, fellows and other medical students, subject to patient consent, once a year for the first two years, increasing to quarterly by year three.
2. Outreach to Enhance Organ Donation and Transplant Services. The applicant will enhance and educate the community on the importance of organ donation and benefits of transplantation. To accomplish this, the applicant will:
 - a. Either host or attend a minimum of six community outreach events per year where it will provide transplant education, organ donation information from Life Alliance and other useful informative material. This will begin immediately at the start-up of the program.
 - b. The applicant will provide public service announcements on radio stations in the south Florida market that will educate listeners on the importance of organ donation.
 - c. The applicant will meet regularly with Life Alliance and assist Life Alliance in meeting with families of minorities.
3. Support Group for End Stage Heart Disease, Heart Transplant Candidates and Recipients. The applicant will host regularly scheduled support groups for patients who have either been diagnosed with end stage heart failure, undergoing evaluation for transplant candidacy, awaiting a heart transplant or have received a heart transplant.
4. Training and Education.
 - a. Community Continuing Medical Education: The applicant will offer a minimum of two Grand Rounds and transplant topics, annually, as part of its surgical series, open to all health care professionals within the community.

- b. Cardiovascular Care Symposium: The applicant will invite and secure an expert in the field of heart transplantation to speak at the Tenet Heart and Vascular Network's yearly Innovations in Cardiovascular Care continuing medical education symposium.
- c. Nurse Orientation: All (not just transplant) new employed Registered Nurses at Delray Medical Center, as part of their orientation, will receive transplant "aware" orientation. Topics to be covered will include but are not limited to organ donation, overall transplant evaluation and eligibility and organ specific education. All existing nurses at DMC will be provided transplant "aware" orientation within six months of initiating the transplant program at the hospital.

NOTE: Should the project be approved, the applicant's conditions would be reported in the annual condition compliance report as required by Rule 59C-1.013 (3) Florida Administrative Code. The Agency will not place a condition on already mandated reporting requirements.

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 application in its entirety with consultation from the financial analyst Eric West of the Bureau of Central Services, who evaluated the financial data. There is no reported construction or renovation associated with the proposed project.

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 heart 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 heart transplants that will be performed in the first years of operation.

TSA 4 includes Districts 10 and 11, Collier County in District 8 and Palm Beach County in District 9. The service area has three operational adult heart transplant programs--Cleveland Clinic Hospital and Memorial Regional Hospital (Broward County, District 10) and Jackson Memorial Hospital (Miami-Dade County, District 11). During CY 2014, TSA 1 had two adult heart transplantation programs, TSAs 2 and three had one each and TSA 4 had three transplantation programs.

Data reported to the Agency by the local health councils for CY 2014 show the following adult heart transplant utilization, by facility, service area and district:

| Florida Adult Heart Transplantation Program Utilization January 2014 – December 2014 | | | |
|---|---------------------|-----------------|-------------------------|
| Hospital | Service Area | District | Total Procedures |
| UF Health Shands Hospital | 1 | 3 | 21 |
| Mayo Clinic | 1 | 4 | 28 |
| Tampa General Hospital | 2 | 6 | 43 |
| Florida Hospital | 3 | 7 | 11 |
| Cleveland Clinic Hospital * | 4 | 10 | 4 |
| Memorial Regional Hospital ** | 4 | 10 | 6 |
| Jackson Memorial Hospital | 4 | 11 | 6 |
| TOTAL | | | 119 |

Source: Florida Adult Organ Transplantation Program Utilization data published April 2015

* Operational 10/21/2014

** Operational 01/07/2014

As shown in the table above, in CY 2014, among Service Area 4 providers, Memorial Regional Hospital (Broward County) and Jackson Memorial Hospital (Miami-Dade County) provided six adult heart transplantation procedures each and Cleveland Clinic Hospital (Broward County) provided four such procedures. Additionally, as shown above, Tampa General Hospital (Hillsborough County) provided 43 procedures, Mayo Clinic provided 28 procedures, UF Health Shands Hospital provided 21 and Florida Hospital (Orange County) performed 11 procedures. Below is a five-year chart to account for adult heart transplantation utilization, by service area, county and facility, CY 2010 through CY 2014.

| Florida Adult Heart 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 | 34 | 21 | 19 | 19 | 21 | 114 |
| 1 | Duval | Mayo Clinic | 26 | 25 | 24 | 24 | 28 | 127 |
| 2 | Hillsborough | Tampa General Hospital | 53 | 54 | 50 | 44 | 43 | 244 |
| 3 | Orange | Florida Hospital * | | | 6 | 5 | 11 | 22 |
| 4 | Broward | Cleveland Clinic Hospital ** | | | | | 4 | 4 |
| 4 | Broward | Memorial Regional Hospital *** | | | | | 6 | 6 |
| 4 | Miami-Dade | Jackson Memorial Hospital | 28 | 27 | 24 | 14 | 6 | 99 |
| | | Total | 141 | 127 | 123 | 106 | 119 | 616 |

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

* Operational 01/31/2012

** Operational 10/21/2014

*** Operational 01/07/2014

During the five-year period shown above, Tampa General Hospital in Hillsborough County in TSA 2 performed the most adult heart transplants in Florida (39.61 percent), followed by Mayo Clinic in Duval County in TSA 1 (20.62 percent), followed by UF Health Shands Hospital in TSA 1 (18.51). The three TSA 4 programs provided the following percentage of heart transplant during the five-year period: Jackson

Memorial Hospital in Miami-Dade County provided 16.07 percent Memorial Regional Hospital in Broward County provided 0.97 percent and Cleveland Clinic Hospital in Broward County provided 0.65 percent of all heart transplants.

It is noted that 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 240 adults in Florida currently registered on the heart transplantation waiting list². 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**

| | Heart |
|-----------------------|--------------|
| Total | 240 |
| < 30 Days | 23 |
| 30 to < 90 Days | 31 |
| 90 Days to < 6 Months | 29 |
| 6 Months to < 1 Year | 44 |
| 1 Year to < 2 Years | 52 |
| 2 Years to < 3 Years | 26 |
| 3 Years to < 5 Years | 22 |
| 5 or More Years | 13 |

Source: <http://optn.transplant.hrsa.gov/latestData/rptData.asp>, as of May 15, 2015

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

**Florida Heart Donors Recovered
January 1, 2009-December 31, 2014
Based on OPTN Data as of May 15, 2015**

| | 2014 | 2013 | 2012 | 2011 | 2010 | 2009 |
|-----------------|-------------|-------------|-------------|-------------|-------------|-------------|
| All Donor Types | 163 | 160 | 176 | 168 | 160 | 144 |
| Deceased Donor | 163 | 160 | 176 | 168 | 160 | 144 |
| Living Donor | 0 | 0 | 0 | 0 | 0 | 0 |

Source: <http://optn.transplant.hrsa.gov/latestData/rptData.asp>, as of May 15, 2015

² As of May 15, 2015 per the OPTN website @ <http://optn.transplant.hrsa.gov>.

As shown above, there were 163 Florida heart donors in 2014. Florida Center for Health Information and Policy Analysis data indicates there were a total of 118 adult heart transplants and 434 adult heart implant assist device procedures performed at Florida hospitals in CY 2014. The total procedures (118 adult heart transplants) were fewer than the donor recovery total of 163--a difference of 45 more donors than adult heart transplant procedures, in CY 2014.

Agency data indicates that 110 of 118 (or 93.22 percent) of the adult patients aged 15+ receiving heart transplants performed in Florida in CY 2014 were Florida residents³. The remaining eight adult patients had an unknown residence. Service Area 4 residents accounted for 18 of the 118 procedures, or 15.25 percent. Below is a chart to account for these totals.

**Adult Heart Transplants at Florida Hospitals
by Patient Residence
Calendar Year 2014**

| Service Area | Transplants Performed | Percent of Total |
|---------------------|------------------------------|-------------------------|
| 1 | 27 | 22.88% |
| 2 | 33 | 27.97% |
| 3 | 32 | 27.12% |
| 4 | 18 | 15.25% |
| Unknown | 8 | 6.78% |
| Total | 118 | 100.00% |

Source: Florida Center for Health Information and Policy Analysis CY 2014 database, MS-DRGs 001 and 002 (excluding heart implant assist devices)

Service Area 4 residents migrated at a rate of 50.0 percent outside their home service area for adult heart transplantation in CY 2014. The reviewer notes that in CY 2014, nine of the 18 TSA 4 residents who had adult heart transplants remained in Service Area 4 for the procedure while the remaining nine residents received the procedure outside of Service Area 4. Tampa General Hospital's service to Service Area 4 residents consisted of procedures for seven TSA 4 residents. In CY 2014 two Palm Beach County residents outmigrated to TSA 1 for heart transplant services.

The reviewer notes that in CY 2014, Service Area 4 had the most operational adult heart transplant providers of any service area statewide and for the same period, had the fewest adult heart transplants according to Agency inpatient discharge data. Cleveland Clinic Hospital and Memorial Regional Hospital first began reporting adult heart transplants in CY 2014 and as relatively new providers of this service

³ There were 119 total adult heart transplant procedures reported to the local health councils for CY 2014. Some variation in the patient data is to be expected.

these two hospitals can be reasonably expected to increase their volume going forward. However, the reviewer also notes that from CY 2010 to CY 2014, statewide, providers reported that adult heart transplants declined from 141 to 119, respectively and for the same period, Service Area 4's reported adult heart transplant volume declined from 28 to 16, respectively.

For the five-year period ending December 31, 2014, given relatively declining demand for adult heart transplantation statewide and at TSA 4's existing adult heart transplantation providers as a whole for the same five-year period and a significant outmigration rate to a non-TSA 4 facility to have heart transplant performed in CY 2014--it is reasonable to conclude that a fourth adult heart transplantation provider could reduce outmigration but could also reduce volumes at existing facilities overall.

It is also reasonable to expect that the implantation of heart assist devices will likely lower heart transplant volume. The applicant provided many Tenet Network and DMC/area physician support letters, indicating that DMC is a premiere provider of TAVR, VAD and LVAD procedures. The chart below overall trends markedly upward in increasing heart assist procedures but indicates somewhat declining statewide heart transplant procedures. A steady rise in heart assist implants seems to correlate with somewhat declining heart transplantations. A Florida hospital is not required to have a heart transplantation program in order to provide heart assist implants. The chart below shows the state's heart transplants and heart assist volume for the previous five calendar years.

**Heart Transplant and Heart Assist Implant Discharges
All Florida Hospitals
CY 2010-2014**

| Year | Heart Transplants | Heart Assist | Total Heart Transplant/ Assist Discharges |
|-------------|--------------------------|---------------------|--|
| 2010 | 148 | 193 | 341 |
| 2011 | 139 | 243 | 382 |
| 2012 | 134 | 303 | 437 |
| 2013 | 127 | 346 | 473 |
| 2014 | 140 | 434 | 574 |

Source: Florida Center for Health Information and Policy Analysis Hospital Discharge data for the appropriate years

Note: Heart Assist ICD-9 Codes include 37.6, 37.60, 37.62, 37.65, 37.66 and 37.68

As shown above, heart assist implantation increased from 193 procedures in CY 2010 to 434 in CY 2014, or by 224.87 percent. According to local health council data, heart transplant volume actually decreased statewide by 15.60 percent from CY 2010 to CY 2014 (141 procedures to 119 procedures, respectively). The Florida Center for Health Information and Policy Analysis database for this same procedure for the same period also shows a decline (148 procedures to 140 procedures) though a more moderate decline of 5.71 percent. The same procedure over the same period decreased for TSA 4 by 42.86 percent (28 procedures to 16 procedures, respectively). As previously shown, TSA 4 already has a total of three operational adult heart transplantation programs, the most of any TSA. Project approval would place a fourth such provider in the TSA.

The three TSA 4 providers of adult heart transplantation (Cleveland Clinic Hospital, Memorial Regional Hospital and Jackson Memorial Hospital) averaged 5.33 procedures each in CY 2014, the first year all three providers were operational to provide adult heart transplants.

The applicant's first year volume estimate is 8.0 procedures, the second year estimate is 12.0 procedures and the third year estimate is 13.0 procedures. DMC's first year estimate (8.0 procedures by December 31, 2016) exceeds by 2.67 procedures (or 50.09 percent) the average (5.33 procedures) at TSA 4's operational providers. The applicant's second year estimate (12.0 procedures by December 31, 2017) exceeds by 6.67 procedures (125.14 percent) the average. Considering statewide volumes declining and TSA 4 volumes declining for the five-year period ending December 31, 2014, the applicant's volume estimates appear ambitious. The Agency notes that the applicant's projections meet the CMS minimum annual volume requirement for 10 procedures, by year two.

According to DMC, the proposed project will:

- Increase access to heart transplant services to residents of Palm Beach County and surrounding areas, where the use rate is currently much lower than the state and national averages
- Decrease outmigration of TSA 4 heart transplant patients who currently travel to other service areas for treatment (six of 13 TSA 4 patient heart transplants received surgery at a hospital outside of TSA 4 in the year ending June 30, 2014)
- Enhance quality of care for patients of DMC and the Tenet Network by expanding the cardiovascular expertise available within the network enabling physician consultation and collaboration across the region

- Complete DMC's continuum of care of cardiovascular services
- Require minimal additional investment, as it is a natural extension of DMC's existing VAD Program and will benefit from much of the infrastructure that is already in place at DMC
- Enhance continuity of care for patients who receive cardiovascular care within the Tenet Florida Heart and Vascular Network, which includes 10 hospitals and 3,483 beds in south Florida

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

(a) Staffing Requirements: An applicant for a heart transplantation program shall have the following program personnel and services. (Rule 59C-1.044(6)(a) Florida Administrative Code).

(1) A board-certified or board-eligible adult cardiologist; or in the case of a pediatric heart transplantation program, a board-certified or board-eligible pediatric cardiologist.

DMC states having a group of experienced board-certified transplant surgeons and a transplant cardiologist who currently administer the VAD program at the hospital. These named physicians are as follows: Brian T. Bethea, MD, Neil I. Galindez, MD, Phillip James Habib, MD and Eric H. Lieberman, MD. The applicant offers curriculum vitae (CV) for each of these physicians in Volume 2, Exhibit H of the application. The reviewer confirms that according to these CV, this staffing requirement is met.

(2) An anesthesiologist experienced in both open heart surgery and heart transplantation.

DMC states having six cardiac anesthesiologists with over 80 years combined experience in cardiac surgery including cardiac transplantation and that the current anesthesia team has participated in more than 40 cardiac transplants over the course of their careers. According to the applicant, this same team participates in DMC's VAD program. DMC additionally states having recruited another cardiac anesthesiologist with experience in cardiac transplant and post-operative critical care. To support these statements,

DMC provides a support letter from Todd Horowitz, DO, Clinical Medical Director Anesthesiology at DMC, in Volume 2, Exhibit R of the application.

(3) A one-bed isolation room in an age-appropriate intensive care unit.

DMC states that an isolation room is available in the Cardiovascular ICU (post-transplant) and in the Cardiac ICU (pre-transplant).

(b) Need Determination: An application for a certificate of need to establish a new heart transplantation program shall not normally be approved in a service area unless: (Rule 59C-1.044(6)(b) Florida Administrative Code).

(1) Each existing heart transplantation provider in the applicable service area performed a minimum of 24 heart transplants in the most recent calendar year preceding the application deadline for new programs, and no other heart transplantation program has been approved for the same service planning area.

The reviewer verifies that according to local health council data, none of the existing heart transplantation providers in the applicable service area performed a minimum of 24 heart transplants in the most recent calendar year preceding the application deadline for new programs. The minimum volume criterion was last met by Jackson Memorial Hospital in CY 2012, performing 24 procedures. The reviewer also confirms that there are no CON approved but not yet operational adult heart transplant programs in TSA 4.

DMC contends that five “not normal” circumstances exist to justify approval of the proposed project. Each is described briefly below.

Historically low adult heart transplant use rates in the primary service area (PSA) and secondary service area (SSA). DMC notes that the United Network for Organ Sharing (UNOS)/OPTN defines “adult” as ages 18+. Using UNOS/OPTN data as of March 2015, from CY 2010 to CY

2014, the applicant indicates that adult heart transplants have declined in TSA 4 and statewide, while nationwide volume has experienced growth. See the figure below.

CY 2010 - 2014 Adult (18+) Heart Transplant Trend

| | 2010 | 2011 | 2012 | 2013 | 2014 | 2010-2014 Change |
|-----------------|-------------|-------------|-------------|-------------|-------------|-------------------------|
| TSA 4 Hospitals | 27 | 27 | 24 | 15 | 13 | -51.9% |
| Florida | 137 | 129 | 119 | 101 | 117 | -14.6% |
| United States | 1,974 | 1,949 | 2,008 | 2,127 | 2,251 | 14.0% |

Source: CON application #10385, page 87, Figure 34

DMC contends that according to January and February 2015 OPTN data, as of May 1, 2015, transplant volume is increasing in TSA 4, with DMC maintaining that this is a result of two new providers entering the area. The applicant estimates a total of 42 adult heart transplantations in TSA 4 for CY 2015, through annualizing the stated seven procedures performed in the first two months of CY 2015. See the figure below.

**TSA 4 Transplant Centers' Adult Heart Transplant Volume
CY 2014 Compared to Jan/Feb 2015 and CY 2015 Annualized**

| | 2014 Total Adult Heart Transplants | Jan/Feb 2015 Adult Heart Transplants | 2015 Annualized |
|----------------------------|---|---|------------------------|
| Jackson Memorial Hospital | 6 | 3 | 18 |
| Cleveland Clinic Hospital | 4 | 1 | 6 |
| Memorial Regional Hospital | 3 | 3 | 18 |
| Total Transplants at TSA 4 | 13 | 7 | 42 |

Source: CON application #10385, page 87, Figure 35

The applicant states that "...heart transplant volume in TSA 4 (which is the same as DMC's proposed PSA and SSA) is declining" (page 87 of the application). However, the reviewer notes that throughout the application, DMC indicates an extended service area including Martin and St. Lucie Counties and in one instance (page 93, Figure 41) also includes Okeechobee County as the total service area.

DMC states that using Agency hospital discharge data, for each of the 12 months ending June 2012, June 2013 and June 2014, TSA 4 (the applicant's stated PSA and SSA), resident heart transplants declined from 35, to 24, to 12, respectively. DMC also indicates that the Palm Beach County resident adult heart transplants, over the same three-year period, has declined significantly, from six

procedures, to one. DMC contends that this could be the result of several factors, including a “pure” lack of access to heart transplant services, the proliferation of VAD implantation as an alternative to transplant for some lower acuity patients, or the use of VAD to lengthen the amount of time a patient can live before a transplant is necessary (delayed transaction volume).

In addition to declining heart transplant volume in TSA 4 and the applicant’s PSA/SSA, DMC discusses adult heart transplants per million adult population. Using Agency discharge data, Agency population estimates, OPTN and Census.gov data, DMC maintains that in order to “smooth the use rate trend” and for comparison purposes, a three-year use rate was calculated using data from the years ended June 30, 2012 to June 30, 2014:

- The three-year average shows that the state average use rate is 7.05 heart transplants per million, while DMC’s PSA (Palm Beach County and Broward County) average is approximately one-half of that rate (3.49 per million), with the three-year nationwide use rate at 8.99 per million
- There is not a single county in the combined PSA, SSA or extended service area that shows a three-year average consistent with the state average

See the figure below.

**Adult Heart Transplants
Per One Million Adult Population**

| Adult Transplant Use Rates (per Million) | | | | |
|---|-------------|-------------|-------------|---------------|
| Area/County | 2012 | 2013 | 2014 | 3-Year |
| Primary Service Area | | | | |
| Palm Beach | 5.4 | 2.68 | 0.88 | 2.97 |
| Broward | 4.84 | 4.79 | 2.04 | 3.89 |
| Subtotal PSA | 5.08 | 3.87 | 1.54 | 3.49 |
| Secondary Service Area | | | | |
| Collier | 10.88 | - | 3.50 | 4.75 |
| Miami-Dade | 9.10 | 6.62 | 2.35 | 6.00 |
| Monroe | - | - | - | - |
| Subtotal SSA | 9.06 | 5.69 | 2.42 | 5.70 |
| PSA and SSA Total (TSA 4) | 7.02 | 4.76 | 1.97 | 4.57 |
| Extended Area | | | | |
| Martin | - | 15.66 | - | 5.21 |
| St. Lucie | 0.00 | 4.32 | 12.69 | 5.74 |
| Subtotal Extended | 0.00 | 8.36 | 8.20 | 5.55 |
| Total All Counties | 6.55 | 5.00 | 2.39 | 4.63 |
| Florida Total | 8.33 | 7.30 | 5.54 | 7.05 |
| United States | 8.69 | 9.06 | 9.20 | 8.99 |

Source: CON application #10385, page 89, Figure 37

DMC asserts that in the proposed service area, particularly Palm Beach County (2.97 procedures per million), which has a large population base, there is a barrier to heart transplantation services for residents of the area.

Atypical population without a heart transplant program. Using Agency population estimates, the applicant anticipates its total PSA/SSA and extended area to have a total resident population of 6,658,874 (in 2015), increasing to 7,026,956 (by 2020), a 5.5 percentage change and an annual average growth rate of 1.1 percent. The applicant states that considering the PSA and extended area, on which DMC will be reliant for its primary heart transplant utilization, that total population of 3,613,576 (in 2014), is to increase to 3,796,442 (by 2020). These population growth rate estimates are indicated to be less than the statewide average annual growth rate as shown on page 90, Figure 38 of the application.

Using Agency population estimates, DMC points out that by 2020 in the PSA/SSA, the elderly population is estimated to be 19.1 percent. DMC contends that more importantly, the rate of growth in the 65+ population is projected to be four times the rate of growth in the adult 15+ population between

CON Action Number: 10385

2015 and 2020 (1.6 percent increase in the age cohort as a percent of total in 65+ as opposed to 0.4 percent increase in 15+). DMC maintains that the elderly population has a much higher heart failure rate compared to the younger adult population. See the figure below.

**2015-2020 Total Resident Population Distribution
Adult 15+ and Elderly 65+
DMC Heart Transplant Service Area**

| Area/County | Adult 15+ | | | Elderly 65+ | | |
|-------------------------------|--------------|--------------|-------------|--------------|--------------|-------------|
| | 2015 | 2020 | Change | 2015 | 2020 | Change |
| Primary Service Area | | | | | | |
| Palm Beach | 83.5% | 83.8% | 0.2% | 22.3% | 23.9% | 1.6% |
| Broward | 82.2% | 82.6% | 0.4% | 15.8% | 17.8% | 2.0% |
| Subtotal PSA | 82.8% | 83.1% | 0.3% | 18.6% | 20.4% | 1.9% |
| Secondary Service Area | | | | | | |
| Miami-Dade | 82.3% | 82.7% | 0.5% | 14.9% | 16.1% | 1.2% |
| Monroe | 87.7% | 87.9% | 0.2% | 20.3% | 24.0% | 3.6% |
| Collier | 84.1% | 84.8% | 0.6% | 27.2% | 29.1% | 1.9% |
| Subtotal SSA | 82.6% | 83.1% | 0.5% | 16.4% | 17.8% | 1.4% |
| Subtotal PSA and SSA | 82.7% | 83.1% | 0.4% | 17.5% | 19.1% | 1.6% |
| Extended Area | | | | | | |
| Martin | 86.6% | 87.4% | 0.8% | 28.9% | 30.9% | 2.0% |
| St. Lucie | 81.9% | 82.4% | 0.5% | 20.4% | 21.7% | 1.3% |
| Subtotal Extended | 83.5% | 84.0% | 0.5% | 23.3% | 24.7% | 1.4% |
| Total All Areas | 82.7% | 83.1% | 0.4% | 17.9% | 19.5% | 1.6% |
| State | 82.7% | 83.2% | 0.4% | 18.5% | 20.3% | 1.8% |

Source: CON application #10385, page 91, Figure 39

In the next two figures, using Agency population estimates, DMC indicates and in narrative discusses adult (age 15+) and elderly (age 65+) populations for the PSA/SSA/extended area and statewide, 2015 to 2020. The applicant also indicates percentage changes and average annual growth rates for these populations.

DMS emphasizes that by 2020, the PSA/SSA total adult population is expected to increase to 5,432,902, an increase of 5.7 percent. DMC asserts that the adult population in the seven county service area will account for approximately one third of the statewide population by 2020. Additionally, DMC indicates that Palm Beach County alone accounts for approximately 21 percent of the total adult population in the combined PSA/SSA/extended area. DMC also particularly discusses the elderly population and population growth estimates for the extended area, pointing out that the

CON Action Number: 10385

PSA/SSA/extended area is currently home to 1.2 million elderly residents and that this population is expect to increase to approximately 1.38 million elderly residents (a 15 percent increase) by 2020. See the two figures below.

**2015-2020 Adult (15+) Resident Population Growth
DMC Heart Transplant Service Area**

| Adult Population 15+ | | | | |
|-------------------------------|-------------------|-------------------|-----------------------|-------------|
| Area/County | 2015 | 2020 | Percent Change | AAGR |
| Primary Service Area | | | | |
| Palm Beach | 1,144,457 | 1,218,929 | 6.5% | 0.3% |
| Broward | 1,480,483 | 1,530,544 | 3.4% | 0.7% |
| Subtotal PSA | 2,624,940 | 2,749,473 | 4.7% | 0.9% |
| Secondary Service Area | | | | |
| Miami-Dade | 2,162,152 | 2,299,622 | 6.4% | 1.3% |
| Monroe | 64,396 | 63,964 | -0.7% | -0.1% |
| Collier | 288,872 | 319,843 | 10.7% | 2.1% |
| Subtotal SSA | 2,515,420 | 2,683,429 | 6.7% | 1.3% |
| Subtotal PSA and SSA | 5,140,360 | 5,432,902 | 5.7% | 1.1% |
| Extended Area | | | | |
| Martin | 130,668 | 138,899 | 6.3% | 1.3% |
| St. Lucie | 239,074 | 270,913 | 13.3% | 2.7% |
| Subtotal Extended | 369,742 | 409,812 | 10.8% | 2.2% |
| Total All Areas | 5,510,102 | 5,842,714 | 6.0% | 1.2% |
| State | 16,284,331 | 17,535,915 | 7.7% | 1.5% |

Source: CON application #10385, page 92, Figure 40

**2015-2020 Elderly (65+) Resident Population Growth
DMC Heart Transplant Service Area**

| Elderly Population 65+ | | | | |
|-------------------------------|------------------|------------------|-----------------------|-------------|
| Area/County | 2015 | 2020 | Percent Change | AAGR |
| Primary Service Area | | | | |
| Palm Beach | 305,589 | 347,227 | 13.6% | 2.7% |
| Broward | 283,860 | 329,228 | 16.0% | 3.2% |
| Subtotal PSA | 589,449 | 676,455 | 14.8% | 3.0% |
| Secondary Service Area | | | | |
| Miami-Dade | 392,097 | 447,866 | 14.2% | 2.8% |
| Okeechobee* | 7,079 | 7,794 | 10.1% | 2.0% |
| Monroe | 14,923 | 17,429 | 16.8% | 3.4% |
| Collier | 93,489 | 109,894 | 17.5% | 3.5% |
| Subtotal SSA | 507,587 | 582,983 | 14.9% | 3.0% |
| Subtotal PSA and SSA | 1,097,036 | 1,259,438 | 14.8% | 3.0% |
| Extended Area | | | | |
| Martin | 43,632 | 49,170 | 12.7% | 2.5% |
| St. Lucie | 59,521 | 71,254 | 19.7% | 3.9% |
| Subtotal Extended | 103,153 | 120,424 | 16.7% | 3.3% |
| Total All Areas | 1,200,189 | 1,379,862 | 15.0% | 3.0% |
| State | 3,635,347 | 4,277,048 | 17.7% | 3.5% |

Source: CON application #10385, page 93, Figure 41

* The reviewer notes that Okeechobee is not elsewhere indicated as one of DMC's SSAs or otherwise indicated as part of the total service area for the proposed project. The addition of Okeechobee County in this single instance constitutes a total of eight counties in the total service area, whereas for all other presentations/figures, the applicant indicated a total of seven counties in DMC's total service area.

DMC reiterates that Palm Beach County is the third largest county in Florida, with 1.3 million current residents, projected to increase to nearly 1.5 million residents by 2020. The applicant points out that four counties smaller than Palm Beach County have operational heart transplant programs. The applicant uses Agency population estimates to reach this conclusion. See the figure below.

**Existing Heart Transplant Program Counties
Ranked by 2020 Projected Population**

| County | Heart Transplant Provider | Projected 2020 Total Population | Statewide Rank in Terms of Population |
|-------------------|----------------------------------|--|--|
| Dade | Jackson Memorial Hospital | 2,780,349 | 1 |
| Broward | Cleveland Clinic Hospital | 1,853,342 | 2 |
| <i>Palm Beach</i> | <i>NO PROGRAM</i> | <i>1,455,359</i> | <i>3</i> |
| Hillsborough | Tampa General Hospital | 1,439,041 | 4 |
| Orange | Florida Hospital | 1,387,617 | 5 |
| Duval | Mayo Clinic | 931,970 | 7 |
| Alachua | UF Health Shands Hospital | 265,026 | 23 |

Source: CON application #10385, page 94, Figure 42

DMC contends that considering the size of Palm Beach County, the number of heart failure discharges generated by the population and the unusual low volume of heart transplants is evidence that there is an access issue to advanced heart failure intervention, including heart transplant. According to the applicant, the seamless integration of heart transplant into the current continuum of care at DMC (which includes VAD procedures) is a remedy to the access issue.

Significant physician support. The applicant provides excerpts of physician support letters on page 94 – 98 of the application. For an overview of support letter comments, see in this report, Item B-Letters of Support.

Proposed program is a natural service extension to an existing VAD provider and DMC’s clinical team and infrastructure is already in place. The applicant states that currently DMC has five patients who have been deemed appropriate for a VAD implantation and another six who have been identified as possible heart transplant patients, pending further assessment and testing. DMC maintains being the only VAD provider in Florida that does not offer heart transplant

services displays that the proposed project is the next logical step to complete the continuum of care for this patient population.

DMC is the flagship of the Tenet Florida Heart and Vascular Network with a strong commitment to medical education and research. The applicant asserts that the 10-hospital Tenet Network currently has 271 adult cardiovascular physicians on its combined medical staff, including 32 cardiovascular and/or cardiothoracic surgeons. DMC further asserts that for the 12-month period ending June 30, 2014, Tenet Network hospitals discharged 3,724 patients with a heart failure diagnosis, 626 of whom were discharged from DMC.

The applicant discusses its role as a teaching hospital. According to DMC, each month, six medical residents rotate through the hospital in the medical specialties of infectious disease, physical and rehabilitation medicine, radiology and emergency medicine. The applicant also discusses other rotations including four second-year residents rotating in cardiology, neurology and gastroenterology. The applicant further discusses other planned residency and cardiovascular research commitments and opportunities (pages 101 – 102 of the application). The reviewer notes that according to the Agency website at www.floridahealthfinder.gov, DMC provides the specialty service of adult open heart surgery but is not designated on the website as a statutory teaching hospital.

- (2) The application contains documentation that a minimum of 12 heart transplants per year will be performed within two years of certificate of need approval. Such documentation shall include, at a minimum, the number of hearts procured by Florida hospitals during the most recent calendar year, and an estimate of the number of patients in the service planning area who would meet commonly-accepted criteria identifying potential heart transplant recipients.**

DMC earlier indicated an expectation of performing eight adult heart transplantations in year one of operation (ending December 31, 2016), 12 procedures in year two and 13 in year three.

DMC states the number of heart transplants per one million population in the PSA, SSA and extended areas is considerably less than the state and national averages for the past three years ended June 30, 2012-2014. The applicant concludes that it is reasonable to assume that the use rate in the area is suppressed and could logically increase as the result of a new provider entering the market. To support this conclusion, DMC uses Agency population estimates. For each of the next two figures, the reviewer reproduces only the applicant’s highlighted counties, the stated Florida average estimates and the presented three-year use rate calculations.

**Three-Year Heart Transplant Use Rate per Million Population
Ages 15-64 for Counties with 15-64 Population of 100,000 or More**

| County | 2012-2014 Average Population 15-64 | Three-Year Use Rate per Million Ages 15-64 |
|------------------------|---|---|
| Miami-Dade | 1,736,454 | 6.72 |
| St. Lucie | 174,885 | 5.72 |
| Collier | 190,822 | 3.49 |
| Broward | 1,190,414 | 3.08 |
| Palm Beach | 825,696 | 2.83 |
| Florida Average | 12,430,424 | 7.00 |

Source: CON application #10385, page 103, Figure 43 (partial representation)

DMC contends that Palm Beach County has the second lowest use rate in the state for heart transplants per million population considering counties with 100,000 or more residents age 15-64. DMC maintains that the Palm Beach County use rate is “significantly” less than half of the statewide average.

DMC states that similarly, it shows the rank of heart transplant use rates for Florida counties with more than 25,000 population ages 65 and older, ranked by blended three-year use rates per million population.

**Three-Year Heart Transplant Use Rate per Million Population
Ages 65 and Older for Counties with 65+ Population
of 25,000 or More**

| County | 2012-2014 Average Population 65+ | Three-Year Use Rate per Million Ages 65+ |
|------------------------|---|---|
| Broward | 267,564 | 7.47 |
| Collier | 90,119 | 7.40 |
| St. Lucie | 57,338 | 5.81 |
| Palm Beach | 296,079 | 3.38 |
| Miami-Dade | 374,886 | 2.67 |
| Martin | 41,467 | -- |
| Florida Average | 3,464,397 | 7.20 |

Source: CON application #10385, page 104, Figure 44 (partial representation)

DMC contends that Palm Beach County and Miami-Dade County have three-year blended use rates that are “significantly” less than half the statewide average. DMC asserts that as such, there appears to be a heart transplant access issue for elderly residents of TSA 4.

DMC maintains that because of the wide range of use rates by county, the applicant analyzed a percentile array of the use rates. The applicant reiterates and the reviewer previously confirmed that Palm Beach County is the largest county in Florida without a heart transplant program. The applicant also reiterates that Palm Beach County has an “unusually low” use rate compared to state and national averages.

DMC asserts that 75th percentile of statewide county-level use rates by age cohort is appropriate to apply to the service area going forward. The applicant indicates that conservatively, the use rate was held constant during the projection period. DMC details the percentile breakdown of the county and age cohort-specific use rates from the two figures above. See below.

**Comparison of Percentile Rank of Statewide Use Rates
Heart Transplants per One Million Population by Age Cohort**

| | Ages 15-64 | Ages 65 and Over |
|-----------------------------|-------------------|-------------------------|
| 75 th Percentile | 10.30 | 10.51 |
| 50 th Percentile | 6.72 | 4.18 |
| 25 th Percentile | 3.49 | 0.00 |

Source: CON application #10385, page 105, Figure 45

The applicant states that based on the application of the 75 percentile use rates by age cohort to the proposed service area population, there will conservatively be 66 heart

CON Action Number: 10385

transplant cases projected in TSA 4 and the extended service area annually during the projection period (2016-2018). The applicant details the projected market of adult (age 15+) heart transplant cases for the applicant’s PSA, SSA and extended service area for the first three years of the proposed project, on page 106, Figure 46 of the application. DMC also details the total expected number of adult heart transplant cases for the same period and total service area as a whole, compared to DMC’s market share and DMC’s projected case numbers. See the figure below.

Projected DMC Heart Transplant Cases (2016-2018)

| Area/County | Adult Transplants 15+ | | | Market Share | | | DMC Project Cases | | |
|----------------------------------|-----------------------|-----------|-----------|--------------|--------------|--------------|-------------------|-----------|-----------|
| | 2016 | 2017 | 2018 | Yr 1 | Yr 2 | Yr 3 | Yr 1 | Yr 2 | Yr 3 |
| Primary Service Area | | | | | | | | | |
| Palm Beach | 13 | 13 | 13 | 38.5% | 53.8% | 61.5% | 5 | 7 | 8 |
| Broward | 17 | 17 | 17 | 5.9% | 11.8% | 11.8% | 1 | 2 | 2 |
| Subtotal PSA | 30 | 30 | 30 | 20.0% | 30.0% | 33.3% | 6 | 9 | 10 |
| Secondary Service Area | | | | | | | | | |
| Collier | 5 | 5 | 5 | 0.0% | 0.0% | 0.0% | 0 | 0 | 0 |
| Miami-Dade | 24 | 24 | 24 | 4.2% | 8.3% | 8.3% | 1 | 2 | 2 |
| Monroe | 2 | 2 | 2 | 0.0% | 0.0% | 0.0% | 0 | 0 | 0 |
| Subtotal SSA | 31 | 31 | 31 | 3.2% | 6.5% | 6.5% | 1 | 2 | 2 |
| PSA and SSA Total (TSA 4) | 61 | 61 | 61 | 11.5% | 18.0% | 19.7% | 7 | 11 | 12 |
| Extended Area | | | | | | | | | |
| Martin | 2 | 2 | 2 | 0.0% | 0.0% | 0.0% | 0 | 0 | 0 |
| St. Lucie | 3 | 3 | 3 | 33.3% | 33.3% | 33.3% | 1 | 1 | 1 |
| Subtotal Extended | 5 | 5 | 5 | 20.0% | 20.0% | 20.0% | 1 | 1 | 1 |
| Total All Areas | 66 | 66 | 66 | 12.1% | 18.2% | 19.7% | 8 | 12 | 13 |

Source: CON application #10385, page 107, Figure 47

As shown in the figure above, the applicant’s year one through year three adult heart transplant cases are eight, 12 and 13, respectively. DMC asserts that using this scenario, there would be at least 53 other cases in the market, which would be sufficient for each of the three existing providers to perform more than 10 cases per year in accordance with CMS certification guidelines. The applicant maintains that project approval would have a positive impact on the lack of access to heart transplant services for residents of Palm Beach County and the surrounding areas. DMC contends that its estimates are reasonable based on market factors previously discussed.

- (3) **The application includes documentation that the annual duplicated cardiac catheterization patient caseload was at or exceeded 500 for the calendar year preceding the certificate of need application deadline; and that the duplicated patient caseload for open heart surgery was at or exceeded 150 for the calendar year preceding the certificate of need application deadline.**

Below is the applicant's figure to account for CY 2014 cardiac catheterizations and open heart surgeries at DMC. This is stated to be from DMC's internal data.

**2014 Cardiac Catheterizations and Open Heart Surgeries
Delay Medical Center**

| | CY 2014 |
|--------------------------|----------------|
| Cardiac Catheterizations | 1,830 |
| Open Heart Surgeries | 324 |

Source: CON application #10385, page 108, Figure 48

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.**

DMC states having a significant number of staff and facilities capable of providing the resources necessary to care for the patient population referenced in this rule. The applicant indicates that it operates a comprehensive heart failure program, recently providing VAD implantation procedures and having services are already in place to manage chronic

cardiac patients. DMC indicates that like its existing VAD Program, the proposed program will have the 24-hour availability of transplant nurses and physicians.

- 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.**

DMC maintains that cadaveric transplantation will be part of the proposed program. The applicant provides a signed, written organ and tissue procurement agreement between DMC and the Life Alliance Organ Recovery Agency (LAORA)-University of Miami, in Volume 2, Exhibit M of the application. According to the support letter from LAORA's Chief Medical Officer, Sam Salama, MD, LAORA is prepared to service the applicant's proposed program. The reviewer confirms that the applicant meets this rule.

- 3. An age-appropriate intensive care unit which includes facilities for prolonged reverse isolation when required.**

DMC assures that following transplantation, patients will be transferred to the adult cardiovascular intense care unit (CVICU), the same unit currently utilized by patients who have had open heart surgery and/or VAD implantation. The applicant also assures that the CVICU currently has the capability to offer prolonged reverse isolation, if needed.

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

DMC indicates that after thorough evaluation, adult heart transplant candidates will be reviewed weekly by the Selection Committee, a multidisciplinary team meeting whereby candidates are presented on a case by case basis and members give feedback on their findings. The applicant further indicates that this committee will include:

- Transplant/mechanical circulatory support cardiologist and surgeon
- Transplant VAD coordinator
- Social worker
- Financial care advisor
- Psychologist
- Nutritionist

DMC states that once approved by the committee, patients will be placed on the waiting list and registered with the local Organ Procurement Organization (OPO), in this case, LAORA and appropriate correspondence will be made to the referring physicians and the patients. DMC provides the proposed Heart Transplant Selection Criteria Policy, the Heart Transplant Recipient Evaluation Policy and the Guidelines for Transplant List Management, in Volume 2, Exhibit I of the application.

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.

DMC references the Transplant Recipient Evaluation Policy, which is stated to outline the heart transplant recipient evaluation standards. According to the applicant, the function of this policy is to ensure patients undergo extensive testing to:

- Ensure that the patient has end-stage heart disease despite optimal medical therapy
- Ensure that the transplant team objectively assesses the patient's functional capacity
- Determine major co-morbid conditions
- Evaluate any potential psychosocial limitations
- Ensure ethical allocation of limited cardiac allografts

The applicant explains that patients referred to the Center for Advanced Heart Therapies at DMC will have an initial consultation with a transplant/mechanical circulatory support cardiologist and must be free of defined contraindications for cardiac transplantation. After this consultation, the patient is then referred to the transplant coordinator, who assess the patient's ability to comply with

the transplant program requirements. DMC states that if accepted into the evaluation program, the patient will proceed to a series of tests. The applicant describes what is involved in Phase I Testing (page 73 of the application) and Phase II Testing (pages 73 – 74) of the application.

DMC maintains that once Phase II Testing is complete, results will be gathered by the transplant coordinator and compiled into a presentation summary for the selection committee. If the committee determines that additional testing or consultations are needed, once those are complete, DMC indicates that a brief presentation update for the committee will be held. Committee acceptance or denial is then determined and according to DMC, denial will result in a letter being sent to the patient and referring physician, acceptance will result in the patient being assigned a status code corresponding to medical urgency, consistent with national guidelines set forth by the OPTN. The applicant provides these steps in draft policy in Volume 2, Exhibit I of the application.

The applicant maintains that additionally, DMC has developed the following policies related to pre-, in- and post-hospital care protocols:

- Guidelines for donor selection for heart transplantation
- Transplant infection disease donor and recipient testing guidelines
- Guidelines for routine follow-up orthotopic heart transplant
- Guidelines for initial immunosuppression and induction
- Chronic immunosuppression for isolated heart transplant recipients
- Guidelines for treatment of acute cellular rejection
- Guidelines for treatment of antibody mediated rejection
- Transplant infectious disease recipient treatment

DMC states and the reviewer confirms that these proposed clinical policies are provided in Volume 2, Exhibit N of the application.

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 discussed this criterion and planned clinical policies above and in Volume 2, Exhibit N of the application. The applicant maintains that DMC and the Tenet Florida Heart and Vascular Network hospitals have a full continuum of services to care for heart transplant recipients, including post-acute levels of care, if needed. DMC attests to operating Pinecrest Rehabilitation and Outpatient Hospital, which DMC states includes a comprehensive inpatient rehabilitation unit. The reviewer confirms that per the Agency's Hospital Beds and Services List July 2015 publication, issued July 17, 2015, Delray Medical Center is licensed for a 90-bed comprehensive medical rehabilitation unit. The applicant also states having relationships with nursing homes and providers of long-term care acute care services, if needed.

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.

DMC indicates that CMS certified that OPO LAORA in TSA 4 for the provision of solid organ recovery services. DMC states that LAORA provides the necessary equipment and personnel to recover solid organs for transplantation, including but not limited to the surgical recovery, organ flushing/cooling, preservation and transplantation of solid organs. The reviewer notes that the applicant previously provided its written agreement with LAORA.

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.

DMC states having entered into a letter of intent with Florida Hospital (Orlando) for the provision of tissue-typing

and other transplant lab support as needed. DMC maintains that Florida Hospital (Orlando) offers extensive laboratory capabilities and that its tissue-typing lab is accredited by the American Society of Histocompatibility and Immunogenetics and the College of American Pathologists. This stated letter of intent, signed by Deborah E. Thoni, MD, Medical Director, Tissue Typing Laboratory, Florida Hospital Laboratories, and Florida Hospital's stated laboratory accreditation, are provided in Volume 2, Exhibit O 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 indicates that after transplant surgery, patients must be monitored through routine endomyocardial heart biopsies--these biopsies are scheduled in advance and are not emergent in nature. DMC states further that the results of the biopsy give post-transplant cardiologists clear information related to the patient and organ's response to the transplant. DMC notes that it will contract with Johns Hopkins Hospital for this service, which will be available 24 hours a day, seven days a week. A letter to this effect, signed by Arlene M. Prescott, Asst. Administrator, Anatomic Pathology, Department of Pathology, Division of Surgical Pathology, Johns Hopkins Hospital, is provided in Volume 2, Exhibit P of the application. According to this letter, all clinical lab testing locations under Johns Hopkins Medical Laboratories are subject to the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) and that the current CLIA is maintained. This letter further indicates accreditation by The College of American Pathologists, with State of Florida license numbers 800016670 and 800016671.

10. Blood banking facilities.

The applicant indicates that DMC, through Tenet Florida, Inc., has a longstanding contract with OneBlood, Inc., for blood banking services. The applicant also indicates that OneBlood, Inc., is in compliance with applicable standards of the College of American Pathologists, The Joint Commission, the American Association of Blood Banks and the U.S. Food and Drug Administration. According to DMC, through this

contract, OneBlood performs functions and services with the recruitment of blood donors, and performs all functions of collection, preparation, processing, quality control, and distribution of transfusable blood products for use by DMC and other Tenet Florida hospitals, on a 24-hour basis. The applicant provides a cover letter for this contract, signed by Donald Doddridge, President and CEO, OneBlood, along with a signed 18-page contract between OneBlood, Inc., and Tenet Florida, Inc., (with additional exhibits and schedules). The contract was effective February 2015. These documents are provided in Volume 2, Exhibit Q of the application.

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

DMC states having a well-developed program for the ongoing education for its staff members. DMC indicates that Tenet's education network offers a combination of traditional, one-on-one educator-led courses and computer-based online classes. DMC asserts that its organization-wide commitment to education will continue with the evolution of its VAD program, as well as the addition of a transplant program to complete its cardiac continuum of care.

DMC maintains that through its VAD program, the applicant has the staff in place to provide additional training to all hospital staff who will provide the special care required by transplant patients. DMC also maintains that the clinical and support staff that will care for DMC's transplant patients are largely the same staff who currently care for VAD recipients at the hospital.

DMC reiterates employing experienced program leaders, including VAD/Transplant Surgeons (Dr. Bethea/Dr. Galindez), VAD/Transplant Cardiologist (Dr. Habib), and VAD/Transplant Coordinator (Meghan Ciganik). DMC asserts that these staff will be responsible for the development, oversight and provision of training for key staff members at DMC who will be involved in the transplant program, including nursing, ancillary and other support staff.

DMC offers additional discussion on Transplant Training Program components, under the major categories of RN Training, Lab and Blood Bank Training and OR Transplant Team Training and Multidisciplinary Team Training, on pages 77 – 79 of the application.

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

DMC maintains having developed a comprehensive education program for patients, families, caregivers and primary care physicians for patients who undergo LVAD procedures at the hospital. The applicant indicates that specific to the VAD program, driveline dressing education begins one to two days after surgery with the VAD coordinator and the patient's primary caregiver. According to the applicant, education and training for patients and caregivers is intense and DMC does not discharge the patient until all mandatory training sessions and tests have been passed by both the patient and primary caregiver. DMC asserts that the same type of education program will be mandatory for heart transplant patients and will be administered by the VAD/Transplant Coordinator, Meghan Ciganik, BSN, RN, CHFNP. According to the practitioner's CV in Volume 2, Exhibit H of the application, Ms. Ciganik's most recent experience is Lead VAD Coordinator, Delray Medical Center, October 2014 to present.

b. Staffing Requirements.

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

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

The applicant states that as a current provider of VAD implantation surgery, DMC already has a wide range of advanced cardiovascular physicians on staff, including a transplant surgeon and transplant cardiologist. The applicant provides a description of each of these physicians on page 80 of the application. A brief review of some of each these physicians' stated affiliations is provided below:

- Brian T. Bethea, MD, Regional Medical Director of Cardiovascular Surgery for the Tenet Florida Heart and Vascular Network, is lead VAD and Transplant Surgeon at DMC and currently performs VAD and open heart surgery at Delray Medical Center
- Neil I. Galindez, MD, a member of the Tenet Florida Heart and Vascular Network, a cardiothoracic surgeon and member of the transplant team, currently provides open heart surgery at Palm Beach Gardens Medical Center
- Phillip Jams Habib, MD, Medical Director, Advanced Heart Failure and Mechanical Circulatory Program for the Tenet Florida Heart and Vascular Network and the VAD/Transplant Cardiologist at DMC
- Eric H. Lieberman, MD, a board-certified cardiologist and Regional Medical Director for Cardiology for Tenet Florida and also Chair, Tenet Annual Cardiovascular Symposium

A CV for each of the physicians listed above is provided in Volume 2, Exhibit H of the application.

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.**

DMC indicates that upon proposed project approval, Dr. Brian Bethea will be program director for the transplant program.

Dr. Bethea's current affiliations/titles were indicated previously. Among other affiliations and associations, the applicant states and the reviewer confirms that according to his CV (Volume 2, Exhibit H), Dr. Bethea completed six years of residency training and three years of cardiothoracic surgery fellowship training at the Johns Hopkins Hospital. Dr. Bethea's CV also indicates he had six years at the University of Texas Southwestern Medical Center where he was an assistant professor in the Department of Cardiovascular and Thoracic Surgery, an Associate Residence Program Director and an Associate LVAD Director. Other academic appointments are also stated.

According to the applicant, Dr. Bethea and Dr. Habib will work collaboratively in administration of the VAD and transplant programs.

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

The applicant notes that the care of chronically ill patients requires nursing staff with training and experience in this specialized area and that due to the complexity of these patients, an episode of care may involve multiple levels of care, e.g., acute care, inpatient rehabilitation, skilled nursing, etc. DMC discusses already having much of this staffing in place, resulting from the development of the Center for Advanced Heart Therapies, through which DMC implemented its VAD program. DMC maintains having linkages with other facilities within the Tenet Florida Heart and Vascular Network, with access to a large number of physicians, nurses, and other staff with specialties in areas of chronic cardiovascular disease.

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.

The applicant indicates that DMC, through Tenet Florida, Inc., has a longstanding contract with OneBlood, Inc., for blood banking services. The applicant also indicates that OneBlood, Inc. is in compliance with applicable standards of the College of American Pathologists, The Joint Commission, the American Association of Blood Banks and the US Food and Drug Administration.

According to DMC, through this contract, OneBlood performs functions and services with the recruitment of blood donors, and performs all functions of collection, preparation, processing, quality control, and distribution of transfusable blood products for use by DMC and other Tenet Florida hospitals, on a 24-hour basis.

The applicant provides a cover letter for this contract, signed by Donald Doddridge, President and CEO, OneBlood, along with a signed 18-page contract between OneBlood, Inc., and Tenet Florida, Inc., (with additional exhibits and schedules). This contract was effective February 2015. These documents are provided in Volume 2, Exhibit Q of the application.

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

DMC states that it has two registered dieticians (RDs) on staff with expertise in patients with cardiovascular disease, open heart surgery, heart failure, LVAD and transplant. These RDs are stated to be part of the VAD/Transplant Team/Selection Committee who will perform an appropriate nutritional assessment and other diet counseling services pre- and post-surgery. The applicant indicates that the Center for Advanced Heart Therapies at DMC uses its RDs to counsel patients with heart failure. The applicant also notes that DMC's VAD/Transplant RDs will develop detailed nutritional plans for patients.

DMC contends that because heart failure-specific dietary counseling is part of the existing VAD program and assessment protocol at DMC, a seamless transition will occur with the proposed project to include transplant patients. Though these RD practitioners are not named in the application narrative, a CV is included in Volume 2, Exhibit H of the application for Stacy Sliver, RD, LD/N and Ragini Raghuvver, MSc, MS, RD, LD/N, FAND.

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

According to the applicant, respiratory therapists are primarily involved with the needs of transplant patients during the inpatient stay and that this is most typically provided either in the CVICU and/or in the step-down unit. The applicant states that the respiratory therapists presently provide care to immunosuppressed and patients who receive LVADs at DMC. The applicant further

states that there is no need to expand its respiratory therapy department in order to provide services to heart transplant patients but if necessary, additional training for the care of transplant patients will be provided by members of the Transplant Team.

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.

DMC indicates having experienced social workers and psychologists on staff to evaluate and counsel potential transplant candidates, patients waiting for a transplant and those who have been transplanted. Additionally, DMC states that in addition to these staff, psychiatrists are available to provide support and assessment to patients who are seeking transplantation and their caregivers/families. DMC assures that all potential transplant patients are assessed by social workers. Though these practitioners are not named in the application narrative, a CV is included in Volume 2, Exhibit H of the application for Sandy Belcher, MSW, social worker and Lora L. LaPointe, PhD, clinical psychology and a licensed psychologist.

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 DMC will comply with the organ transplant data reporting requirements of the Agency and also agrees to provide data as required for the proposed project.

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.**

Regarding geographic access, Delray Medical Center is 34.69 driving miles distant from Memorial Regional Hospital, 40.80 driving miles distant from Cleveland Clinic Hospital and 50.80 driving miles distant from Jackson Memorial Hospital. The next nearest adult heart transplantation provider is Florida Hospital-Orlando, in TSA 3, at 191.56 driving miles distant from Delray Medical Center. All remaining operational adult heart transplantation providers are greater than 191.56 driving miles distant⁴. As shown in Item E.1.a. of this report, Tampa General Hospital in TSA 2, was the single highest volume adult heart transplant provider statewide for the five-year period ending December 31, 2014 and was also the single highest volume adult heart transplant provider for TSA 4 residents, in CY 2014. According to the same source, Delray Medical Center is 226.60 driving miles distant from Tampa General Hospital.

Delray Medical Center contends that the declining number of adult heart transplantations in TSA 4 indicates a potential access problem for patients needing heart transplants and further contends that the large and growing population base should generate a larger number of transplants, based on markets of similar size and age.

DMC reiterates that according to January and February 2015 OPTN data, as of May 1, 2015, transplant volume is increasing in TSA 4, with DMC maintaining that this is a result of two new providers entering the area. The applicant estimates a total of 42 adult heart transplantations in TSA 4 for CY 2015, through annualizing the stated seven procedures performed in the first two months of CY 2015. See the figure below.

**TSA 4 Transplant Centers' Adult Heart Transplant Volume
CY 2014 Compared to Jan/Feb 2015 and CY 2015 Annualized**

| | 2014 Total Adult Heart Transplants | Jan/Feb 2015 Adult Heart Transplants | 2015 Annualized |
|----------------------------|---|---|----------------------------|
| Jackson Memorial Hospital | 6 | 3 | 18 |
| Cleveland Clinic Hospital | 4 | 1 | 6 |
| Memorial Regional Hospital | 3 | 3 | 18 |
| Total Transplants at TSA 4 | 13 | 7 | 42 |

Source: CON application #10385, page 109, Figure 50

⁴ <http://www.mapquest.com/>

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.

Delray Medical Center states having a long history in the provision of high quality care to residents of South Florida. DMC provides current Agency licensure as a Class 1 hospital and accreditation by The Joint Commission in Volume 2, Exhibit A of the application. DMC maintains being deemed a Joint Commission Top Performer on Key Quality Measures for heart attack, heart failure, pneumonia and surgical care for the past three years and also having Joint Commission Advanced Certification as a Primary Stroke Center.

DMC provides a list of quality awards and accolades pertaining to cardiac, orthopedics, stroke, pulmonary, vascular, gastrointestinal, crucial care, women's health and rehabilitation, described on pages 110 – 111 and Volume 2, Exhibit B of the application. Some of these recognitions and awards are listed below:

Cardiac

- One of America's Best Hospitals for Cardiac Care™ and Cardiac Surgery™ (2014)
- Recipient of the HealthGrades Cardiac Care Excellence Award™ and the HealthGrades Cardiac Surgery Excellence Award (2014)
- Five-Star Rating for Coronary By-Pass Surgery, Heart Attack and Heart Failure for 12 consecutive years (2003-2014)
- Ranked among the Top 10 in Florida for Overall Cardiac Services and Cardiac Surgery (2013–2014)
- Blue Distinction Center for Cardiac Care by BlueCross BlueShield
- American Heart Association Get With the Guidelines – Heart Failure Gold Plus Achievement Award
- One of the nation's Top 100 Hospitals with Great Heart Programs by Becker's Hospital Review

Stroke

- One of HealthGrades America's 100 Best Hospitals for Stroke Care™ (2012–2014)
- Recipient of the HealthGrades Neuroscience Excellence Award™ (2012-2014)
- Recipient of the HealthGrades Stroke Care Excellence Award™ for five consecutive years (2010-2014)
- Ranked among the top five percent in the nation for Treatment of Stroke (2012-2014)

CON Action Number: 10385

- Ranked among the top five percent in the nation for Neurosciences (2014)
- Five-Star Rated for Treatment of Stroke for Seven Years in a Row (2008-2014)
- American Heart Association Get With the Guidelines – Stroke Gold Plus Award

Pulmonary

- Five-Star Rating for Treatment of Pneumonia for 12 consecutive years (2003-2014)
- One of HealthGrades America’s 100 Best Hospitals for Pulmonary Care™ (2014)
- Recipient of the HealthGrades Pulmonary Care Excellence Award (2014)
- Ranked among the top five percent in the nation for Overall Pulmonary Services (2014)

Vascular

- Five-Star Recipient for Carotid Surgery (2013-2014)

Critical Care

- Recipient of the HealthGrades Critical Care Excellence Award (2012-2014)
- Ranked among the top 10 percent in the nation for Critical Care (2012-2014)
- Five-Star Rating for treatment of sepsis for 11 consecutive years (2004-2014)

Rehabilitation

- Comprehensive Integrated Inpatient Rehabilitation Program 3-Year Status from CARF International
- Pinecrest Rehabilitation and Outpatient Hospital has been designated by the State of Florida Brain and Spinal Cord Injury Center for Adults

DMC discusses on page 111 of the application and provides a 97-page hospital-wide Plan for the Provision of Care Policy in Volume 2, Exhibit S of the application. The reviewer notes no signatures on page 97 of the policy, the approvals page.

The applicant notes on page 112 and provides a 15-page (with Appendix A through D) Performance Improvement Plan in Volume 2, Exhibit T.

The reviewer notes no signatures on page seven of the plan, the approvals page. According to the applicant, under the plan, DMC:

- Provides high quality, clinical services and demonstrates outcomes of services
- Achieves performance improvement goals in a systematic manner through collaboration with physicians
- Provides a mechanism to assure that all patients receive the same level of care
- Provides a culture where care is delivered in a safe environment and quality care is measured, monitored and continuously improved
- Utilizes performance improvement information and aggregate data in formulating and achieving objectives of the strategic plan
- Fosters an environment of proactive reduction of safety risks to patients and integration of safety priorities

DMC discusses on page 112 of the application and provides a six-page Patient Safety Plan in Volume 2, Exhibit U of the application. The reviewer notes no signatures on page six of the plan, the approvals page.

The applicant maintains that the proposed project will be handled with the same commitment to quality and patient safety that currently exists among DMC's service lines.

Agency complaint records indicate, for the three-year period ending June 1, 2015, Delray Medical Center had no substantiated complaints.

Tenet, the parent company of Delray Medical Center, operates 10 Florida hospitals with 3,483 beds. A single complaint can encompass multiple complaint categories. Agency complaint records indicate, for the three-year period ending June 1, 2015, Tenet had 38 substantiated complaints in the following complaint categories:

| Tenet Substantiated Complaint Categories for the 36 Months Ending June 1, 2015 | |
|--|----|
| Quality of Care/Treatment | 13 |
| Emergency Access | 7 |
| Admission/Transfer and Discharge Rights | 5 |
| Nursing Services | 5 |
| Resident/Patient/Client Rights | 5 |
| Resident/Patient/Client Assessment | 4 |
| EMTALA | 3 |
| Physical Environment | 3 |
| Administration/Personnel | 2 |
| Infection Control | 2 |
| State Licensure | 2 |
| Physician Services | 1 |

Source: Florida Agency for Health Care Administration Complaint Records

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

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 Tenet Florida Hospitals, 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.

CON Action Number: 10385

| Tenet Florida Hospitals | | |
|---|-----------------|-----------------|
| | Dec-14 | Dec-13 |
| Current Assets | \$411,212,207 | \$366,278,758 |
| Total Assets | \$1,389,583,325 | \$1,351,033,217 |
| Current Liabilities | \$184,708,413 | \$170,455,248 |
| Total Liabilities | \$262,406,962 | \$256,053,039 |
| Net Assets | \$1,127,176,363 | \$1,094,980,178 |
| Total Revenues | \$2,018,337,184 | \$1,853,141,253 |
| Excess of Revenues Over Expenses | \$88,075,131 | \$72,252,306 |
| Cash Flow from Operations | \$152,311,964 | \$106,382,443 |
| Short-Term Analysis | | |
| Current Ratio (CA/CL) | 2.2 | 2.1 |
| Cash Flow to Current Liabilities (CFO/CL) | 82.46% | 62.41% |
| Long-Term Analysis | | |
| Long-Term Debt to Net Assets (TL-CL/NA) | 6.9% | 7.8% |
| Total Margin (ER/TR) | 4.36% | 3.90% |
| Measure of Available Funding | | |
| Working Capital | \$226,503,794 | \$195,823,510 |

| 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 currently has \$95,680,705 of current and expected capital projects. These include a tower project, capitalization for fiscal years 2015 through 2018, the CON currently being reviewed, and contingency. A letter of support for funding was provided signed by the Chief Executive Officer of Tenet Florida.

Staffing:

The table below shows the Delray Medical Center’s projected staffing for the proposed project in years one, two and three, ending December 31, 2016, December 31, 2017 and December 31, 2018, respectively. By the end of year two, DMC estimates an FTE increase in the nursing category and another FTE increase in this same category by the end of year three.

In all the remaining categories, for all three years, the FTE counts remain constant. The table accounts for FTEs to be added as a result of the proposed project, if approved.

| Delray Medical Center, Inc., d/b/a Delray Medical Center CON application #10385 Adult Heart Transplantation Program Staffing Patterns | | | |
|--|---|---|---|
| | Year One Ending 12/31/16 | Year Two Ending 12/31/17 | Year Three Ending 12/31/18 |
| ADMINISTRATION | | | |
| Administrator | 0.5 | 0.5 | 0.5 |
| Physician Liaison | 1.0 | 1.0 | 1.0 |
| Transplant Assist. | 0.7 | 0.7 | 0.7 |
| Financial Coordinator | 0.4 | 0.4 | 0.4 |
| Secretary | 0.2 | 0.2 | 0.2 |
| NURSING | | | |
| Transplant Coordinators | 1.0 | 2.0 | 2.0 |
| Mid-Level Provider | 0.7 | 0.7 | 0.7 |
| OR Perfusion | 0.3 | 0.3 | 0.3 |
| Transplant Unit Staff (R.N./Other) | 2.6 | 3.9 | 4.2 |
| ANCILLARY | | | |
| Pharmacist | 0.4 | 0.4 | 0.4 |
| Psychologist | 0.2 | 0.2 | 0.2 |
| Dietary | | | |
| Dietary Nutritionist | 0.4 | 0.4 | 0.4 |
| SOCIAL SERVICES | | | |
| Social Service-Transplant | 0.5 | 0.5 | 0.5 |
| GRAND TOTAL | 8.9 | 11.2 | 11.5 |

Source: CON application #10385, Schedule 6A

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 Utilization Reporting System reports. For

our comparison group, we selected hospitals from the same group (Group 6: Large Suburban Hospital 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 | 351,101,600 | 2,507 | 3,822 | 2,213 | 1,837 |
| Total Expenses | 294,108,821 | 2,100 | 3,356 | 2,056 | 1,818 |
| Operating Income | 56,992,779 | 407 | 452 | 161 | -108 |
| Operating Margin | 16.23% | | Comparative Group Values | | |
| | Days | Percent | Highest | Median | Lowest |
| Occupancy | 103,044 | 57.3% | 77.9% | 61.7% | 37.8% |
| Medicaid | 6,076 | 5.9% | 38.6% | 11.0% | 3.0% |
| Medicare | 56,331 | 54.7% | 56.0% | 39.5% | 13.4% |

NRPD, CPD, and operating margin all fall within their respective ranges. Overall, the project appears profitable.

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.

The answer to this question is 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 60.6 percent of patient days are expected to come from Medicare and Medicaid with 11.7 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? Do they comply with ss. 408.035(1)(h), Florida Statutes; Chapter 59A-3, Florida Administrative Code.**

The proposed project does not involve construction or renovation.

- 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
Delray Medical Center (CON application #10385)
Compared to the District for FY 2013**

| Applicant | Medicaid and Medicaid HMO Days | Charity Percentage Service | Combined Medicaid and Charity Care |
|---------------------------|---------------------------------------|-----------------------------------|---|
| Delray Medical Center* | 7.81% | 1.28% | 9.09% |
| District 9 Average | 17.67% | 2.75% | 20.42% |

Source: Fiscal Year 2013 Agency for Health Care Administration Actual Hospital Budget Data
Note: * For this review, Delray Medical Center's fiscal year ended 12/31/2013

The table below illustrates Delray Medical Center's FY 2014-2015 low-income pool (LIP) participation, as of May 21, 2015. The applicant did not participate in the disproportionate share hospital (DSH) program for FY 2014-2015.

| Delray Medical Center (CON application #10385) LIP Program Participation for FY 2014-2015 | | |
|--|--------------------------------|---|
| Applicant/Program | Annual Total Allocation | Year-to-Date Total Allocation As of May 21, 2015 |
| Delray Medical Center/LIP | \$4,075,790 | \$2,947,221 |

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

CON Action Number: 10385

DMC states that it routinely provides care to Medicaid patients and those who are medically indigent. The applicant indicates through using 2011 – 2013 Agency Hospital Financial Reports (Worksheet C-3), DMC details its deductions from revenue for these populations for the most recent reporting years ended September 30, 2011 - 2013. See the figure below.

**DMC Historical Deductions from Revenue
Charity Care and Conventional Medicaid**

| | Years Ended September 30 | | | |
|-----------------------|--------------------------|--------------|--------------|--------|
| | 2011 | 2012 | 2013 | Growth |
| Charity Care | \$18,627,791 | \$19,512,075 | \$21,974,396 | 18.0% |
| Conventional Medicaid | \$64,965,424 | \$64,955,768 | \$67,627,093 | 4.1% |

Source: CON application #10385, page 115, Figure 51

According to the applicant’s Schedule 7A, DMC’s proposed adult heart transplantation patient days and percentage of patient days by payer source is shown below for year one (ending December 31, 2016), year two (ending December 31, 2017) and year three (ending December 31, 2018).

**Delray Medical Center, Inc./CON application #10385
Adult Heart Transplantation Only**

| Patient Days and Percent | Year One (Ending December 31, 2016) | | | |
|--------------------------|---------------------------------------|----------|--------------------|--------|
| | Medicaid | Medicare | Other Managed Care | Total |
| Patient Days | 0 | 180 | 180 | 360 |
| Percent of Patient Days | 0.0% | 50.0% | 50.0% | 100.0% |
| Patient Days and Percent | Year Two (Ending December 31, 2017) | | | |
| | Medicaid | Medicare | Other Managed Care | Total |
| Patient Days | 45 | 225 | 270 | 540 |
| Percent of Patient Days | 8.3% | 41.7% | 50.0% | 100.0% |
| Patient Days and Percent | Year Three (Ending December 31, 2018) | | | |
| | Medicaid | Medicare | Other Managed Care | Total |
| Patient Days | 45 | 225 | 315 | 585 |
| Percent of Patient Days | 7.7% | 38.5% | 53.8% | 100.0% |

Source: CON application #10385, Schedule 7A

Assumptions to the applicant’s Schedule 7A indicate the proposed program’s projected payer mix, expressed as cases, for the first three years of operation. See the notes table to the schedule below.

| Payer | Year One Cases | Year Two Cases | Year Three Cases |
|--------------------|----------------|----------------|------------------|
| Medicare | 4 | 5 | 5 |
| Medicaid | 0 | 1 | 1 |
| Managed Care | 4 | 6 | 7 |
| Total Cases | 8 | 12 | 13 |

Source: CON application #10385, Schedule 7A-Assumptions

The reviewer notes that statewide during CY 2014, there were 47 Medicaid patients that received adult heart transplantation.⁵ DMC offers no Medicaid or charity care patient day condition(s) regarding the proposed project.

F. SUMMARY

Delray Medical Center, Inc., d/b/a Delray Medical Center (CON application #10385), proposes to establish an adult heart transplantation program at Delray Medical Center, in Delray Beach, Palm Beach County, Florida, District 9, TSA 4. Tenet, the parent company of DMC, operates a total of 10 hospitals in Florida, all in TSA 4.

DMC is a 493-bed general hospital, licensed for 350 acute care, 48 adult psychiatric, five adult substance abuse and 90 comprehensive medical rehabilitation beds. DMC offers non-CON regulated Level II adult cardiovascular services and is a comprehensive stroke center. DMC is also a Level I Trauma Center. The applicant currently does not provide any transplantation services.

The applicant indicates that the proposed project service area is based on parts of TSA 4, primarily Palm Beach County, with the assumption that there will be immigration volume generated by other counties close to Palm Beach County, specifically Martin and St. Lucie, served by the Tenet Florida Heart and Vascular Network.

DMC proposes video conferencing, outreach to enhance organ donation and transplantation services, support group for end stage heart disease, heart transplant candidates and recipients and training and education conditions to CON approval on the application's Schedule C.

Total project cost is estimated at \$329,725. The project does not involve construction or renovation. If approved, the project is anticipated to be licensed and to initiate service on January 1, 2016.

⁵ 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 adult heart 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.

DMC offers several factors as justifying need for the proposed project:

- Increase access to heart transplant services to residents of Palm Beach County and surrounding areas, where the use rate is currently much lower than the state and national averages
- Decrease outmigration of TSA 4 heart transplant patients who currently travel to other service areas for treatment (six of 13 TSA 4 patient heart transplants received surgery at a hospital outside of TSA 4 in the year ended June 30, 2014)
- Enhance quality of care for patients of DMC and the Tenet Network by expanding the cardiovascular expertise available within the Network, which enables physician consultation and collaboration across the region
- Complete DMC's continuum of care of cardiovascular services
- Require minimal additional investment, as it is a natural extension of DMC's existing VAD Program and will benefit from much of the infrastructure that is already in place at DMC
- Enhance continuity of care for patients who receive cardiovascular care within the Tenet Florida Heart and Vascular Network, which includes 10 hospitals and 3,483 beds in south Florida
- Historically low adult heart transplant use rates in the PSA and SSA
- Atypical population without a heart transplant program
- Significant physician support (59 physician signatures in support of the proposed project)
- A strong commitment to medical education and research
- Palm Beach County is the largest county (by population) in Florida without an adult heart transplant program
- At DMC, five patients have been deemed appropriate for a VAD implantation and another six identified as possible heart transplantation candidates, pending further assessment and testing
- DMC is the only VAD provider in Florida that does not offer heart transplantation services

Two Palm Beach County residents outmigrated to TSA 1 for heart transplant services in CY 2014.

Approval of the proposed project would likely have a detrimental impact on the existing provides, based on the TSA 4, as well as statewide, relatively declining total volume of adult heart transplantation procedures for the five-year period ending December 31, 2014.

Additionally, the Agency recognizes that the two newest adult heart transplant providers in TSA 4 (Memorial Regional Hospital and Cleveland Clinic Florida) have not had adequate time to establish volume levels sufficient to ensure favorable outcome quality and safety. Moreover, project approval would likely additionally dilute already declining volume, based on historical data, and further erode a critical mass of procedures needed to reach desired quality standards. Finally, the Agency finds that it would be premature to introduce a fourth provider into the area, for this tertiary service, without first granting the existing providers an opportunity to establish a material impact on the existing outmigration rate in the area.

Quality of Care:

Delray Medical Center demonstrates the ability to provide quality care.

The applicant provides multiple awards and accolades regarding multiple services lines at its facility, including but not limited to cardiac, stroke, pulmonary, vascular, critical care and rehabilitation. DMC is Agency licensed and is accredited by The Joint Commission.

Agency complaint records indicate, for the three-year period ending June 1, 2015, Delray Medical Center had no substantiated complaints. Tenet operates 10 Florida hospitals with 3,483 beds. For the same three-year period, Tenet's Florida hospitals had 38 substantiated complaints.

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.

Medicaid/Indigent Care:

According to the Agency's 2013 FHURS Data Report, DMC provided 7.81 percent of its total annual patient days to Medicaid/Medicaid HMO patients and 1.28 percent to charity care patients in FY 2013.

The applicant participates in the LIP program but not the DSH program. DMC's annual total LIP allocation for FY 2014-2015 was \$4,075,790, with a total allocation of \$2,947,221 as of May 21, 2015.

According to Schedule 7A, DMC anticipates providing to its adult heart transplantation program year one (ending December 31, 2016) 0.0 percent Medicaid, year two (ending December 31, 2017) 8.3 percent Medicaid and year three (ending December 31, 2018) 7.7 percent Medicaid for its total annual patient days. Schedule 7A assumptions further estimate zero Medicaid cases in year one and one Medicaid case in year two and year three. Charity care days and cases are not indicated.

DMC offers no Medicaid and no charity care patient day condition(s) regarding the proposed project.

G. RECOMMENDATION

Deny CON #10385.

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