



Via OHS Electronic Certificate of Need Portal

Final Decision

Applicants: **Manchester Memorial Hospital, Inc.**
71 Haynes St.
Manchester, CT 06040

Saint Francis Hospital and Medical Center, Inc.
114 Woodland St.
Hartford, CT 06105

Docket Number: **18-32224-CON**

Project Title: **Establishment of a Diagnostic Cardiac Catheterization Laboratory and Primary and Elective Percutaneous Coronary Intervention Program at Manchester Hospital without On-Site Surgical Backup**

The undersigned, Victoria Veltri, Executive Director of the Office of Health Strategy (“OHS”), hereby issues her final decision in Certificate of Need (“CON”) Docket No. 18-32224-CON in which Manchester Memorial Hospital, Inc. and Saint Francis Hospital and Medical Center, Inc., seek to establish a diagnostic cardiac catheterization laboratory and a primary and elective percutaneous coronary intervention (“PCI”) program at Manchester Memorial Hospital. This decision is issued pursuant to Connecticut General Statutes (“Conn. Gen. Stat.”) § 4-180.

Following the issuance of the Proposed Final Decision of Hearing Officer Micheala L. Mitchell on June 10, 2019, the Applicants requested an opportunity to file exceptions and present briefs and oral argument. In response thereto, July 19, 2019, was set as the deadline for submission of briefs and additional evidence.

On June 25, 2016, an Order was issued setting the date of oral argument on July 25, 2019. The Order also required the Applicants to submit additional information to OHS. On that date the undersigned commenced a hearing affording the Applicants an opportunity to fully address any legal claims and exceptions to the Proposed Final Decision. Upon the close of the hearing, the undersigned took the matter under advisement.

Having had the opportunity to review the brief submitted by the Applicants, the administrative record in this matter and giving due consideration to the oral argument presented on July 25, 2019, I hereby issue the following Final Decision.

Findings of Fact

The Executive Director rules upon the Applicants' exceptions to the Findings of Fact as follows:

FF#7 Granted

HHVI is among the highest-volume cardiac cath programs in the region. In Fiscal Year ("FY") 2017, the physicians participating in the program performed 2,522 cardiac caths, 159 primary PCI and 640 elective PCI procedures. Ex. A, Main Application, p. 23

FF#17 Denied

The Finding correctly represents the PCI Guideline as written.

FF#18 Denied

The Finding correctly reflects the PCI Guideline requirements.

FF#21 Denied

The Finding correctly represents the PCI Guideline as written.

FF#22 Denied

The Finding correctly represents the PCI Guideline as written.

FF#26 Granted

The Applicants' proposed service area is illustrated below.

FF#29 Granted

Bates page 47 of the Application lists the towns included in this Finding, and does *not* include Willington. However, the Applicants' data in Figure 14 does reflect a greater than 30 minute drive time from Willington to any Hartford area hospital. Accordingly, while the original Finding accurately represents and cites to the Application, it will be updated as follows:

The Applicants' proposed service area includes the towns of Ashford, Columbia, Ellington, Mansfield, Somers, Stafford Springs and Willington which are outside of the 30-minute drive time radius set forth in the plan.

FF#30 Denied

The Finding correctly applies the State Plan's definition of Service Area.

FF#32 Granted

Hartford, Saint Francis and John Dempsey hospitals are the existing cardiac cath and PCI-capable providers nearest to Manchester and Rockville. Ex. A, Main Application, p. 702

FF#33 Granted

Historical volumes of patients diagnosed with acute myocardial infarction (AMI) transferred from Manchester and Rockville emergency departments (EDs) to the nearest PCI-capable hospitals for each FY between 2015 through 2017 equaled 62, 55 and 46, respectively. Ex. E, Applicants’ Addendum to First Completeness Response, p. 1241; Ex. G, Applicants’ Second Completeness Response, p. 1277

**TABLE 3
TRANSFERS FROM MANCHESTER /ROCKVILLE TO A PCI-CAPABLE HOSPITAL**

Transferring Hospital	Number of Patients Transferred to PCI-Capable Hospital								
	Saint Francis			Hartford			John Dempsey		
	FY 2015	FY 2016	FY 2017	FY 2015	FY 2016	FY 2017	FY 2015	FY 2016	FY 2017
Manchester	36	31	24	6	9	7	0	0	0
Rockville	15	14	11	5	1	4	0	0	0
Total¹	51	45	35	11	10	11	0	0	0
No. receiving Primary PCI	26	24	14	6	5	4	0	0	0
% of Total	51%	53%	40%	55%	50%	36%	-	-	-

¹The declining volume is because state and regional EMS protocols require ambulances to bypass ECHN hospitals and transport AMI patients directly to the nearest PCI-capable provider. However, some AMI patients arrive at ECHN emergency departments by other means of transport.
Ex. D, Applicants’ First Completeness Response, p. 1241; Ex. G, Applicants’ Second Completeness Response, p. 1277

FF#34 Granted

Between FYs 2015 and 2017, the average door-to-balloon time for primary PCI patients transferred from Prospect Eastern Connecticut Health Network (“ECHN”) hospital emergency departments was 109 minutes (2015), 113 minutes (2016) and 101 minutes (2017). The longest door-to-balloon time experienced by a primary PCI patient transferred from a Prospect ECHN hospital emergency department was 147 minutes (2015), 207 minutes (2016) and 146 minutes (2017). Ex. A, Main Application, pp. 1241-1242; Ex. G, Applicants’ Second Completeness Response, p. 1280

FF#35 Granted

The average inpatient and outpatient surgery discharge rates for ischemic heart disease and AMI for adults in the proposed service area are lower than the statewide rates. The mortality rates for the same two conditions for the area and statewide are similar.

**TABLE 4
AVERAGE ANNUAL ISCHEMIC HEART DISEASE AND AMI DISCHARGES AND
CRUDE MORTALITY RATES IN THE PROPOSED SERVICE AREA, FY 2015-2017**

Service Area	Discharges (FY 2015-2017)*				Mortality (2012-2014)**			
	Ischemic Heart Disease ¹		AMI ²		Ischemic Heart Disease ³		AMI ⁴	
	Discharges	Adult Rate	Discharges	Adult Rate	Deaths	Adult Rate	Deaths	Adult Rate
Primary	3,154	224.5	420	29.9	179	12.7	44	3.2
Secondary	2,635	209.7	418	29.9	182	13.0	42	3.0
Total Service Area	6,088	217.1	838	29.9	361	12.9	86	3.1
Connecticut	73,360	246.9	10,313	34.7	3,777	12.7	941	3.2

Ex. V, OHS' Revised Ischemic Heart Disease and AMI Discharge Count, p. 2

*OHS Acute Care Hospital Inpatient Discharge and Outpatient Surgery Databases.

**CT DPH Connecticut Residents Death Tables 2012-2014, Age Adjusted Mortality Rates.

¹Inpatient discharges assigned ICD-9-CM diagnosis codes 410 – 414 or ICD 10 CM codes I20 - I25.

²Inpatient discharges assigned ICD-9-CM diagnosis codes 410 or ICD 10 CM codes I21.

³ CT DPH Age Adjusted Mortality Rates Codnum 129.1. Rates are not calculated for counts below 15 because such rates are statistically unreliable and unstable.

⁴ CT DPH Age Adjusted Mortality Rates Codnum 129.2. Rates are not calculated for counts below 15 because such rates are statistically unreliable and unstable.

Note: The adult rate was calculated by dividing the average annual total number of ischemic or AMI discharges or deaths originating in the service area or state by the adult population (age 15 and older) in that area or state and multiplying the result by 10,000.

FF#36 Denied

The Finding appropriately incorporates accurate and applicable data.

FF#37 Denied

The Finding correctly applies the State Plan's definition of Service Area.

FF#38 Granted

The overall average annual growth rate for all cardiac catheterization procedures in the proposed service area was 6.5% between FYs 2015 through 2018 and resulted from an increase in diagnostic and elective PCI procedures.

FF#44 Granted

Nine Saint Francis and Manchester cardiac interventionists have the ability to provide 24/7 coverage primary PCI service. Ex. D, Applicants' First Completeness Response, p. 1238

FF#49 Granted

The Applicants anticipate that cost reductions will be derived, in part, by eliminating duplicate transfers, admissions, assessments, chest x-rays, lab work, EKGs and ambulance transport. Ex. A, Main Application, p. 68

The Executive Director modifies the following Findings of Fact based upon her review of the Administrative Record.

FF#19

b. A goal of 90 minutes or less, “door-to-balloon,” from first medical contact to device, with direct EMS transport to a PCI-capable hospital as the recommended triage strategy; and
c. A maximum of 120 minutes “door-to-balloon” time for the transfer of STEMI patients presenting at a non-PCI capable hospital to a PCI-capable hospital. Ex. A, Main Application, p. 519

FF#39

The average rate for primary PCI in the proposed service area demonstrated an average 6.0% year-to-year decline between FY’s 2015 through 2018. Ex. T, Late File Response, p. 15

The Executive Director adds the following Findings of Fact from the Applicants’ Brief and its Responses to the June 25, 2019 Order.

FF#53

For FYs 15 – 17, door-in-door-out average times for the transfer of ECHN primary PCI patients to Saint Francis Hospital exceeded the 30 minute maximum identified in the Guidelines, averaging 63.8 minutes in FY15, 58.2 minutes in FY16, and 43 minutes in FY17. Applicants’ July 18, 2019 Brief in Opposition to the Proposed Final Decision, p. 1

FF#54

Clinical and other factors may negatively impact a facility’s ability to achieve the Guideline’s stated goals. These factors include the presence of an acute presentation requiring immediate intervention, difficulty confirming a STEMI diagnosis, and delays in the coordination and implementation of transfers. Applicants’ July 18, 2019 Brief in Opposition to the Proposed Final Decision, pp. 3-5

FF#55

The highest volume of cardiac patients presenting at the Manchester and Rockville Hospital Emergency Departments is typically between 9:00AM and 9:00PM.
Exhibit U, Public Hearing transcript, Testimony of Dr. Robert Carroll, Chair of the Emergency Departments, pp. 51-52

FF#56

Traffic patterns for Interstate 84 (“I-84”), the primary route between the Service Area and the existing primary PCI capable hospitals, experience frequent and unpredictable adverse impacts on travel times. Applicants’ July 18, 2019 Brief in Opposition to the Proposed Final Decision, Exhibit A. p. 12

FF#57

In FY18, there were 672 reported vehicle crashes within the Service Area of I-84 between 9:00AM and 9:00PM. Applicants’ July 18, 2019 Brief in Opposition to the Proposed Final Decision, Exhibit A. p. 12

Discussion

The Applicants propose the establishment of a cardiac catheterization laboratory and primary and elective PCI service at Manchester Memorial Hospital without on-site surgical back-up. The Hearing Officer concluded, based upon the Findings of Fact and Discussion contained in the Proposed Final Decision, that the Applicants failed to meet their burden of proof in satisfying the statutory requirements of Conn. Gen. Stat. §§ 19a-639 to establish the services requested in the Application. Upon review of the administrative record, the Applicants' brief and the Applicants' responses to the Hearing Officer's June 25, 2019 Order, the undersigned finds that the Applicants have met their burden of proof, by a preponderance of the evidence, that the establishment of diagnostic and primary PCI services at Manchester Memorial Hospital satisfies the statutory requirements of Conn. Gen. Stat. §§ 19a-639.

It is undisputed that emergent heart conditions must be treated as soon as possible following the onset of symptoms to circumvent the deterioration of heart muscle. The American College of Cardiology Foundation and the American Heart Association ("ACCF/AHA" or "Guideline") Task Force on Practice Guidelines and Consensus Documents set forth, in relevant part, a goal of 90 minutes or less, "door-to-balloon," from first medical contact to device, with direct Emergency Medical System ("EMS") transport to a PCI-capable hospital as the recommended triage strategy. The North Central Connecticut EMS Guidelines local ST-Elevation Myocardial Infarction ("STEMI") agreement plan affirms the ACCF/AHA Task Force recommendations by directing emergency medical vehicles to transport STEMI patients to a primary PCI-capable hospital within a 30-minute drive time to ensure that the patient receives the procedure within 90 minutes of first medical contact. For STEMI patients presenting at a non-PCI capable hospital, the ACCF/AHA Task Force recommends a maximum of 120 minutes door-to-balloon time for the transfer to a PCI-capable hospital.

Evidence submitted by the Applicants demonstrates that the longest door-to-balloon times exceeded the state and national goals of 90 minutes or less in each of FYs 2015-2017. Additionally, the average "door-in-door-out" times for the transfer of ECHN primary PCI patients to Saint Francis Hospital during that same period greatly exceeded the 30-minute maximum identified in the Guidelines, averaging 63.8 minutes in FY15, 58.2 minutes in FY16, and 43 minutes in FY17. In their brief, the Applicants identified additional factors that contribute to extended patient transfers, including significant vehicular crash volume on the primary transfer route to Saint Francis and Hartford Hospitals during peak hours.

OHS acknowledges the Applicants' alternative request for provisional approval of all three cardiac services to allow the Applicants to validate Manchester Memorial Hospital's ability to meet national volume thresholds. However, volume projections in the record indicate that Manchester Memorial Hospital would not immediately achieve the requisite institutional volume specified in the Guideline; conversely, it would take a minimum of two (2) years to build that volume. It is inappropriate to grant the Applicants the relief that they request as the Guidelines expressly state that a lack of volume directly correlates to "worse outcomes."

In their brief, the Applicants reiterate that the provision of elective PCI at Manchester Memorial Hospital will be cost-effective. As indicated in the Proposed Decision, OHS cannot grant the

Applicants' request to establish a full PCI program based upon cost-efficiencies when the Guideline is not met.

The Applicants presented no new facts or evidence to support a conclusion that their request to establish an elective PCI program at Manchester Memorial Hospital satisfies Conn. Gen. Stat. §§ 19a-639, the ACCF/AHA or the North Central Connecticut EMS Guidelines. The undersigned does conclude, however, that the Applicants' establishment of diagnostic and primary PCI services at Manchester Memorial Hospital, in collaboration with St. Francis' Hoffman Heart and Vascular Institute, supports national and state goals of promoting the earliest possible clinical intervention for STEMI patients.

Order

Based upon the amended Findings of Fact and Discussion contained herein, the Certificate of Need Application of Manchester Memorial Hospital and Saint Francis Hospital and Medical Center to establish diagnostic and primary PCI services at Manchester Memorial Hospital is **GRANTED**. The Applicants' request to establish elective PCI services at Manchester Memorial Hospital is **DENIED**.

All of the foregoing constitutes the final Order of the Office of Health Strategy.

By Order of the
Office of Health Strategy

October 18, 2019
Date

Victoria Veltri, JD, LLM
Executive Director