Proposed 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**

Project Description: Manchester Memorial Hospital, Inc. ("Manchester") and Saint Francis Hospital and Medical Center ("Saint Francis") herein collectively referred to as (the "Applicants") seek authorization to establish and operate an interventional cardiac program comprised of a diagnostic cardiac catheterization laboratory ("cardiac cath lab") and primary and elective percutaneous coronary intervention ("PCI" or angioplasty) services at Manchester without on-site cardiac surgical backup.

Procedural History: The Applicants published notice of their intent to file a Certificate of Need ("CON") application in *Hartford Courant* (Hartford County) and *Journal Inquirer* (Manchester) on February 7, 8, and 9, 2018. On April 25, 2018, the Health Systems Planning Unit ("HSP") of the Office of Health Strategy ("OHS") received the CON application from the Applicants for the above-referenced project. On November 15, 2018, OHS deemed the application complete.

On December 14, 2018, Mayor Jay Moran,[1] submitted a request to OHS for a public hearing. On January 28, 2019, the Applicants were notified of the date, time, and place of the hearing.[2] On January 29, 2019, a notice to the public announcing the hearing was published in *Hartford Courant* (Hartford County) and *Journal Inquirer* (Manchester). Thereafter, pursuant to Connecticut General Statutes ("Conn. Gen. Stat.") § 19a-639a(f)(2), the public hearing regarding the CON application was held on February 27, 2019.

[1] Mayor of Manchester, Connecticut.
[2]The Hearing Notice is dated January 25, 2019, but was not uploaded to the Certificate of Need portal until January 28, 2019. See, Ex. M

Executive Director Veltri designated Attorney Micheala Mitchell as the hearing officer in this matter. The hearing was conducted in accordance with the provisions of the Uniform Administrative Procedure Act (Chapter 54 of the Connecticut General Statutes) and Conn. Gen. Stat. § 19a-639a(f)(2).

III. Provisions of Law

The proposal constitutes the establishment of cardiac services pursuant to Conn. Gen. Stat. § 19-638a(9). OHS considered the criteria set forth in Conn. Gen. Stat. § 19a-639(a) in rendering its decision.

IV. Findings of Fact

1. Manchester, a for-profit, wholly-owned affiliate of Prospect Eastern Connecticut Health Network ("Prospect ECHN"), Inc. and part of Prospect Medical Holdings, Inc. ("PMH"), is a 283-bed/bassinet acute care community hospital located at 71 Haynes Street in Manchester, CT. Ex. A, Main Application, pp. 20, 22

2. Currently, Manchester offers the following cardiac diagnostic testing and therapeutic services:
    a. Electrocardiogram (EKG);
    b. Holter monitor;
    c. Cardiac event monitor;
    d. Exercise (stress test) electrocardiogram;
    e. Exercise stress test with cardiolite/nuclear scan;
    f. Pharmacologic (lexiscan/cardiolite) stress test;
    g. Transthoracic echocardiogram;
    h. Exercise stress echocardiography;
    i. Dobutamine stress echocardiography;
    j. Transesophageal echocardiogram (TEE);
    k. Tilt table test; and
    l. Cardiac rehabilitation services.

    Ex. A, Main Application, p. 24

3. Rockville ("Rockville") Hospital also operates under Prospect ECHN, Inc. and is Manchester's sister hospital.[3] Ex. A, Main Application, pp. 22-23

4. Manchester and Rockville hospitals serve the same towns and cities in the Northeast region of Connecticut. Ex. A, Main Application, pp. 22-23

[3]In 2002, Rockville established a diagnostic cardiac cath lab without on-site surgical back-up. At inception, the Rockville cath lab exceeded projected volumes. Without PCI, however, support from referring providers declined causing Rockville to eventually wind down those services. Ex. A, Main Application, pp. 26, 41

5. Saint Francis, located in Hartford, Ct, is part of Trinity Health of New England's integrated health care delivery system. Saint Francis is a 682-bed/bassinet major teaching hospital that houses the Hoffman Heart and Vascular Institute ("HHVI"). Ex. A, Main Application, p. 23

6. Saint Francis' HHVI is a full service cardiac provider that offers the following services:
    a. Open heart surgery;
    b. Vascular care;
    c. Cardiac catheterization;
    d. Heart failure management
    e. Electrophysiology; and
    f. Primary and elective PCI.

    Ex. A, Main Application, p. 23

7. 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, 129 primary PCI and 640 elective PCI procedures. Ex. A, Main Application, p. 23

8. Together, Manchester and Saint Francis propose[4] to expand cardiac services at Manchester by establishing and operating a cardiac cath lab and primary and elective PCI services[5] without on-site cardiac surgical back-up. Ex. A, Main Application, pp. 22, 36

9. Diagnostic cardiac cath involves passing a catheter into the right or left side of the heart to obtain diagnostic information about the heart or its blood vessels. Ex. A, Main Application, p. 24

10. Angioplasty/PCI is an interventional procedure whereby a catheter, usually inserted into an artery in the groin, is threaded through the circulatory system to a diagnosed blockage in the heart. During the procedure, an expandable balloon is passed through the artery and inflated, flattening blockage-causing plaque and improving blood-flow. Ex. A, Main Application, p. 24

11. Emergent heart conditions must be treated as soon as possible following the onset of symptoms as the more time that elapses before treatment commences, the more the heart muscle deteriorates. Ex. A, Main Application, p. 24

12. Primary PCI is used to treat emergent heart conditions, such as ST-Segment Elevation Myocardial Infarctions ("STEMI"), which occur when an acute coronary thrombosis blocks a coronary artery. Ex. A, Main Application, p. 24

13. Elective PCI is often a scheduled procedure following extensive cardiac testing or a post-cardiac event to relieve chest pain and related symptoms and to reduce the risk of future cardiac events. Ex. A, Main Application, p. 24

[4] Manchester operates the Coordinated Regional Care Model and participates in the Next Generation Accountable Care Model under which physicians, affiliated medical groups and hospitals collaborate and partner with health plans to provide coordinated care for patients. Ex. A, Main Application, p. 36

[5] The Applicants state that a cath lab providing only primary PCI is not sustainable due to the lack of volume necessary to ensure the best quality of the program. Ex. U, Transcript, Testimony of Dennis Mcconville, Senior Vice President and Chief Strategy Officer, ECHN, p. 40

14. Elective PCI procedures for patients with non-ST-Segment Elevation Myocardial Infarction ("NSTEMI") ideally take place within 24-48 hours of diagnosis.[6] Ex. A, Main Application, p. 24

15. The American College of Cardiology Foundation ("ACCF") and the American Heart Association ("AHA") have jointly produced guidelines in the area of cardiovascular disease since 1980. Ex. A, Main Application, p. 577

16. In 2011, the American College of Cardiology Foundation, American Health Association and the Society for Cardiovascular Angiography and Interventions ("ACCF/AHA/ SCAI") issued a PCI Guideline in which they concluded that primary PCI is reasonable in hospitals without on-site cardiac surgery as long as appropriate planning for program development had been accomplished. Ex. A, Main Application, p. 575

17. The 2011 ACCF/AHA/ SCAI Guideline advised "it is only appropriate to consider the initiation of the PCI program without on-site cardiac surgical backup if the program will clearly fill a void in the healthcare needs of the community…" The Guideline further stated that "institutional financial gain, prestige, market share, or other similar motives" were inappropriate considerations for initiation of PCI programs without on-site cardiac surgery." Ex. A, Main Application, pp. 409,596

18. The 2011 ACCF/AHA/ SCAI Guideline also set forth personnel and facility requirements, including the execution of written agreements for the emergency transfer of patients to a facility with cardiac surgery. Ex. A, Main Application, p. 575

19. In 2013, the American College of Cardiology Foundation and the American Heart Association ("ACCF/AHA") Task Force[7] on Practice Guidelines recommended the following timelines with regard to STEMI patients presenting at non-PCI capable hospitals:
    a. A goal of 30 minutes or less, "door-in-door out," for the assessment of STEMI patients; and
    b. 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

20. In 2014, the Society for Cardiovascular Angiography Interventions, American College of Cardiology and American Heart Association ("SCAI/ACC/AHA") issued an Expert Consensus Document that was a composite of recommendations previously set forth in prior guidelines and consensus documents and that included new recommendations. Ex. A, Main Application, p. 24

[6] Between 2015 and 2017, over 94% of diagnostic cardiac cath patients for whom elective PCI was indicated received elective PCI on the same day. Ex. D. Applicant's First Completeness Response, p. 1244

[7] The ACCF/AHA Task Force on Practice Guidelines is charged with developing, updating, and revising practice guidelines for cardiovascular diseases and procedures. The first ACC/AHA Task Force report on guidelines for coronary balloon angioplasty was published in 1988 with subsequent iterations and consensus documents issued by various writing committees to address new studies and changes in the field of interventional cardiology. Ex. A, Main Application, pp. 577, 580

21. The writers of the 2014 Expert Consensus Document concluded that geographic isolation exists when the *emergency* transport time between a non-PCI *facility*[8] and a PCI-capable *facility* is more than 30 minutes. Ex. A, Main Application, pp. 414-415 (Emphasis Added.)

22. Qualitatively, the 2014 SCAI/ACC/AHA 2014 Guideline indicated that "an institutional volume threshold of less than 200 PCIs per year was associated with worse outcomes" and therefore "continued operation of laboratories performing less than 200 procedures annually that are not serving isolated or underserved populations should be questioned." Ex. A., Main Application, pp. 119-121

23. Performing primary PCI for STEMI requires an additional technical skill set. The 2014 and 2016 Expert Consensus Documents set forth qualitative recommendations requiring that:
    a. Primary PCI procedures be performed by experienced operators who perform a minimum of 50 elective PCI procedures per year and at least 11 primary PCI procedures per year; and
    b. PCI procedures be performed in institutions that perform more than 200 elective PCIs per year and more than 36 primary PCI procedures for STEMI per year. Ex. A, Main Application, pp. 371, 414

24. The Connecticut Statewide Health Care Facilities and Services Plan ("Facilities and Services Plan") requires hospitals seeking to establish a PCI program without on-site cardiac surgery to:
    a. Meet the conditions required in the ACCF/AHA/SCAI Practice Guideline for PCI procedures without on-site surgical backup; and
    b. Demonstrate a clear public need for the program.
    Ex. A, Main Application, p. 596

25. In alignment with the ACCF/AHA/SCAI Guideline, the Applicants submitted the following agreements between the Applicants as well as policies and protocols for the proposed program:
        1. Patient Selection Guidelines (Ex. A, Main Application, pp.1134-1136)
        2. The ACCF/AHA/SCAI Guidelines and Updates for Percutaneous Coronary Intervention and Cardiac Catheterizations (Ex. A, Main Application, pp. 369-679)
        3. How Manchester will meet the SCAI Guidelines (Ex. A, Main Application, pp.1137-1161)
        4. Cardiac Surgery Transfer Protocol and Agreement between the Applicants (Ex. A, Main Application, pp.1102-1108)
        5. Comprehensive Interventional Cardiac Program Development, Staffing and Training Services agreement between the Applicants (Ex. A, Main Application, pp.1109-1120, 1122-1131)
        6. Cardiac Program Medical Director Services (Ex. A, Main Application, p.1121)

    Ex. A, Main Application, pp. 1102-1136

26. The Applicants' proposed service area includes three towns (Ashford, Bolton and Willington) for which Manchester and Rockville are the most significant providers and

[8]Geographic isolation does not take into consideration the drive time between each individual service area town to the nearest PCI-capable facility. Ex. A, Main Application, p. 412; Ex. T, Applicants' Late File Response pp.19-20

eight towns for which other hospitals are the significant providers (Andover, Columbia, East Windsor, Hebron, Mansfield, Somers, Stafford and Union). [9]

FIGURE 1
APPLICANTS' PROPOSED SERVICE AREA*

*The Applicants' proposed service area includes nine primary service area towns shaded orange and nine secondary service area towns shaded yellow. Ex. A, Main Application, p. 23

27. The North Central Connecticut EMS Guidelines local STEMI agreement plan (the "Plan") directs emergency medical vehicles to transport patients with emergent STEMI 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 or to contact medical control at the nearest facility to determine patient destination. Ex. A, Main Application, pp. 48, 700, 973, 1093-1096[10]

28. The Plan further provides that if transport time is more than 30 minutes, the decision regarding the appropriate hospital should be made in conjunction with indirect and/or direct medical oversight. Ex. A, Main Application, pp. 1093-1096

29. The Applicants' proposed service area includes the towns of Ashford, Columbia, Ellington, Mansfield, Somers and Stafford Springs which are outside of the 30-minute drive time radius set forth in the plan. Ex. A, Main Application, pp. 47

[9]Manchester Hospital has used the proposed service area in prior filings to the Office of HealthCare Access which was renamed the Health Systems Planning Unit of the Office of Health Strategy pursuant to Connecticut Public Act 18-91.

[10]The goal of the Department of Public Health Office of Emergency Management Services, Connecticut EMS STEMI Guidelines ("DPH OEMS Guidelines") is to "ensure that authorized EMS personnel obtain a 12-lead electrocardiogram in the field on all patients with suspected MI, thereby increasing the likelihood they will be transported for treatment with percutaneous coronary intervention within 90 minutes of first medical contact." It directs emergency medical vehicles transporting a patient already identified as STEMI to bring the patient to a PCI-capable facility if it is less than 30 minutes away. Ex. A, Main Application, pp. 1093-1096

30. Based on FY 2017 inpatient discharges, however, the towns below comprise Manchester and Rockville's actual service area ("SA").[11]

TABLE 1
MANCHESTER & ROCKVILLE HOSPITALS COMBINED INPATIENT DISCHARGES, FY 2017

Patient Town	Discharges	% of Total Discharges	Cumulative %
Manchester	3,409	29	29
Vernon	1,931	16	45
East Hartford	979	8	53
South Windsor	777	7	59
Tolland	695	6	65
Ellington	574	5	70
Coventry	310	3	73
Glastonbury	276	2	75
Remaining Towns/States	2,997	25	100
Total	**11,948**	**100**	**100**

Source: OHS Acute Care Hospital Inpatient Discharge Database

31. The 2016 Manchester Memorial Hospital Community Health Needs Assessment ("CHNA") identified cardiovascular disease and cancer as the leading causes of death within the service area.[12]

INTENTIONALLY LEFT BLANK.

[11] A hospital's primary service area is the geographic area (by town), for the service location in the application, consisting of the lowest number of contiguous zip codes from which the applicant draws at least 75% of its patients for this service at such location. *Connecticut Department of Public Health, Statewide Health Care Facilities and Services Plan*, 2016 Supplement, p. 149. https://portal.ct.gov/-/media/OHS/ohca/HC_Facilities_Advisory_Body/Facilities/2016/CT-OHCA-2016-Facilities-Plan_FINAL.pdf?la=en

[12] *2016 ECHN Community Health Needs Assessment for Manchester Memorial Hospital Service Area*, October 2016, p. 15. http://www.echn.org/filemanager/userfiles/pdfs/2016_PRC_CHNA_Report_-_Manchester_Memorial_Hospital.pdf

32. Hartford, Saint Francis and John Dempsey hospitals are the existing cardiac cath and PCI-capable providers nearest to Manchester and Rockville.

TABLE 2
REGIONAL PCI CAPABLE PROVIDERS

PCI-Capable Hospital	To Manchester		To Rockville	
	Distance (in Miles)	Travel Time (in Minutes)	Distance (in Miles)	Travel Time (in Minutes)
Hartford*	9.6	23	9.2	19
Saint Francis**	10.3	22	9.9	17
John Dempsey	18.3	28	17.9	23
Central Connecticut	21.2	34	29.3	38
Baystate Memorial, Springfield, MA	32.3	39	27.5	39

Source: Travel miles and times from Google Maps
*Non-emergency typical travel duration from Manchester to Hartford Hospital at 7:43 a.m. ranges between 20 to 35 minutes.[13]
**Non-emergency typical travel duration from Manchester to Saint Francis can range between 20 to 40 minutes at 7:43 a.m.
Ex. A, Main Application, p. 702, Ex. T Applicant's Late File, p.14

33. 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
Total[1]	**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%**	**-**	**-**	**-**

[1]The 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. E, Applicants' Addendum to First Completeness Response, p. 1241; Ex. G, Applicants' Second Completeness Response, p. 1277

[13] The Applicants also submitted documentation from Google Maps that on Thursday, February 14, 2019, at 7:43 a.m., the non-emergency drive time from Manchester to Saint Francis and from Manchester to Hartford was 30 minutes or less. Ex. T, Applicant's Late File Response, p. 14

34. Between FYs 2015 and 2017, the average door-to-balloon time for primary PCI patients transferred from Prospect ECHN hospital emergency departments was 108 minutes. Ex. A, Main Application, pp. 1241-1242; Ex. G, Applicants' Second Completeness Response, p. 1280

35. The average inpatient 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

	Discharges (FY 2015-2017)*				Mortality (2012-2014)**			
	Ischemic Heart Disease[1]		AMI[2]		Ischemic Heart Disease[3]		AMI[4]	
Service Area	**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**	**29.5**	**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.
[1]Inpatient discharges assigned ICD-9-CM diagnosis codes 410 – 414 or ICD 10 CM codes I20 - I25.
[2]Inpatient 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 20.
[4] CT DPH Age Adjusted Mortality Rates Codnum 129.2. Rates are not calculated for counts below 20.
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.

36. Historical volumes for cardiac caths and PCIs in the proposed service area and the state are below:

TABLE 5
HISTORICAL DISCHARGE/VISIT VOLUMES FOR CARDIAC CATHS AND PCI IN THE PROPOSED SERVICE AREA AND CONNECTICUT, FY 2015 - FY 2017

	Cardiac Caths			Primary PCIs[1]			Elective PCIs[2]		
Service Area	**FY 2015**	**FY 2016**	**FY 2017**	**FY 2015**	**FY 2016**	**FY 2017**	**FY 2015**	**FY 2016**	**FY 2017**
Primary	853	980	1,009	117	113	105	145	154	170
Secondary	598	718	803	109	113	114	70	92	146
Total Service Area	**1,451**	**1,698**	**1,812**	**226**	**226**	**219**	**215**	**246**	**316**
Y-T-Y % Chng.	**-**	**17%**	**7%**	**-**	**0%**	**-3%**	**-**	**14%**	**28%**
Connecticut	**14,511**	**15,488**	**17,534**	**2,839**	**2,916**	**2,993**	**2,534**	**2,704**	**3,247**
Y-T-Y % Chng	**-**	**7%**	**13%**	**-**	**3%**	**3%**	**-**	**7%**	**20%**

Source: OHS Acute Care Inpatient Discharge and Outpatient Surgery Databases
[1]Inpatient discharges assigned ICD 9 diagnosis codes 410-410.99 or ICD 10 codes I21 – I21.A9 as a primary diagnosis and an ICD 9 procedure or ICD 10 PCS PCI code from Ex. B 18-32224-CON Cardiac Program as a principal procedure.

37. There are no cardiac cath or PCI providers in the Applicants' proposed service area. Below are the discharges for hospitals that have administered cardiac caths and PCIs to patients originating from Manchester's primary service area:

TABLE 6
PROVIDERS OF CARDIAC CATHERIZATION[1] AND PCI[2]
FOR PRIMARY SERVICE AREA RESIDENTS FOR FYS 2015-2017 (COMBINED)

	Cardiac Catheterizations			PCI		
Patient Towns	**Saint Francis**	**Hartford**	**Other[3]**	**Saint Francis**	**Hartford**	**Other[4]**
Coventry	113	78	11	34	38	<6
East Hartford	460	322	50	115	106	7
Ellington	150	54	6	38	21	-
Glastonbury	120	236	23	40	63	8
Manchester	857	166	33	215	48	7
South Windsor	279	96	24	80	35	<6
Tolland	139	46	10	40	13	-
Vernon	418	108	21	134	39	<6
3-yr PCI vol. in Service Area	**2,536**	**1,106**	**178**	**696**	**363**	**35**
Hospital 3-yr PCI/Cath Vol.	**7,420**	**8,321**	**17,142**	**2,347**	**3,011**	**6,046**
Services Area vol. as % of Hospital 3-yr PCI/Cath Vol.	**34%**	**13%**	**1%**	**30%**	**12%**	**1%**

Source: OHS Acute Care Hospital Inpatient Discharge and Outpatient Surgery Databases.
[1]Inpatient discharges assigned ICD-9-CM procedure codes or ICD 10 PCS codes and outpatient encounters assigned CPT codes from Ex. B 18-32224-CON Cardiac Program ICD10 or CPT Code. Both inpatient and outpatient counts are unduplicated and utilize all procedure codes
[2]Inpatient discharges assigned ICD-9-CM procedure codes or ICD 10 PCS codes and/or outpatient encounters assigned CPT codes from Ex. B 18-32224-CON Cardiac Program ICD10 or CPT Code. Both inpatient and outpatient counts are unduplicated and utilize all procedure codes.
[3]Includes five hospitals: John Dempsey, Yale, L+M, Waterbury and Central CT.
[4]Includes seven hospital: John Dempsey, Yale, L+M, Middlesex, Waterbury, Central CT and CCMC.
Note: Cell counts that are less than six are replaced with "<6" for patient confidentiality.

38. The overall average annual growth rate for cardiac catheterization procedures in the proposed service area was 6.5% between FYs 2015 through 2018 and resulted from an increase in elective PCI procedures. Ex. T, Late File Response, p. 15

39. The average annual growth rate for primary PCI in the proposed service area between FY's 2015 through 2018 was 6.0%. Ex. T, Late File Response, p. 15

40. In order for the proposed program to meet national standards for volume and quality, patient volume would need to be shifted from Saint Francis and Hartford to Manchester. Ex. A, Main Application, pp. 25, 39, 89, Ex. D, Applicants' First Completeness Response, p. 1236

41. Currently, there are twenty-three cardiologists who provide outpatient services to residents within the proposed service area, and are affiliated with Prospect ECHN and/or Saint Francis and who will be referring patients to the proposed program. Other referral sources for the proposed program are the area EMS/ambulance service organizations that transport STEMI patients to PCI providers. Ex. D, Applicants' First Completeness Response, pp. 1234, 1262

42. The Applicants project that approximately one in ten of projected procedures will be covered by Medicaid:

TABLE 7
MANCHESTER HOSPITAL'S PROJECTED PAYER MIX FOR THE PROPOSAL

Payer	Projected Procedure**					
	FY 2020		FY 2021		FY 2022	
	Volume	%	Volume	%	Volume	%
Medicare	174	37	261	37	347	37
Medicaid	51	11	75	11	100	11
CHAMPUS & TriCare	3	1	4	1	7	1
Other Government	0	0	0	0	0	0
Total Government	**228**	**49**	**340**	**49**	**454**	**49**
Commercial Insurers	234	50	351	50	468	50
Uninsured	4	1	6	1	7	1
Workers Compensation	-	0	-	0	-0	0
Total Non-Government	**238**	**51**	**357**	**51**	**475**	**51**
Total Payer Mix*	**464**	**100**	**697**	**100**	**929**	**100**

*Totals are different due to rounding
Ex. A, Main Application, pp. 81, 1238

43. Projected utilization for the proposed services are below:

TABLE 8
PROPOSED CARDIAC PROGRAM PROJECTED UTILIZATION

Inpatient + Outpatient Services (Procedures)	FY 2020	FY 2021	FY 2022
Cardiac Catherization[1]	337	505	674
Primary PCI[2]	42	64	85
Elective PCI[3]	85	128	171
Total PCI	**127**	**192**	**256**
Total Procedures	**464**	**697**	**930**
Inpatient + Outpatient Services (Patient)			
Inpatient Discharges	153	207	276
Outpatient Visits	270	405	540
Total	**423**	**612**	**816**

[1] Utilizes a three-year ramp up period during which physician referral patterns and EMS patterns will adjust to achieve a 41% capture rate equivalent to the hospital's emergency department (ED) market share of the proposed service area. Based on historical volumes, assumes the inpatient to outpatient ratio is 35% to 65%.
[2]Assumes a conservative 75% capture rate because area emergency transport services will transport nearly all service area primary PCI patients to Manchester as required by the Department of Public Health and Regional EMS cardiac guidelines and protocols. Volumes are based on inpatient discharges only.
[3]Assumes a three-year ramp up period to achieve a capture rate of 41%, which is equivalent to the hospital's ED market share of the proposed service area. Based on historical volumes, assumes the inpatient to outpatient ratio is 35% to 65%.
Ex. A, Main Application, pp. 28, 70, 78-79; 697; Ex. E, Applicants' Addendum to First Completeness Response, pp. 1234-1235

44. Nine Saint Francis and Manchester cardiac interventionists, residing between 6.5 and 15.6 miles from the proposed location, have the ability to provide 24/7 coverage primary PCI service. Ex. D, Applicants' First Completeness Response, p. 1238

45. The Applicants' proposed capital expenditures are as follows:

TABLE 9
TOTAL PROPOSAL CAPITAL EXPENDITURES

Purchase/Lease	Cost
Equipment	
Imaging system,[1]	$1,498,587
Cardiac monitoring system	269,018
OCT/tomography systems	120,000
Intra-aortic pumps, contrast injector, defibrillator, other	180,138
Construction/Renovation	687,007
Other (specify) (contingency)	345,250
Total Capital Expenditure (TCE)	**3,100,000**

[1] Philips 100243 Allura FD20 imaging system equipped to handle a broad spectrum of applications, including, but not limited, those related to angioplasty, cardiac, neuro and vascular interventional procedures. https://info.blockimaging.com/philips-allura-fd10-vs.-allura-fd20-cath/angio-comparison
Ex. A, Main Application, pp. 68, 1198-1228

46. The Applicants will fund the proposal through Manchester's operational income. Ex. A Main Application, p. 69

47. The Applicants project incremental gains in the amount of $1,007,896; $1,888,265 and $3,158,677 in FY's 2020 through 2022, respectively. Ex. A Main Application, p. 69

48. Saint Francis will experience incremental losses with the proposal but the operating revenues the hospital generates are sufficient to offset those losses.

TABLE 10
PROJECTED REVENUES AND EXPENSES FOR
SAINT FRANCIS WITH CON OR WITHOUT CON

	WITH CON			WITHOUT CON		
	FY 2020	**FY 2021**	**FY 2022**	**FY 2020**	**FY 2021**	**FY 2022**
Revenue from Operations[1]	$960,226,000	$978,744,000	$999,061,000	$962,524,000	$983,109,000	$1,005,264,000
Total Operating Expenses[2]	$910,898,000	$936,152,000	$961,469,000	$911,461,000	$937,023,000	$963,665,000
Gain/Loss from Operations	$49,328,000	$42,592,000	$37,592,000	$51,063,000	$46,086,000	$41,589,000

[1]Net patient revenues will improve even with the reduced volumes of inpatient discharges and outpatients associated with the proposal.
[2]FTE is unchanged and supplies and drugs expenses will be reduced by the amount associated with treating patients from the project's proposed service area.
Ex. E, Applicants' Addendum to First Completeness Response, p. 1269

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

50. As illustrated in Table 12, the Applicants project that the annual average cost per patient for the proposed services for FYs 2020 through 2022 will be lower at Manchester than at Saint Francis.

TABLE 11
PROJECTED ANNUAL AVERAGE COST PER PATIENT FOR THE PROPOSED SERVICES AT MANCHESTER AND SAINT FRANCIS FY2020-FY 2022

Setting	Service	Average Cost per Patient		Cost Difference	
		Manchester[1]	St. Francis	in $	in %
Inpatient	Cardiac Cath	$16,106	$16,319	$213	1%
	Elective PCI	$20,118	$22,279	$2,161	10%
	Primary PCI	$19,280	$25,436	$6,156	24%
Outpatient*	Cardiac Cath	$4,759	$6,414	$1,655	26%
	Elective PCI	$5,589	$16,410	$10,821	66%

*Primary PCIs are performed in inpatient settings only.
[1] Cost estimates as based on FY17 patient attributes such as DRG, length of stay, revenue and procedure codes from ChimeData utilization and payer mix statistics and the hospital's current contractual agreements with major payers and reimbursement experience.
[2] Cost estimates are based on expected payments to the hospital for FY17 and four months of FY18 for ECHN service area cardiac patients and the payer mix which drives average patient costs. Ex. E, Applicants' First Completeness Response, pp. 1245-1245, Ex. G, Applicants' Second Completeness Response, pp. 1283-1286

51. All cardiac interventionists plan to enroll as Medicaid providers and to adhere to Manchester's indigent care policy. Ex. A, Main Application p. 85-86

52. Manchester plans to extend its existing charity care policy to the program. Ex. A, Main Application p. 85-86

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V. Discussion

The Applicants propose the expansion of cardiac services at Manchester by establishing a cardiac cath lab, and primary and elective PCI service without on-site surgical back-up. In support of this Application, the Applicants contend that the proposed program will improve access to services to patients within the proposed service area of Manchester, and its sister hospital, Rockville, and that the proposal will offer high quality cardiac services to patients at a lower cost than Saint Francis.

The Applicants bear the burden of proof in this matter by a preponderance of the evidence. *Jones v. Connecticut Medical Examining Board*, 309 Conn. 727 (2013). OHS finds, based upon an analysis of the facts and evidence in the record, that the Applicants did not meet all of the statutory criteria set forth in Conn. Gen. Stat. § 19a-639(a).

The Applicants have not satisfactorily identified the population to be served by the proposal.

Rather than basing the service area on Manchester's inpatient discharges, the Applicants based the projected population to be served on a combination of towns that ECHN has historically used to review, analyze, and assess its current operations and future business plans and service lines. The Applicants additionally contend that OHS must recognize this service area as the former Office of Health Care Access ("OHCA") had previously acknowledged the same service area and included it in a 2015 CON decision.

The Applicants' proposed service area is inappropriate for two reasons. First, the Facilities and Services Plan defines a hospital's primary service area as the towns that make up the top 75% of a hospital's discharges. Additionally, the ACCF/AHA/SCAI Guideline, which sets national standards for cardiac intervention programs, states that it is only "appropriate to consider the initiation of the PCI program without on-site cardiac surgical backup if the program will clearly fill a void in the healthcare needs of the community…" In order to assess whether there is a need to establish a new PCI program in a given region, and to determine the impact of the proposed program on existing providers, the number of patients that would likely receive treatment at the new program must be determined. Based upon Manchester's historic inpatient discharges, its actual service area and projected population to be served is: Manchester, Vernon, East Hartford, South Windsor, Tolland, Ellington, Coventry and Glastonbury.

Second, CON applications are decided on a case-by case basis and do not lend themselves to general applicability due to the uniqueness of the facts in each case. *Jones v. Connecticut Medical Examining Board*, 309 Conn. 727 (2013). On May 14, 2018, OHCA became the Health Systems Planning Unit and was combined with the newly created Office of Health Strategy.[14] Given the definition of primary service area in the Facilities and Services Plan and the evidence in the record, OHS finds that the Applicants did not satisfactorily identify the population to be served by the proposal.

[14] See, Conn. Gen. Stat. §19a-754a(b)(5)

The Applicants have not demonstrated clear public need for the proposal due to the declining rate of primary PCI procedures within the proposed service area, the volume shift required to successfully implement the program, and because Manchester is not "geographically isolated."

The Applicants erroneously utilize the ACCF/AHA/SCAI Guideline for primary PCI to justify the need for comprehensive cardiac services. Primary PCI is used to treat STEMI patients diagnosed with emergent heart conditions. However, the evidence in the record supports a finding that there was no growth in the rate of primary PCI procedures in Manchester's proposed service area between FY's 2015 and 2018. In fact, the rate of primary PCI procedures declined by 6% during that period. Conversely, the reason for the overall growth in PCI procedures during the same period was due to an increase in elective PCI procedures in which timing is less critical.

The Guideline recommends that a facility perform at least 200 PCIs per year, 36 of which should be primary. The Applicants acknowledge that volume must shift from PCI-capable hospitals to Manchester in order to sustain the requisite volume for the proposed program. The Applicants argue that this shift will have no adverse effect upon other area providers, however, as stated previously, this volume shift does not fill a void in the healthcare community when that population already has access to those services at Saint Francis and Hartford hospitals.

Additionally, Manchester is currently meeting the ACCF/AHA/SCAI recommendations for door-to-balloon time. Various iterations of the Guideline and Consensus Documents set forth, in relevant part, a goal of 30 minutes or less, door-in-door out, for the assessment of STEMI patients at non-PCI capable facilities, and a maximum of 120 minutes door-to-balloon time for the transfer of STEMI patients from a non-PCI capable hospital to a PCI-capable hospital. Data for FYs 2015-2017 demonstrates that Manchester's door-to-balloon time averaged 12 minutes less than the maximum time frame of 120 minutes permitted in the ACCF/AHA/SCAI Guideline.

Furthermore, the Applicants' claim that several towns within the proposed service area are "geographically isolated" is without merit. OHS acknowledges the rural nature of those towns and the fact that they are farther from Manchester than the towns situated within Manchester's actual service area. Nonetheless, the 2014 Expert Consensus Document explicitly states that geographic isolation exists when the *emergency* transport time between a non-PCI *facility* and a PCI-capable *facility* is more than 30 minutes.

Saint Francis and Hartford hospitals are PCI-capable hospitals. Both are approximately 10 miles away from Manchester and the average travel duration to those hospitals is 22.5 minutes. There is no evidence in the record that Google Maps, utilized by the Applicants to show that the average travel time to Saint Francis and Hartford had the potential to exceed 30 minutes during rush hour, factored in travel time in an emergency vehicle with lights and sirens. Therefore, OHS finds that Manchester is within a 30-minute drive to both Saint Francis and Hartford hospitals and that it is not geographically isolated.

Finally, OHS acknowledges that Manchester's most recent CHNA revealed cardiovascular disease and cancer to be the leading causes of death within the service area. However, the average inpatient discharge rates for ischemic heart disease and AMI for adults in the proposed service area are lower than statewide rates. OHS notes that the objective of the current DPH OEMS Guidelines is to ensure that STEMI patients residing in rural areas receive timely access to cardiac care. OHS does not substitute its judgment for that of the Applicants but further notes that

investments in primary care, which is preventive and more cost-effective than surgery, could obviate the need for additional cardiac surgical intervention programs.

The Applicants have demonstrated that the proposal will result in financial gains for Manchester, however, it will also adversely impact utilization of existing PCI-capable facilities that already serve patients residing in the proposed service area.

The Guideline explicitly states that "institutional financial gain…market share, or other similar motives" are inappropriate considerations for initiation of PCI programs without on-site cardiac surgery." Manchester indicates that it can fund the capital expenditure of $3,100,000 for the proposed program through operational income. Additionally, Manchester projects three (3) consecutive years of incremental gains between FY's 2020 and 2022. Although Saint Francis projects incremental losses following implementation of the program, they opine that operating revenues will be sufficient to offset those losses. The Applicants further claim that while a requisite percentage of Manchester's market share will need to shift to Manchester Hospital, it is not material and will not have an adverse impact on quality at Saint Francis or Hartford hospital.

Although the project is financially feasible for the Applicants, OHS cannot grant a CON to the Applicants on that basis. Furthermore, despite the Applicants' assertion that the volume shift will not affect quality at or financial stability of PCI programs at Saint Francis and Hartford hospitals, the proposed program *will* adversely impact utilization by reducing the current volume of PCIs at those facilities.

The Applicants have satisfactorily demonstrated that the proposal will improve patient cost and provider diversity, however, they have not satisfactorily demonstrated that it will improve quality and accessibility.

In reviewing an application, OHS must evaluate whether Applicant(s) meet each of the applicable statutory criteria. When there are deficiencies in the record, OHS must then make a determination about whether an application should be granted with conditions. In the instant application, there is evidence that the addition of the proposed program would increase the diversity of providers to patients within the proposed service area. There is also evidence that patient costs may decrease, in part, because a stay at a tertiary hospital like Saint Francis is more expensive than receiving care at Manchester. Lastly, the Applicants project that 48% of the payer mix will be governmental payers.

However, OHS cannot grant the Applicants' CON application based upon provider diversity and cost-efficiencies alone. There are already two PCI-capable providers available to patients residing within the service area. Even though the proposal may reduce patient cost, the record reveals that Manchester will have to increase PCI volumes in order to establish a program that will meet state and national guidelines. Additionally, Manchester is not geographically isolated and the Applicants have not established clear public need for the proposal.

Moreover, there is nothing in the record that firmly establishes that quality and accessibility will be *improved* by the Applicants' proposal. OHS appreciates the collaboration between the two hospitals to plan for the safe delivery of cardiac care to patients in their surrounding communities. The record includes examples of existing high-quality measures for PCI procedures currently

available at Saint Francis' HHVI. In their application, the Applicants expressed intent to expand those quality measures at Manchester through the execution of written agreements, the development of unified schedules and the identification of nine area cardiac interventionists who would be available 24/7 to respond to cardiac emergencies at both hospitals. Notwithstanding, the aforementioned steps do not constitute an improvement in quality, but rather, an extension of the quality already available to patients within the proposed service area at Saint Francis. Furthermore, the Applicant's own projections indicate indicates that it would take Manchester at least 2 years to meet baseline standards for PCI volume pursuant to the Guideline.

OHS understands that a major benefit to minimizing the time between when a patient presents at the emergency department and when an obstructed artery is reopened is the preservation of the heart muscle. The record additionally establishes that access to the appropriate level of cardiac intervention is key in NSTEMI and STEMI patients. While elective procedures can be scheduled within 24-48 hours, most are likely to be performed the same day, eliminating duplication of patient procedures. Although a primary PCI program at Manchester would decrease transport time for patients in the Applicants' proposed service area, the Guideline states that the door-to-balloon time should be within 120 minutes. Since the data in the record indicates that Manchester routinely meets the timeframe for door-to balloon time, OHS cannot find that access to services will improve as a result of the Applicants' proposal.

VI. Conclusion

The Applicants satisfactorily established that the proposed service is financially feasible, may result in cost savings and that it would improve provider diversity. However, the proposed service is not consistent with the PCI standards in the ACCF/AHA/SCAO Guideline and the Connecticut Statewide Health Care Facilities and Services Plan. Additionally, the Applicants did not establish that the proposed program would improve quality and access to services. Finally, the Applicants did not satisfactorily identify the population to be served. Even if OHS were to consider the application using the Applicants' proposed service area, the record reflects that the Applicants still failed to establish clear public need for the establishment of the requested cardiac services at Manchester Hospital.

Based upon the aforementioned findings of fact and discussion, OHS concludes that the Applicants did not meet their burden of proof in satisfying the statutory requirements of Conn. Gen. Stat. §§ 19a-639a (2),(3),(5),(7),(8) and (9).

Sections 19a-639a(1),(10) and (12) are inapplicable to this application because OHS has not set forth policies and standards adopted in regulations, the Applicants have not failed to provide or reduced service access to Medicaid and indigent persons, and the proposal is neither a termination nor consolidation of health care providers.

Order

Based upon the foregoing Findings of Fact and Discussion, I respectfully recommend that the Certificate of Need application of Manchester Hospital and Saint Francis Hospital to establish a diagnostic cardiac catheterization lab and primary and elective PCI services at Manchester Memorial Hospital be **DENIED.**

Respectfully Submitted,

Digitally signed by Micheala Mitchell
Date: 2019.06.10 13:14:58 -04'00'

June 10, 2019

Date

Micheala L. Mitchell, JD
Hearing Officer