

STATE OF CONNECTICUT

DEPARTMENT OF PUBLIC HEALTH

Raul Pino, M.D., M.P.H.
Commissioner



Dannel P. Malloy
Governor
Nancy Wyman
Lt. Governor

Office of Health Care Access

Final Decision

Applicants: **The William W. Backus Hospital**
326 Washington Street,
Norwich, CT 06360

Hartford Hospital
80 Seymour Street,
Hartford, CT 06102

Docket Number: **15-32031-CON**

Project Title: **Establishment of a Primary and Elective Percutaneous Coronary Intervention Program at Backus Hospital without On-Site Surgical Backup**

Project Description: The William W. Backus Hospital ("Backus") and Hartford Hospital ("Hartford") (Backus and Hartford are herein collectively referred to as the "Applicants") seek authorization to establish and operate a primary and elective percutaneous coronary intervention ("PCI" or angioplasty) program at Backus without on-site cardiac surgical backup, at an associated capital cost of \$4,982,053.

Procedural History: The Applicants published notice of their intent to file a Certificate of Need ("CON") application in *The Bulletin* (Norwich) on September 7, 8 and 9, 2015. On September 30, 2015, the Office of Health Care Access ("OHCA") received the CON application from the Applicants for the above-referenced project. On January 29, 2016, OHCA deemed the application complete.

On March 9, 2016, the Applicants were notified of the date, time, and place of the public hearing. On February 11, 2016, a notice to the public announcing the hearing was published in *The Bulletin* (Norwich). Thereafter, pursuant to Connecticut General Statutes ("Conn. Gen.



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Stat.”) § 19a-639a(f)(2), the public hearing regarding the CON application was held on March 23, 2016 and continued on June 14, 2016.

Commissioner Pino designated Attorney Kevin T. Hansted 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 General Statutes) and Conn. Gen. Stat. § 19a-639a(f)(2).

On March 16, 2016, Lawrence + Memorial Hospital (“L+M”) filed a petition requesting intervenor status. L+M was granted intervenor status with full rights in this matter on March 17, 2016.

On March 22, 2016 the Applicants filed a Motion in Limine to preclude use of data regarding out-of-state PCI providers. On March 23, 2016 L+M filed an objection to the Applicants’ Motion in Limine. On March 31, 2016, Hearing Officer Hansted denied the Applicants’ motion and sustained L+M’s objection. The public hearing record was closed on June 22, 2016.

On August 25, 2016 OHCA issued a Proposed Final Decision denying the Applicants’ CON application. Pursuant to section 19a-9-29(h) of the Regulations of Connecticut State Agencies the Applicants had twenty-one days from the date the Proposed Final Decision was issued to file exceptions or a brief or request oral argument. On September 14, 2016 the Applicants notified OHCA that it would not challenge the Proposed Final Decision. Deputy Commissioner Addo reviewed the entire record in this matter.

Findings of Fact

1. Backus is a 233-bed/bassinets acute care hospital, located at 326 Washington Street in Norwich, CT, and is affiliated with Hartford. Exhibit A, p. 13.
2. Hartford is an 867-bed major teaching hospital affiliated with the University of Connecticut School of Medicine and a regional referral center serving New England. Hartford's Henry Low Heart Center is a full service cardiac provider that offers the following services:
 - a. Cardiac catheterization, angioplasty, electrophysiology and rehabilitation programs;
 - b. A congestive heart disease center;
 - c. Echocardiography;
 - d. Extracorporeal membrane oxygenation;
 - e. A heart failure infusion program;
 - f. Heart surgery and transplants;
 - g. Nuclear cardiology; and
 - h. A transcatheter aortic valve replacement program.Exhibit A, p. 13, 24.
3. Backus currently offers the following inpatient and outpatient cardiac services:
 - a. Diagnostic cardiac catheterizations;
 - b. Pacemaker insertions, evaluations and follow-ups;
 - c. Implantable cardiac defibrillator insertions, evaluations and follow-ups;
 - d. Stress testing;
 - e. Nuclear cardiac imaging;
 - f. Cardiac imaging services;
 - g. Echocardiology;
 - h. 24- and 48-hour monitoring;
 - i. ECG testing;
 - j. Electrical cardioversions;
 - k. Intra-aortic balloon pumping;
 - l. Vascular surgical services offered by interventional radiology staff such as peripheral angioplasty and stenting;
 - m. Heart failure program that offers monitoring and a program coordinator for patients beyond the inpatient setting; and
 - n. Three phase cardiac rehabilitation program consisting of inpatient, outpatient and outpatient maintenance.Exhibit A, p. 20-21.
4. The Applicants are proposing the expansion of cardiac services at Backus by establishing and operating a primary and an elective PCI program without on-site cardiac surgical back-up. Backus' 12-bed critical care unit would be the primary unit for all post-PCI patients. Exhibit A, pp. 13, 21.

5. Angioplasty 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. An expandable balloon is passed through the artery and inflated, flattening blockage-causing plaque and allowing for improved blood-flow. Exhibit A, p. 14.
6. Primary PCI is used to treat emergency situations, such as ST-Segment Elevation Myocardial Infarctions (“STEMI”), which occur when an acute coronary thrombosis blocks a coronary artery. Elective PCI is often a scheduled procedure following extensive cardiac testing or a post-cardiac event to relieve chest pain and related symptoms. Exhibit A, p. 14.
7. STEMI patients requiring primary PCI, need the most urgent care and are treated on an emergency basis. Elective PCI procedures for patients with non-ST-segment elevation myocardial infarction (“NSTEMI”) are often scheduled, but ideally take place within 24-48 hours of diagnosis, effectively reducing the risk of future cardiac events. Ex. A, pp. 14-15; Ex. BB, Transcript, Dr. Francis J. Kieman, Director of Cardiac Laboratory, Hartford Hospital, pp. 103-104.
8. Hartford provides comprehensive cardiac services and performs more than 1,000 angioplasties annually. Hartford and Backus have entered into an agreement for the emergency transfer of patients to Hartford for off-site surgical backup for urgent cases at all hours and for elective cases at mutually agreed upon hours, as well as the necessary training and oversight of the proposed PCI program at Backus. Ex. A, pp. 46, 99, 892-93.
9. The Applicants submitted the following agreements, policies and protocols:
 - Primary PCI Patient Selection Guidelines
 - 2011 ACCF/AHA/SCAI Guidelines for Percutaneous Coronary Intervention and How Backus Will Meet the Standards
 - Elective PCI Patient Selection Guide
 - Transfer Protocol and Agreement between the Applicants
 - Cardiac Surgery Transfer Agreement Between Hartford and Backus
 - Clinical Guidelines for Transfer of Catheterization Lab Patients to Acute Care FacilityEx. A, pp. 88, 84-87, 89, 892-897
10. The Applicants claim benefits of the proposal include:
 - a. Improved access for an area of the state that:
 - (i) is “geographically isolated” from the nearest PCI provider;
 - (ii) has an older population with a relatively higher risk than the state for coronary artery disease;
 - (iii) has current rates of emergency/primary and elective PCI interventions for residents that are significantly below state and national levels leading to relatively higher rates of morbidity and mortality;
 - b. Minimized out-of-pocket costs associated with second hospital admission and duplicative procedures; and

- c. Improved future care coordination and management for patients with heart conditions.
Exhibit A, p. 13.
- 11. The ACC/AHA STEMI Guidelines provide that “door-to-balloon” time, measured from the time a patient presents at the emergency department of a PCI-capable hospital to the time a balloon is inflated to open the occluded artery, should not exceed 90 minutes. The recommended door-to-balloon time for patients presenting at a non-PCI capable hospital from which the patient must be transferred to another hospital is 120 minutes. Exhibit A, pp. 47, 500.
- 12. The presence of a PCI program on-site at Backus would obviate the need for revascularization following a cardiac catheterization diagnosis, enabling the diagnostic and elective procedure to be completed together. This would reduce patient exposure to radiation and intravenous contrast used during the procedure. Ex. A, p. 62.
- 13. The Statewide Health Care Facilities and Services Plan states that hospitals seeking to establish an elective PCI program without on-site cardiac surgery must:
 - a. Meet the conditions required in the American College of Cardiology Foundation/American Health Association/Society for Cardiovascular Angiography and Interventions (“ACCF/AHA/SCAI) Practice Guideline (the “ Guideline”) for percutaneous coronary intervention without on-site surgical backup; and
 - b. Demonstrate a clear public need for the program. Specifically, the Guideline indicates that it is only appropriate to consider the initiation of the PCI program without on-site cardiac surgical backup if this program will clearly fill a void in the healthcare needs of the community as competition with another PCI program in the same geographic area may not be in the best interests of the community.
Exhibit A, pp. 38-39, 47.
- 14. The Applicants’ proposed service area (“proposed service area”) included a) towns within a 30 minute drive-time to Backus, and b) towns outside of the 30-minute radius but for which Backus would be the closest PCI-capable facility in Connecticut. This classification excluded out-of-state PCI providers.

**TABLE 1
APPLICANTS’ PROPOSED SERVICE AREA**

Towns within a 30-minute drive time of Backus Hospital			Towns for which Backus would be the closest in-state PCI provider
Bozrah	Killingly	Preston	East Haddam
Brooklyn	Griswold-Lisbon	Scotland	Hampton
Canterbury	Hebron	Sprague	Pomfret
Chaplin	Killingly	Sterling	Putnam
Colchester	Mansfield Center	Voluntown	Thompson
Columbia	Norwich	Windham	Woodstock
Franklin	Plainfield		

Exhibit A, p. 35.

15. Based on fiscal year (“FY”) 2015 inpatient discharges for Backus, the towns below comprise Backus’ service area (“SA”).¹ The Applicants’ proposed service area included 20 towns beyond Backus Hospital’s SA (Bozrah, Brooklyn, Columbia, Franklin, Hebron, Killingly, Lebanon, Mansfield Center, Scotland, Sprague, Sterling, Voluntown, Windham, East Haddam, Hampton, Pomfret, Putnam, Thompson and Woodstock). Additionally, the proposed service area omitted three towns that are in the SA (Groton, Ledyard and Montville).

TABLE 2
BACKUS HOSPITAL DISCHARGES, FY 2015

Patient Town	Discharges	% of Total Discharges	Cumulative %
Norwich	3,729	35%	35%
Griswold- Lisbon	1,169	11%	46%
Montville	910	8%	54%
Plainfield	843	8%	62%
Preston	346	3%	65%
Colchester	322	3%	68%
Canterbury	273	3%	71%
Ledyard	269	3%	73%
Groton	251	2%	76%
Remaining Towns/States	2,611	24%	100%
Total	10,723	100%	100%

Source: CT DPH, Office of Health Care Access Acute Care Discharge Database

16. The Applicants stated that they selected drive time as the basis for the proposed service area because of the “urgency of time, in order to access [PCI] services.” Additionally, they stated that they selected 30 minutes as the perimeter of the drive time based on the Department of Public Health Office of Emergency Management Services, *Connecticut EMS STEMI Guidelines* (“DPH OEMS Guidelines”). Ex. T, Transcript, Mr. M. Shane Foreman, CEO, 3d Health, p. 34; Ex. K, Pre-filed Testimony, Foreman, 1543.
17. The stated goal of the 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 PCI 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. It also states that emergency vehicles

1. SA is defined as towns that make up the top 75% of a hospital’s discharges. CT DPH, *Statewide Health Care Facilities Plan 76* (2014 Supplement.).

should be 12-lead echocardiogram-equipped to facilitate early identification of STEMI patients. Ex. A, p. 969-970.

18. There are proven beneficial outcomes associated with reducing the time between a patient’s presentation at the emergency department to inflation of the balloon to open the occluded artery (“door-to-balloon time”) during a primary PCI procedure. Ex. T, Transcript, Dr. Paul Thompson, Chief of Cardiology, Hartford Hospital, p. 29.
19. From 2011 through 2015, Backus’ median door to balloon time for primary PCI was 134 minutes. Transport time to a PCI-capable hospital accounted for the largest portion of the door-to-balloon time. Ex. A, p. 473, 476.
20. Backus has historically transferred patients to Hartford and Yale New Haven Hospital for primary PCI, transferring only three patients in the past to the closest PCI-provider, L+M. The Applicants stated this was due primarily to referral patterns. Ex. T, Transcript, Dr. Kyle McClaine, EMS Director, Backus Hospital, p. 151-152; Ex. BB, Transcript, Dr. John Foley, Director of Cardiovascular Service Line, Hartford Medical Group, p. 138.
21. UMass Memorial Medical Center (“UMass”) submitted a letter stating that it has an ongoing relationship with Day Kimball Hospital (“Day Kimball”) and established protocols are in place for receiving NSTEMI transfer patients from Day Kimball. It also states that UMass’ PCI program currently has capacity to continue treating transfers and referrals from Day Kimball. Ex. V; pp. 1-2.
22. UMass is the closest existing PCI provider, based on travel time, for four out of the six towns in northeast Connecticut the Applicants included in their proposed service area.

**TABLE 3
TRAVEL TIMES FROM NORTHEAST TOWNS INCLUDED IN THE
PROPOSED SERVICE AREA TO CLOSEST HOSPITAL***

Select Towns	Drive time to Backus Hospital	Drive time to UMass Hospital
East Haddam	27 minutes	78 minutes
Hampton	27 minutes	46 minutes
Pomfret	36 minutes	33 minutes
Putnam	33 minutes	26 minutes
Thompson	35 minutes	23 minutes
Woodstock	39 minutes	33 minutes

* Based on Google Maps travel time without traffic from center of town

23. Day Kimball, located at 320 Pomfret Street, Putnam, stated in its 2015 Community Health Needs Assessment and Implementation Plan that it “continues to work closely with UMass for STEMI patient transfers via Life Star helicopter within 90 minutes of

- admission to the emergency department and meets regularly to review STEMI data.” Ex. W, p. 4.
24. In 2010, towns in the proposed service area experienced an incidence rate of 104.3 STEMIIs per 100,000; Connecticut overall experienced a rate of 83. Towns in the proposed service area experienced an incidence rate of 237.2 for NSTEMIIs; Connecticut overall had a higher incidence of NSTEMIIs at 242.3. Ex. A, p. 463.
 25. Over a seven year period, patients in the proposed service area underwent fewer inpatient elective PCIs; declining from 316 in FY09 to 171 in FY15. This is consistent with state-wide trends. Ex. A, p. 466, 1499-1500.
 26. The number of patients transferred for an elective PCI following a cardiac catheterization at Backus was 90 in 2012, 90 in 2013, 55 in 2014, 46 in 2015 and 33 in 2016 (annualized). The percentage of cardiac catheterization patients transferred from Backus to a PCI-capable facility also decreased, from 28.4% in 2012 to 19.4% in 2015. Ex. CC, p. 1570.
 27. According to the SCAI/ACC/AHA’s *Expert Consensus Document: 2014 Update on Percutaneous Coronary Intervention Without On-Site Surgical Backup* (“2014 Guidelines”), multiple factors have contributed to the decline in PCI procedures, including “a reduction in restenosis by drug-eluting stents, a greater emphasis on medical therapy for the treatment of stable coronary artery disease, enhanced primary and secondary prevention efforts, and a reduction in incidence of STEMI...” Ex. A, p. 113.
 28. According to the Applicants, there are an insufficient number of emergency advanced life support vehicles in the Backus region, with 15 covering 13 towns in the Backus region. Ex. A., p. 34.
 29. The 2014 Guidelines state that “an institutional volume threshold of <200 PCIs/year was associated with worse outcomes” and therefore “continued operation of laboratories performing <200 procedures annually that are not serving isolated or underserved populations be questioned.” It continues to say that “multiple low-volume and partial service PCI centers within a geographic area diffuse PCI expertise, increase costs for the overall health system and have not been shown to improve access.” It defines “geographic isolation” as a hospital that is more than 30 minutes away from a PCI-capable facility by emergency transport. Ex. A, pp. 119-121.
 30. L+M, a PCI-capable facility, is located 17 miles, or 21 minutes from Backus. Ex. T, Transcript, Dr. Brian Cambi, Director of Cardiology, L+M Hospital, p. 51.

31. Based on historic PCI utilization of residents originating from Backus' SA at other area hospitals¹, the Applicants project Backus would perform 163 PCIs in FY16, increasing slightly to 169 in FY18.²

TABLE 4
PROJECTED PCI UTILIZATION AT BACKUS HOSPITAL

Category	FY16	FY 17	FY18
Primary PCI	55	54	54
Elective PCI	108	111	115
Total	163	165	169

¹ Includes Backus SA patients receiving PCIs at: Hartford Hospital, Yale New Haven, Saint Francis, John Dempsey, The Hospital of Central Connecticut, UMass Memorial and Lawrence + Memorial Hospital.

² Assumes a retention rate of 100% of patients receiving PCIs at Hartford Hospital and 36% from other hospitals based on Backus' ED market share.
Ex. K, p. 1497; Ex. E, pp. 1458, 1466.

32. There are no PCI providers in the Applicants' proposed service area. However, the following hospitals have administered PCIs to 369 patients originating from Backus' SA in 2015.

TABLE 5
2015 PCI PROVIDERS TREATING PATIENTS ORIGINATING FROM BACKUS' SA

PCI Providers	Distance from Backus ¹	No. of PCIs Originating from Backus SA	No. of PCIs	No. of PCIs minus No. from Backus SA	% of PCIs from Backus SA
Hartford Hospital	40 minutes	50	1,099	1,049	4.5%
Yale New Haven Hospital	53 minutes	145	1,575	1,430	9.2%
Saint Francis Hospital	39 minutes	24	784	760	3%
John Dempsey Hospital	58 minutes	30	399	369	7.5%
The Hospital of Central CT	48 minutes	15	85	70	17.6%
UMass Memorial	60 minutes	54	~1,100	1,046	~5%
Lawrence + Memorial Hospital	21 minutes	63*	216	165	23.6%

¹ Distance based on Google Maps normal travel time

* Based upon 2015 inpatient discharge data. All other figures reflect 2014 inpatient discharge data.
Ex. A, p. 46; Ex. E, p. 1458.

33. In 2015, L+M performed 216 PCIs, 63 of those PCI patients originated from Backus' SA.

TABLE 6
2015 PCI PATIENTS FROM SA TREATED AT L+M

SA Towns	2015 Town Totals		2015 L+M PCIs	
	No. Primary PCIs	No. Inpatient Elective PCIs*	No. Primary PCIs	No. All Elective PCIs
Norwich	17	31	10	3
Canterbury	3	3	1	
Preston	1	6	1	3
Plainfield	7	16		1
Colchester	7	8		
Griswold	3	18	2	
Lisbon	-	-		
Montville	10	15	3	2
Ledyard	7	10	6	4
Groton	-	-	20	7
TOTAL	55	107	43	20
L+M Total			121	95
No. Remaining at L+M			78	75

* Outpatient elective PCI data unavailable

Ex. A, pp. 1499-1500; Ex. M, p. 12.; Compliance Reporting for Docket No. 12-31769

34. L+M stated that it has additional capacity to handle transfers from other non-PCI centers. Ex. BB, Transcript, Dr. Cambi, p. 158.
35. The 153 primary and elective PCI patients that would remain at L+M if Backus were to have a PCI program and capture all patients from its SA towns falls below the 200 level recommended by the 2014 Guidelines. Exhibit A, pp. 1499-1500.
36. The Applicants and L+M submitted conflicting claims as to the average retention rate of patients from a PCI provider's service area. The Applicants initially based their projection assumptions on an 80% retention rate of PCI patients from their proposed service area based on observed emergency department market share from the area. L+M asserted that those seeking scheduled elective PCIs would not mimic emergency room patterns and that L+M experienced an overall PCI retention rate of 54%. The Applicants then based final projection rates on a 100% retention rate for patients who had previously received PCIs at Hartford and 36% for those visiting all other hospitals. Ex. A, p. 489; Ex. BB, Testimony, Ms. Edwards, p. 139; Ex. BB, Testimony, Mr. Bitmal Patel, President of the East Region and Senior Vice President, Hartford HealthCare, p. 139; Ex. K, p. 197.

- 37. L+M established its elective PCI program in 2013. Per the Agreed Settlement with OHCA approving establishment of its program, L+M is expected to perform a quantity of procedures above those recommended by the 2014 Guidelines. L+M has stated it is likely to fall well below the minimum threshold should Backus initiate its own PCI program. Ex. M, p. 26; OHCA Docket Number 12-31768-CON.
- 38. Backus projects a financial loss from the operation of a PCI program with increasing incremental losses from operations, from FY2017 through FY2019.

**TABLE 7
PROJECTED INCREMENTAL REVENUES AND EXPENSES**

	FY 2017	FY 2018	FY 2019
Revenue from Operations*	\$4,750,000	\$4,911,295	\$4,970,474
Total Operating Expenses**	\$5,208,730	\$5,470,996	\$5,676,231
Gain/Loss from Operations	(\$457,817)	(\$559,701)	(\$705,757)

* Net revenue per case remains flat and assumes no increase in payer reimbursement
 ** 2.68% inflation rate applied over five resulting in increasing expenses; 2.6 new FTE cardiology staff, on-call payment and call back pay to staff, 24/7 on call physician expenses at \$125/hr. Exhibit A, p. 1409; Ex. BB, Transcript, Ms. Janette Edwards, Backus Hospital, p. 128.

- 39. Backus would need to perform 385 PCI procedures in year five of the program to break even financially. The Applicants project they would perform 233 procedures in the year 2020. Ex. A, pp. 68, 70.
- 40. Estimated capital expenditures associated with the proposal are almost \$5 million. Capital costs would support an additional catheterization lab, new software and equipment upgrades. An additional 3% of net patient revenues would be committed to ongoing capital needs. The Applicants' proposed capital expenditures are as follows:

**TABLE 8
TOTAL PROPOSAL CAPITAL EXPENDITURES**

Purchase/Lease	Cost
Equipment (Medical, Non-medical Imaging)	\$344,000
Construction/Renovation	\$4,500,000
Other (specify) (estimated 3% of operating revenue for additional capital needs)	\$138,053
Total Capital Expenditure (TCE)	\$4,982,053
Total Capital Cost (TCO)	\$0
Total Project Cost (TCE+TCO)	\$4,982,053

Exhibit A, pp. 67, 77.

- 41. The Applicants would fund the proposal through Backus' income from operations. Exhibit A, p. 65.

42. The Applicants project overall gains from Backus’ operations from FY17 through FY19.

**TABLE 9
 BACKUS HOSPITAL PROJECTED REVENUES AND EXPENSES WITH CON**

	FY 2017	FY 2018	FY 2019
Revenue from Operations	\$308,297,624	\$317,799,924	\$329,208,612
Total Operating Expenses	\$270,537,970	\$276,777,162	\$285,116,496
Gain/Loss from Operations	\$37,759,653	\$41,1022,761	\$44,062,116

Exhibit A, p. 1409.

43. The projected patient population mix for the proposed PCI program is as follows:

**TABLE 10
 BACKUS HOSPITAL'S PROJECTED PAYER MIX**

Payer	Projected**					
	FY 2016		FY 2017		FY 2018	
	Volume	%	Volume	%	Volume	%
Medicare*	109	50%	110	50%	113	50%
Medicaid*	25	11%	25	11%	26	11%
CHAMPUS & TriCare	-	0%	-	0%	-	0%
Other Government	2	1%	2	1%	2	1%
Total Government	135	62%	136	62%	140	62%
Commercial Insurers	79	37%	80	37%	82	37%
Uninsured	2	1%	2	1%	2	1%
Workers Compensation	-	0%	-	0%	-	0%
Total Non-Government	81	38%	82	38%	85	38%
Total Payer Mix	216	100%	218	100%	225	100%

*Includes managed care activity

**Payor-weighted reimbursement by DRG based on the payor mix of all PCI patients originating from the proposed service area.

Ex. A, p. 1469

44. OHCA is currently in the process of establishing its policies and standards as regulations. Therefore, OHCA has not made any findings as to this proposal’s relationship to any regulations yet to be adopted by OHCA. (Conn. Gen. Stat. § 19a-639(a)(1))
45. The CON application is inconsistent with the Statewide Health Care Facilities and Services Plan. (Conn. Gen. Stat. § 19a-639(a)(2))
46. The Applicants have not sufficiently demonstrated that there is a clear public need for the proposal. (Conn. Gen. Stat. § 19a-639(a)(3))

47. The Applicants have satisfactorily demonstrated that the proposal is financially feasible. (Conn. Gen. Stat. § 19a-639(a)(4))
48. The Applicants have not satisfactorily demonstrated that access to services, cost effectiveness and the quality of health care delivery would be maintained. (Conn. Gen. Stat. § 19a-639(a)(5))
49. The Applicants have satisfactorily shown that there will be no change in access to primary and elective PCI services to the relevant populations and payer mix, including Medicaid patients and indigent persons. (Conn. Gen. Stat. § 19a-639(a)(6))
50. The Applicants have not satisfactorily identified the population to be served or that this population has a need. (Conn. Gen. Stat. § 19a-639(a)(7))
51. The Applicants' historical utilization in the area does not support this proposal. (Conn. Gen. Stat. § 19a-639(a)(8))
52. The Applicants have not satisfactorily demonstrated that the proposal will not result in an unnecessary duplication of existing services in the area. (Conn. Gen. Stat. § 19a-639(a)(9))
53. The Applicants have satisfactorily demonstrated that the proposal would not result in a reduction or change in access to services for Medicaid recipients or indigent persons. (Conn. Gen. Stat. § 19a-639(a)(10))
54. The Applicants have satisfactorily demonstrated that the proposal would not negatively impact the diversity of PCI providers in the area. (Conn. Gen. Stat. § 19a-639(a)(11))
55. The Applicants have satisfactorily demonstrated that the proposal will not result in any consolidation that would affect health care costs or accessibility to care. (Conn. Gen. Stat. § 19a-639(a)(12))

Discussion

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. In rendering its decision, OHCA considers the factors set forth in Conn. Gen. Stat. § 19a-639(a). The Applicant bears the burden of proof in this matter by a preponderance of the evidence. *Jones v. Connecticut Medical Examining Board*, 309 Conn. 727 (2013).

Backus is a 233-bed/bassinet acute care hospital, located at 326 Washington Street in Norwich, CT, and is affiliated with Hartford. *FF1*. Hartford is an 867-bed major teaching hospital affiliated with the University of Connecticut School of Medicine and a regional referral center serving New England. *FF2*. Backus currently offers inpatient and outpatient cardiac services including diagnostic cardiac catheterizations, cardiac imaging services, echocardiology, intra-aortic balloon pumping and vascular surgical services offered, such as peripheral angioplasty and stenting, by interventional radiology staff. *FF3*.

The Applicants are proposing to expand cardiac services at Backus to include a primary and an elective PCI program. *FF4*. Backus' 12-bed critical care unit would be the primary unit for all post-PCI patients. *FF4*. Hartford would provide off-site surgical back-up. *F8*. Hartford provides comprehensive cardiac services and performs more than 1,000 angioplasties annually and, in addition to tertiary back-up, would provide the necessary training and oversight of Backus' newly established PCI program. *FF8*.

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

Rather than basing the service area on Backus' inpatient discharges, the Applicants based the projected population to be served on a combination of a) towns within a 30-minute radius from Backus and b) towns for which Backus would be the closest PCI-provider by travel time. *FF14*. According to the Applicants, it selected drive time because of the "urgency of time, in order to access [PCI] service." The Applicants stated they selected 30 minutes as the perimeter of the drive time based on the DPH OEMS Guidelines. *FF16*.

The Applicants' proposed service area is inappropriate for three reasons. First, the Applicants failed to provide an adequate rationale for its selection of 30 minutes as the perimeter for the towns to be served. The stated goal of the DPH OEMS Guidelines is to "ensure that authorized EMS personnel obtain a 12-lead electrocardiogram in the field on all patients with suspected MI." It is intended to provide guidance to emergency transport vehicles as to what hospital patients who have a pre-hospital diagnosed STEMI should be directed. *FF17*. Although it is well established that the time to reperfusion correlates to the extent of heart muscle damage in a patient experiencing acute myocardial infarction ("AMI"), the Applicants provided no recognized standard that establishes that every town should be within 30 minutes of a PCI-

capable facility. The Applicants' basis for a 30 minute drive time standard misinterprets the standards and the purpose of the DPH OEMS Guidelines.

Second, for NSTEMI patients requiring an elective -- as opposed to primary -- angioplasty, timing is less critical. According to the Applicants, patients presenting with a one or more significant arterial blockages that are non-life threatening, or NSTEMI, should receive an elective angioplasty within 24 to 48 hours of being diagnosed. *FF7*. Therefore, the application of a travel time constraint of 30 minutes when identifying the projected population to be served by the elective angioplasty program is unfounded as patients may travel to existing elective PCI programs in the area within 24 to 48 hours.

Finally, the Applicants incorrectly state that several of the towns included in their proposed service area are closer to Backus than any other PCI-capable facility. Backus would not be the closest PCI-capable hospital for several of the towns it included in its proposed SA. For example, UMass would be the closest PCI facility for patients originating from Thompson, Putnam, Pomfret or Woodstock. *FF22*. Additionally, as the only acute care hospital in Northeast Connecticut, Day Kimball would likely be the hospital at which patients from that area (including Thompson, Putnam, Pomfret and Woodstock) showing signs of AMI would likely present. Day Kimball, as a hospital lacking PCI capabilities, has stated that it intends to transfer AMI patients to UMass. *FF23*. Due to Day Kimball's proximity to UMass and stated referral patterns, it is uncertain whether patients from multiple towns in the Applicant's proposed service area would seek treatment at Backus. Therefore, the Applicants have failed to adequately identify the population the proposed program may likely serve.

In order to assess whether there is a clear public need for the establishment of a new angioplasty program in a given region and a new program's anticipated impact on existing providers, it must be determined, in part, how many patients would likely receive treatment at the new program. Based on Backus' historic inpatient discharges, its service area, and projected population to be served, is: Canterbury, Colchester, Griswold, Lisbon, Ledyard, Montville, Norwich, Preston, Plainfield and Groton. *FF15*.

Based on declining utilization rates, the increasing use of non-surgical medications and alternate methods of treatment and diagnosis of cardiovascular events the Applicants have not demonstrated that there is a clear public need for a new angioplasty program in the service area.

The Applicants claim that towns in their service area experience elevated incidents of STEMI and NSTEMI compared to Connecticut overall and that this indicates an unmet need for PCI services exists in the proposed service area. While the proposed service area did have a 2010 incidence rate of 104.3 STEMIs per 100,000 people--higher than Connecticut's 83 -- its incidence rate of NSTEMI for the same period was lower than that of the state -- 237.2 compared to 242.3. *FF24*. This suggests that although there may be a need for primary PCI services to address STEMI patients in the area, the NSTEMI data provided by the Applicants does not support the need for an elective program. Additionally, according to Applicants-provided

inpatient elective PCI procedure volume, there is a declining trend in elective PCIs in the area -- consistent with the trend observed state-wide. *FF25*.

Furthermore, other indicators of the need for an elective PCI program in the area are also declining. The number and percentage of cardiac catheterization transfers from a non-PCI facility to a PCI-capable facility for elective angioplasties are two such indicators. The number of patient transfers for an elective PCI following a cardiac catheterization at Backus decreased from 90 in 2012 to 46 in 2015. The transfer rate similarly decreased, from 28.4% in 2012 to 19.4% in 2015. *FF26* This mirrors the state and national data indicating a declining need for elective PCIs.

According to the 2014 Guidelines, due to the increased use of non-surgical alternatives, the number of PCIs performed is likely to continue to decline. It states that drug-eluting stents, enhanced primary and secondary prevention efforts and a greater emphasis on medical therapy are increasingly replacing PCIs as the choice treatment in certain situations. *FF27*.

Additionally, as discussed above, the Applicants cite the DPH OEMS Guidelines as evidence of the need for a PCI program at Backus but misstate the standards and goals of the policy. The Applicants state that “[residents] to the north and east of Norwich do not have timely access to a Connecticut primary or elective PCI-equipped hospital within 30 minutes’ drive time, as specified by DPH OEMS Guidelines.” *Ex.A, p. 16*. However, the referred-to standard pertains to EMS transport of patients with pre-hospital-diagnosed STEMI and is intended to assess whether such patients should be transported to a PCI-capable hospital based on travel time, recommending STEMI patients be transferred to a PCI-capable hospital if one is less than 30 minutes away. *FF17*. The OEMS Guidelines make no indication as to the ideal location of PCI facilities and do not recommend that all towns be within a 30 minute drive time of a PCI facility.

The Applicants again cite DPH OEMS Guidelines regarding EMS transport, stating that STEMI patients should be identified in the field via an electrocardiogram (ECG) in effort to direct patients expeditiously to the appropriate level of care. The Applicants continue that there are only 15 emergency advanced life support vehicles with ECGs to cover 13 towns in the Backus region. The Applicants suggest that because there may be an insufficient number of ECG-equipped emergency transport vehicles, some patients may not be identified as STEMI prior to delivery at a hospital and therefore Backus requires PCI capabilities to treat these patients. *Ex. A, p. 34*. An insufficient number of ECG-equipped vehicles does not equate to the need for a PCI program at every hospital, but rather speaks to whether there is a need for additional appropriately-equipped emergency vehicles.

The Applicants-provided data shows that there may be elevated incidence of STEMIs in the Backus area, potentially warranting a primary PCI program. A shortage of ECG-capable emergency transport vehicles may also highlight the need for additional advanced life support vehicles in the region. However, the declining incidence of NSTEMIs in the region and declining number of cardiac catheterization patients transferred from Backus to an elective PCI-capable hospital do not demonstrate the need for an elective PCI program at Backus. As such, the

Applicants have not demonstrated a clear public need for the as-proposed PCI program at Backus.

The Application does not meet the ACCF/AHA/SCAI Guidelines for proposed PCI programs and, as such, is not consistent with the Statewide Health Care Facilities and Services Plan.

The Department of Public Health's *2012 Statewide Health Care Facilities and Services Plan* standards and guidelines for proposed primary and elective PCI programs draw from those set forth by ACCF/AHA/SCAI. The ACCF/AHA/SCAI Guidelines establish the appropriate minimum volume of PCIs that should be performed at both a facility and by the individual medical professionals administering the procedures. *FF13.*

A facility volume of fewer than 200 PCIs performed per year is, according to the 2014 update of the Guidelines, associated with worse patient outcomes. *FF29.* Therefore, it is recommended that a facility perform at least 200 PCIs per year, 36 of which should be primary PCIs. According to the Plan, "a facility with a volume of fewer than 200 procedures per year, unless located in a region that is underserved because of geography, should carefully consider whether it should continue to offer this service." Geographic isolation exists if the emergency transport time from a non-PCI facility to a PCI capable facility is greater than 30 minutes. *FF29.*

In 2015, patients originating from Backus' service area received approximately 369 PCIs at existing PCI-capable hospitals. *FF32.* Based on a presumed 100% retention rate of patients who went to Hartford and 36% of those who went to the other six hospitals not affiliated with Backus, the Applicants projected Backus would initially perform 165 PCIs—55 of which were primary. *FF32,33,35.* This projection falls significantly short of the 200 procedures recommended by the Guidelines.

L+M, which provides both primary and elective PCIs, is a 21-minute drive from Backus. *FF30.* It can be expected that the emergency transport time would be potentially shorter. As such, Backus does not qualify as geographically isolated and, according to the Guidelines, should not establish a PCI facility due to the likelihood it would fall below the minimum volume recommended for even a low-volume operator.

The Guidelines also state that "[m]ultiple low-volume and partial service-PCI centers within a geographic area diffuse PCI expertise, increase costs for the overall health system and have not been shown to improve access." *FF29.* Not only would Backus' PCI program be unlikely to meet the recommended minimum volume, it would likely have a negative impact on L+M patient volumes, creating precisely the multiple low-volume provider situation the Guidelines warn against. In 2015, L+M performed 216 angioplasty procedures. Sixty-three PCI patients originated from Backus' service area. *FF33.* Had those 63 patients gone to Backus, L+M would have performed only 153 PCI procedures, also falling below the recommended guidelines. *FF35.* L+M has stated that it has no backlog and can accept additional volume. *FF34.*

The Applicants have not satisfactorily demonstrated that the proposal will not result in an unnecessary duplication of services or how the proposal is needed based on utilization at existing PCI providers.

As discussed above, maintaining a certain level of utilization at existing providers is considered necessary to upholding the competency of a hospital and its physicians in performing PCIs. According to the Applicants, residents from Backus' service area who receive PCI treatment currently do so at Hartford, Yale-New Haven Hospital, L+M, Saint Francis Hospital, John Dempsey Hospital, The Hospital of Central Connecticut or UMass Memorial. *FF32*.

The proposal will impact existing providers and the existing providers are not currently being fully utilized by the Applicants. L+M would likely be the existing PCI provider most impacted by the Applicants' proposal. L+M performed 216 PCIs in 2015, 63 of which originated from Backus' service area. *FF32,33*. The Applicants and L+M presented multiple estimates as to the number of patients from Backus' service area who would seek service at Backus rather than the existing hospitals. The proposed retention rate estimates varied from 36% to 80%. *FF36*. Regardless of the precise retention rate applied, either L+M or Backus would not reach the minimum 200 procedures recommended by the Guidelines if the proposal is approved.

Additionally, L+M established its elective PCI program subsequent to entering into an Agreed Settlement with OHCA in 2013. *FF37*. The agreement was based on the expectation that L+M would be able to perform the Guidelines-established minimum number of PCIs of 200 per year. L+M does not anticipate that it will be able to meet the Guidelines minimum and will not be able to comply with this term of the agreement if Backus establishes a program. *FF37*.

The Applicants state that Backus is currently unable to meet the 120 minute door-to-balloon guideline regarding transferring AMI patients to a primary PCI-capable hospital. *FF19*. From 2011 through 2015, Backus' median door-to-balloon time was 134 minutes and travel time to a PCI-capable hospital accounted for the largest portion of Backus' transfer times. *FF19*. However, according to the Applicants, Backus has only transferred three patients to L+M, which is 21 minutes away. According to the Applicants, due to referral patterns, Backus transfers the majority of patients in need of primary PCI to Hartford, 40 minutes away. *FF20,32*. As such, the Applicants have not provided sufficient evidence demonstrating a need for a PCI program. The majority of patients that would be treated at Backus are currently being treated by other providers and, therefore, this proposal represents merely a shift in patient volume due to siphoning patients from existing providers.

The Applicants would likely be able to absorb the financial losses of the program.

The Applicants estimate Backus would need to perform 385 PCI procedures for the program to break even financially, and do not anticipate performing the necessary number of procedures through 2020, at which point they project the program would perform approximately 233 procedures *FF39*. The Applicants also estimate the proposal would necessitate nearly \$5 million of capital expenditures in the form of an additional catheterization lab, new software and

equipment upgrades, as well as 3% of net patient revenues for ongoing capital needs. *FF40*. The program would operate at a loss of \$355,363 in FY16, increasing to \$705,757 in FY19. *FF38*.

The Applicants' projections, however, were conservative and assumed no increase in payer reimbursement but included increased costs and accounted for inflation. *FF38*. Additionally, the Applicants project income gains from overall operations at Backus from FY17 through FY19, sufficient to compensate for the program's increasing year-to-year losses. *FF42*. Although the program in itself would not be financially feasible due to increasing losses, the Applicants would be able to absorb those losses. As such, the proposal is financially feasible.

The Applicants have not satisfactorily demonstrated how the proposal would improve quality, accessibility and cost effectiveness of health care delivery, including to indigent and Medicaid patients.

The presence of a PCI program on-site at Backus would obviate the need for revascularization following a cardiac catheterization diagnosis, allowing the diagnostic and elective procedure to be completed together. This would reduce patient exposure to radiation and intravenous contrast used during the procedure. *FF12*. Currently, when Backus performs a cardiac catheterization and discovers a partial blockage, a patient must schedule an elective PCI elsewhere and then have the catheterization re-performed at that time. With the proposal, Backus would be able to perform the elective PCI at the time of catheterization.

As discussed, there are indisputable benefits to minimizing the time between when a patient presents at the emergency department and when the colluded artery is reopened. *FF18*. AMI patients currently presenting at Backus must be transported to a PCI-capable hospital, delaying treatment. Although a primary PCI program at Backus would decrease transport time, the Guidelines state that the door-to-balloon time should be within 120 minutes. *FF11*. Currently PCI-capable hospitals exist in Backus' area to which Backus could transport patients and the 120 minute window could be met. *FF32*. Although the Applicants have demonstrated how the proposal would improve quality of care, it is unclear the extent of the improvement.

Despite these potential benefits of the proposal, the Guidelines state that the minimum number of PCIs a facility should perform is set to maintain the competency of the hospital and its physicians. *FF29*. Should Backus' proposed program not meet that minimum, it is possible competency may not be maintained. Furthermore, the proposed program risks syphoning enough patients from existing hospitals to also depress the number of procedures performed at other area hospitals. *FF32,33,35*. It is possible quality may be compromised not only at Backus, but surrounding PCI-providers, as well.

The proposal would, as the establishment of a new service, likely increase access to care for Medicaid and indigent patients as Applicants' projected payer mix is comprised of 11% Medicaid and 37% uninsured. *FF43*.

Based on the aforementioned findings of fact, the Applicants have failed to meet their burden of proof in satisfying the statutory requirements of Conn. Gen. Stat. §§ 19a-639. The Applicants have neither satisfactorily identified the patient population to be served with an elective and primary PCI program nor have they demonstrated, in light of decreasing utilization and the existence of other providers in the area, that there is a clear public need for the proposed service. Furthermore, the proposal is likely to have a detrimental effect on existing providers in the area and may negatively impact the quality of care afforded patients. Finally, the Applicants have not sufficiently shown that the proposal is consistent with the PCI standards in the ACCF/AHA/SCAI Guideline and Statewide Health Care Facilities and Services Plan. However, as the proposal is neither a termination nor consolidation of health care providers, the proposal would not negatively impact the diversity of providers or choice for patients in the area.

Order

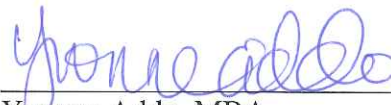
Based upon the foregoing Findings and Discussion, the Certificate of Need application of The William W. Backus and Hartford Hospital to establish a primary and elective PCI program without on-site surgical backup is hereby **DENIED**.

All of the foregoing constitutes the final order of the Office of Health Care Access in this matter.

By Order of the
Department of Public Health
Office of Health Care Access

9/16/16

Date



Yvonne Addo, MBA
Deputy Commissioner