

STATE OF CONNECTICUT
DEPARTMENT OF PUBLIC HEALTH
Office of Health Care Access

February 4, 2013

IN THE MATTER OF:

An Application for a Certificate of Need filed
Pursuant to Section 19a-638, C.G.S. by:

Notice of Agreed Settlement
Office of Health Care Access
Docket Number: 12-31768-CON

Lawrence & Memorial Hospital

To:

Ms. Shraddha Patel
Director of Business Development & Planning
Lawrence & Memorial Hospital
365 Montauk Avenue
New London, CT 06320

Dear Ms. Patel:

This letter will serve as notice of the approved Certificate of Need Application in the above-referenced matter. On February 4, 2013, the Agreed Settlement, attached hereto, was adopted and issued as an Order by the Department of Health, Office of Health Care Access.

A handwritten signature in black ink, appearing to read "Kim Martone".

Kimberly R. Martone
Director of Operations

Enclosure
KRM:amv

An Equal Opportunity Provider
(If you require aid/accommodation to participate fully and fairly, contact us either by phone, fax or email)
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Office of Health Care Access
Certificate of Need Application

Agreed Settlement

Applicant: Lawrence & Memorial Hospital
365 Montauk Avenue, New London, CT 06320

Docket Number: 12-31768-CON

Project Title: Establish and Operate an Elective Angioplasty
Program at Lawrence & Memorial Hospital

Project Description: Lawrence & Memorial Hospital proposes to establish and operate an elective angioplasty program without onsite surgical backup at Lawrence & Memorial Hospital, with no associated capital expenditure.

Nature of Proceedings: On August 31, 2012, the Office of Health Care Access ("OHCA") received a completed Certificate of Need ("CON") application from Lawrence & Memorial Hospital to establish an elective angioplasty program without onsite backup at Lawrence & Memorial Hospital, with no associated capital expenditure. Lawrence & Memorial Hospital published notice of its intent to file the CON Application in *The Day*, on April 30, May 1 and 2, 2012. A public hearing regarding the CON application was held on December 13, 2012. On December 4, 2012, the Applicants were notified of the date, time and place of the hearing. On November 26, 2012, a notice to the public announcing the hearing was published in *The Day*.

Attorney Kevin Hansted was the designated hearing officer in this matter. The hearing was conducted as a contested case in accordance with the provisions of the Uniform Administrative Procedure Act (Chapter 54 of the General Statutes) and Conn. Gen. Stat. § 19a-639a. OHCA's authority to review and approve, modify or deny this proposal is established by Conn. Gen. Stat. § 19a-638. These provisions, as well as the principles and guidelines set forth in Conn. Gen. Stat. § 19a-639, were fully considered by OHCA in its review.

Findings of Fact

1. Lawrence & Memorial Hospital is a not-for-profit 280-bed acute care hospital located at 365 Montauk Avenue in New London, Connecticut and a health care facility or institution as defined by Conn. Gen. Stat. §19a-630. Ex. A. 9
2. Lawrence & Memorial Hospital proposes establishing and operating an elective angioplasty¹ program without onsite backup.
3. The proposed elective PCI program will be supported by a collaborative relationship with Yale-New Haven Hospital and Yale School of Medicine. Ex. A, p. 9.
4. Yale-New Haven Hospital is a not-for-profit, 944-bed acute care hospital located in New Haven, Connecticut. Yale-New Haven Hospital is a full service (i.e., cardiac catheterization², angioplasty and open-heart surgery) cardiac provider.
5. The proposed elective PCI program would build upon Lawrence & Memorial's primary³ PCI program (approved by OHCA in Docket Number: 04-30297-CON) and would employ the same cardiac interventionalists, equipment, staff and facilities. Ex. A, p. 9.

¹Elective (Scheduled) Percutaneous Coronary Intervention (PCI) or Coronary Angioplasty (PCA) is an interventional procedure performed in a catheterization laboratory whereby a catheter, usually inserted into an artery in the groin, is threaded through the circulatory system to a previously diagnosed blockage in the heart. An expandable balloon is passed to this spot and inflated several times, thereby flattening the blockage-causing plaque, potentially widening the artery, and thus improving blood flow.

Source: DPH/OHCA Statewide Facility and Services Plan Chapter 3.

² Cardiac catheterization is defined as a medical procedure requiring the passage of a catheter into one or more cardiac chambers of the left and right heart, with or without coronary arteriograms, for the purpose of diagnosing congenital or acquired cardiovascular disease, or for determining measurement of blood pressure flow.

Source: DPH/OHCA Statewide Facility and Services Plan Chapter 3

³ Primary (emergent) Percutaneous Coronary Intervention (PCI) or Coronary Angioplasty (PCA) is an interventional procedure whereby a catheter, usually inserted into an artery in the groin, is threaded through the circulatory system to a previously diagnosed blockage in the heart. An expandable balloon is passed to this spot and inflated several times, thereby flattening the blockage-causing plaque, potentially widening the artery, and thus improving blood flow.

Source: DPH/OHCA Statewide Facility and Services Plan Charter 3.

6. Lawrence & Memorial Hospital has submitted the following agreements, policies and protocols:

- Patient selection guidelines policies (*Attachment F*)
- Policies and Procedures for PCI Procedure (*Attachment F*)
- Joint quality assurance reviews process and training between Lawrence & Memorial Hospital and Yale-New Haven Hospital (*Attachment I*)
- Transfer Protocol and Agreement between Lawrence & Memorial Hospital and Yale-New Haven Hospital (*Attachment I*)
- Yale-New Haven Hospital Department of Surgery surgical backup policy for the Lawrence & Memorial Hospital elective PCI program (*Attachment I*)

Ex. A. p. 37-38

7. Lawrence & Memorial Hospital has a primary tertiary cardiac referral relationship with Yale-New Haven Hospital whereby Yale-New Haven Hospital provides surgical backup to Lawrence & Memorial Hospital. Since the establishment of the primary PCI program in 2009, 98% or 545 out of 555 transfers from Lawrence & Memorial Hospital to other acute care hospitals for advanced cardiac services were to Yale-New Haven Hospital. Ex. A. p. 23

8. The proposed elective PCI program will be developed and managed by Lawrence & Memorial Hospital in collaboration with Lawrence & Memorial Hospital Physician Association, Inc. in order to achieve clinical quality and outcomes that meet or exceed national standards. Ex. A. (*Attachment I*) p. 425

9. The proposed elective PCI service will be performed in Lawrence & Memorial Hospital's two existing and fully functioning diagnostic cardiac catheterization laboratories by interventional cardiologists on staff at Lawrence & Memorial Hospital and Yale-New Haven Hospital/Yale School of Medicine. Ex. A. pp. 26, 531

10. The proposed elective PCI program will augment existing primary PCI services as well as inpatient and outpatient cardiac services at Lawrence & Memorial Hospital which include:

- Coronary Care and Telemetry Unit (25 beds)
- Coronary Intensive Care Unit (10 beds)
- Diagnostic cardiac catheterization (2,400 procedures completed between 2009 and 2011)
- Interventional Radiology Laboratory
- Pacemaker Insertions and Evaluation
- Implantable Cardiac Defibrillator (ICD) Insertions and Evaluation
- Vascular and Thoracic Surgery
- Cardiac Rehabilitation
- Cardiac Imaging Services including CT (64-slice scanner) and MRI (3.0 Tesla) scanner
- Direct audio/video link between Lawrence & Memorial Hospital and Yale-New Haven Hospital
- Stress testing (Exercise and Echocardiogram)
- Nuclear stress testing (Stress, Rest, Pharmacological)
- Echocardiography

- 24- Hour Holter monitoring and 30-Day Event Monitoring
- Tilt table studies
- Echocardiograms
- Outpatient cardiovascular care
- Community education programs

Ex. A. pp. 26-27, 532

11. Lawrence & Memorial Hospital defined the population to be served through this proposal as being represented by the towns that are part of the primary (“PSA”) and secondary (“SSA”) service area, which comprise 75% of Lawrence & Memorial Hospital’s inpatient volume (“Proposed Service Area”):

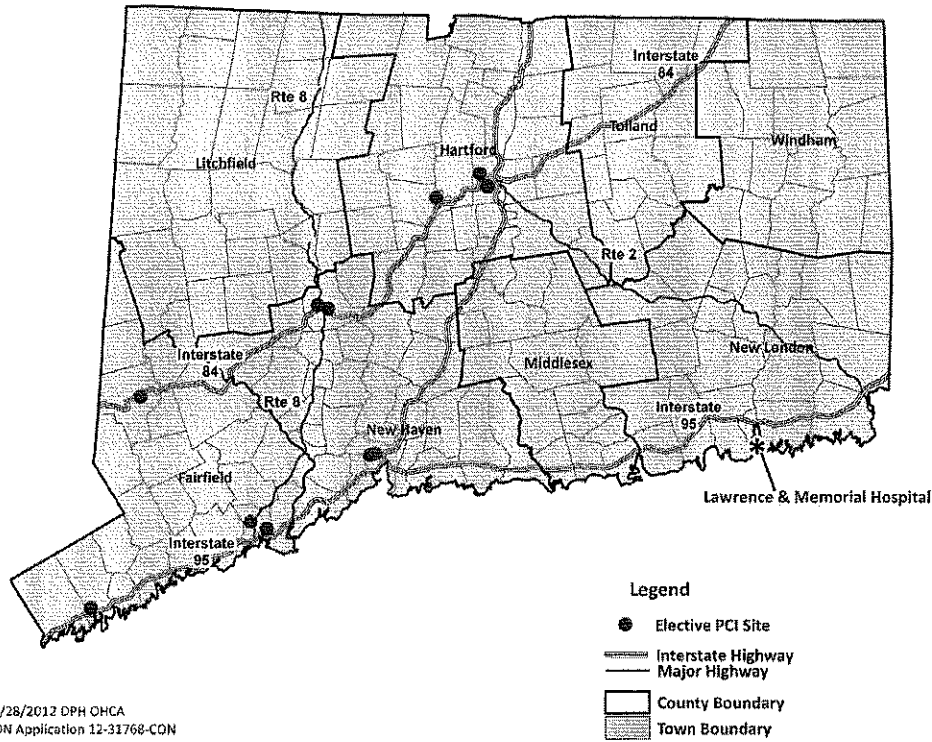
Table 1: Primary and secondary service area

PSA	SSA
East Lyme	Bozrah
Groton	Colchester
Ledyard	Franklin
Lyme	Griswold
Montville	Lisbon
New London	Old Saybrook
Old Lyme	Preston
Stonington	Norwich
North Stonington	Salem
Waterford	Voluntown
	Westerly (RI)

Ex. A. p. 27

12. The map below shows New London County’s geographical isolation from facilities that perform elective PCI procedures for patients residing in southeastern Connecticut.

Sites that Offer Elective Percutaneous Coronary Intervention (PCI) in Connecticut



Prepared 9/28/2012 DPH OHCA
 Source: CON Application 12-31768-CON

13. Travel distances from Lawrence & Memorial Hospital to the nearest existing full-service cardiac providers are as follows:

Table 2: Mileage from Town of New London to closest facilities

Hospital	City, State	Miles from Town of New London
YNHH	New Haven, CT	49
St. Francis Hospital	Hartford, CT	48
Hartford Hospital	Hartford, CT	49
Miriam Hospital	Providence, RI	61

Ex. A. p. 20

14. A study by the Robert Wood Johnson Foundation in 2012 evaluating the health of Connecticut communities indicated that New London County had higher than state and national rates of adult smoking and obesity and also exceeded state and national benchmarks with respect to the ratio of the population to primary care physicians and preventable hospitalizations. Below are the key statistics from the study that relate to cardiac health.

Table 3: Key statistics

	New London County	Connecticut	United States Benchmark
Health Behaviors			
Adult Smoking	19%	16%	14%
Adult Obesity	24%	23%	21%
Clinical Care			
Primary Care Physicians	1,098:1	729:01:00	631:01:00
Preventable Hospital Stays	70	63	49

Source: Robert Wood Johnson Foundation, County Health Rankings & Roadmaps
(<http://www.countyhealthrankings.org/#app>).
Ex. A. pp. 538-539

15. Lawrence & Memorial Hospital presented heart disease death rate and hospitalization data provided by the Centers for Disease Control and Prevention. According to these data, New London County has high heart disease death and hospitalization rates. Coupled with the lack of elective PCI services in Lawrence & Memorial’s service area and New London County, these data further demonstrate the area’s need for elective PCI. Ex. A. pp. 30-31, 539

16. Age is another key risk factor for coronary heart disease. Lawrence & Memorial Hospital states that cardiovascular disease is the leading cause of death in the state for residents aged 85+ and the second leading cause of death for residents ages 65-84. Data presented by Lawrence & Memorial Hospital shows that the overall population within Lawrence & Memorial Hospital’s proposed service area is expected to increase by 1.6% in 2015. However, the rate of growth in the age groups (65-74) and (85+) is expected to increase by 18.4% and 14.3%, respectively, in 2015. The table below represents the demographic characteristics within Lawrence & Memorial Hospital’s Proposed Service Area.

Table 4: Total Service Area Population Statistics

Age Cohort	2010	2015	% Change
0-44	170,507	165,257	-3.10%
45-54	45,925	45,447	-1%
55-64	33,181	39,230	18.20%
65-74	20,345	24,084	18.40%
75-84	14,473	14,225	-1.70%
85+	6,637	7,587	14.30%
Total	293,078	297,845	1.60%

Ex. A. p. 31-32

17. The physicians who will participate in the proposed elective PCI program currently perform PCI procedures at both Lawrence & Memorial Hospital and Yale-New Haven Hospital and provide on-call coverage for Lawrence & Memorial Hospital's existing primary PCI program. Ex. A. p. 524
18. Lawrence & Memorial Hospital does not anticipate an expansion in the physician referral base either geographically or in terms of quantity of physicians in the service area. Lawrence & Memorial Hospital's volume projections in the initial CON filing were not based on assumptions regarding new physicians in the market or an expansion of Lawrence & Memorial Hospital's geographic reach beyond the existing service area. Rather, Lawrence & Memorial Hospital's volume projections were based on actual data of transfers from Lawrence & Memorial Hospital's catheterization lab to Yale-New Haven Hospital for elective PCI and, in the future, the retention of select patients (i.e., non-high risk patients) that could remain at Lawrence & Memorial Hospital for their elective PCI procedure. Ex. A. p. 524
19. Lawrence & Memorial Hospital's historical volume of diagnostic cardiac catheterizations and volume transferred same day for elective PCI since 2009 is as follows:

Table 5: Lawrence & Memorial Hospital Diagnostic Catheterization Volume and Volume Transferred Same Day for Elective PCI

Fiscal Year	Total Diagnostic Caths	Total Patients Transferred for Elective PCI	Location of Transfer		
			YNHH	St. Francis	Hartford Hospital
2009	810	168	161	7	0
2010	858	200	198	2	0
2011	724	138	137	1	0
2012*	266	49	49	0	0

*Note: Represents actual volumes for FY 2012 (10/1/11 through 03/01/12) Ex. A. p.23

20. Lawrence & Memorial Hospital's historical volume for primary or emergent PCI is shown in the following table:

Table 6: Total Primary PCI Cases at Lawrence & Memorial Hospital

Program	FY 2009	FY 2010	FY 2011	Actual FY 2012*	Annualized FY 2012
Primary PCI	78	81	74	44	88

*Note: Represents actual volumes for FY 2012 (10/1/11 through 03/01/12) Ex. A. p. 40

21. Projected volume for elective PCI at Lawrence & Memorial Hospital is shown in the table below:

Table 7: Total projected PCI cases at Lawrence & Memorial Hospital

Program	FY 2013	FY 2014	FY 2015
Primary PCI	89	89	89
Elective PCI	73	130	135
Total	162	219	224

Ex. A. p. 40

22. The 2011 ACCF/AHA/SCAI⁴ Guidelines for PCI recommend criteria and standards for the performance of angioplasty at hospitals without on-site cardiac surgery. All of these criteria and standards will be utilized by Lawrence & Memorial Hospital. Ex. A. pp. 12-13
23. The CPORT-E⁵ (Cardiovascular Patient Outcomes Research Team Elective) study indicates that programs with case totals over 200 have sufficient volume to sustain a quality and safe emergent and elective PCI program. Lawrence & Memorial Hospital is projected to exceed 200 total cases in Year 2 of operation. Ex. A. pp. 40, 44
24. The following data from OHCA's Acute Care Hospital Inpatient Discharge Database ("HIDD") represents OHCA's market share analysis of the Lawrence & Memorial service area for fiscal year 2011.

⁴ The American College of Cardiology Foundation (ACCCF) / The American Heart Association Task Force on Practice Guidelines (AHA) / The Society for Cardiovascular Angiography and Intervention (SCAI)

⁵ CPORT-E is a randomized trial, concluded on March 31, 2011, comparing medical, economic and quality of life outcomes of non-primary PCI at hospitals with and without on-site cardiac surgery. Source: http://my.americanheart.org/idc/groups/ahamah-public/@wcm/@sop/@scon/documents/downloadable/ucm_433712.pdf

Table 8: Service Area Discharge Data & Market Share

Town	FY11			
	Total Town Discharges	Total Lawrence & Memorial Discharges	% of Hospital Discharges	Share of Town
<i>Primary Service Area</i>				
New London	4,040	3,390	22%	84%
Groton	5,341	4,266	28%	80%
Waterford	2,665	2,047	13%	77%
East Lyme	1,845	1,332	9%	72%
Stonington	722	475	3%	66%
Ledyard	1,470	835	5%	57%
Montville	2,345	863	6%	37%
Old Lyme and Lyme	912	251	2%	28%
<i>Secondary Service Area</i>				
Norwich	5,667	464	3%	8%

Source: OHCA's Acute Care Hospital Inpatient Discharge Database ("HIDD")

25. Per 2011 ACCF/AHA/SCAI guidelines and recommendations, Lawrence & Memorial Hospital participates in the ACC-NCDR PCI registry for quality assurance and benchmarking for its emergent PCI program. Lawrence & Memorial Hospital will continue to submit data to the ACC registry in order to ensure quality outcomes for its proposed elective PCI program. Ex. A. p. 49
26. Yale-New Haven Hospital, a full cardiac service provider, will be the receiving facility for patients from Lawrence & Memorial Hospital that require surgical intervention. Ex. A. p. 522
27. Lawrence & Memorial Hospital states that since the inception of Lawrence & Memorial Hospital's primary PCI program in 2005 there have been 13 total mortalities including patients who expired due to non-cardiac deaths (e.g., pre-existing conditions such as infections, neurological conditions, etc.). The 13 total deaths translate into a 4.1% mortality rate. This outcome is favorable compared to data from the 2011 ACCF/AHA/SCAI guidelines indicating a national in-hospital mortality rate of 4.81% in ST-segment elevation myocardial infarction (STEMI) patients that required primary PCI intervention. Ex. A. p. 47.
28. Lawrence & Memorial Hospital's proposed elective PCI program would utilize the same Yale-New Haven Hospital/Yale School of Medicine interventionalists and same clinical staff (catheterization laboratory technicians, nurses, etc.) that currently support the emergent PCI program. Lawrence & Memorial Hospital's Medical Director of its Primary Angioplasty Program and of the proposed elective program is five years post-fellowship training and has performed over 500 PCI procedures. Ex. A. p. 527

29. Lawrence & Memorial Hospital has asserted that elective PCI at Lawrence & Memorial Hospital would increase quality of care as patients who are currently transferred from Lawrence & Memorial Hospital to another facility for elective PCI are at enhanced risk of infections, bleeding complications, and other adverse events associated with multiple procedures at two facilities. Ex. A. p. 527
30. Eliminating transfers for elective PCI would reduce costs to the health care system from duplicate testing and redundant costs for dyes, catheters, surgical trays, and other supplies. Ex. A. p. 527
31. The November 2011 ACCF/AHA/SCAI Practice Guidelines note a location for elective PCI without on-site surgery is the one that “will clearly fill a void in the healthcare needs of the community” and “the cardiology community [should] foster “the [elective PCI without on-site surgery] programs...when such programs improve access to a higher level of cardiovascular care than would otherwise be available.” Ex. A. Attachment B/ 2011 ACCF/AHA/SCAI Clinical Practice Guidelines
32. Lawrence & Memorial Hospital has stated that it will adhere to strict patient selection criteria recommended by ACCF/AHA/SCAI in determining which patients are eligible to receive elective PCI at Lawrence & Memorial Hospital. According to SCAI, non-high risk patients are the best candidates for elective PCI without on-site cardiac surgery and, therefore, Lawrence & Memorial Hospital will only perform procedures on these patient types. Ex. A. pp. 36, 526
33. Lawrence & Memorial Hospital currently finances its primary PCI program through an annual fee of \$1.45 million paid to Yale-New Haven Hospital. Adding elective PCI would reduce the cost per case while utilizing the same Yale-New Haven Hospital physicians to perform both elective and primary cases. Ex. A. pp. 53, 524
34. This proposal will not incur any additional capital or overhead costs thereby improving the cost effectiveness of the PCI service. Ex. A. p. 52
35. Lawrence & Memorial Hospital’s current and three year projected payer mix is below.

Table 9: Patient Population Mix

	Current**	Year 1	Year 2	Year 3
	FY 2012	FY 2013	FY 2014	FY 2015
Medicare*	46.90%	46.90%	46.90%	46.90%
Medicaid*	10.00%	10.00%	10.00%	10.00%
CHAMPUS & TriCare	0.00%	0.00%	0.00%	0.00%
Total Government	56.90%	56.90%	56.90%	56.90%
Commercial Insurers*	41.90%	41.90%	41.90%	41.90%
Uninsured	1.30%	1.30%	1.30%	1.30%
Workers Compensation	0.00%	0.00%	0.00%	0.00%
Total Non-Government	43.10%	43.10%	43.10%	43.10%
Total Payer Mix	100.00%	100.00%	100.00%	100.00%

Ex. A. p. 51

36. OHCA is currently in the process of establishing its policies and procedures as regulations. Therefore, OHCA has not made any findings as to this proposal's relationship to any regulations adopted by OHCA. (Conn. Gen. Stat. § 19a-639(a)(1))
37. This CON application was deemed complete by OHCA prior to the state-wide health care facilities and services plan being published. Therefore, OHCA has not made any findings as to the relationship between this CON application and the state-wide health care facilities and services plan. (Conn. Gen. Stat. § 19a-639(a)(2))
38. Lawrence & Memorial Hospital has satisfactorily demonstrated that there is a clear public need for its proposal. (Conn. Gen. Stat. § 19a-639(a)(3))
39. Lawrence & Memorial Hospital has satisfactorily demonstrated that its proposal is financially feasible. (Conn. Gen. Stat. § 19a-639(a)(4))
40. Lawrence & Memorial Hospital has satisfactorily demonstrated that its proposal would improve quality, accessibility and cost effectiveness of health care delivery in the region. (Conn. Gen. Stat. § 19a-639(a)(5))
41. Lawrence & Memorial Hospital has shown that there would be improvements to the provision of health care services to the relevant populations and payer mix. (Conn. Gen. Stat. § 19a-639(a)(6))
42. Lawrence & Memorial Hospital has satisfactorily identified the population to be served by their proposal and satisfactorily demonstrated that said population has a need as proposed. (Conn. Gen. Stat. § 19a-639(a)(7))
43. There are no existing elective PCI programs in Lawrence & Memorial Hospital's service area. Therefore, OHCA has not made any findings as to the utilization of existing elective PCI programs in the service area. (Conn. Gen. Stat. § 19a-639(a)(8))
44. Lawrence & Memorial Hospital has satisfactorily demonstrated that the proposal would not result in an unnecessary duplication of existing or approved elective PCI services. (Conn. Gen. Stat. § 19a-639(a)(9))

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. *Goldstar Medical Services, Inc., et al. v. Department of Social Services*, 288 Conn. 790 (2008).

Lawrence & Memorial Hospital is a not-for-profit 280-bed acute care hospital located in New London, Connecticut and a health care facility or institution as defined by Conn. Gen. Stat. § 19a-630. Lawrence & Memorial Hospital proposes to establish and operate an elective PCI program without onsite cardiac surgical backup. *FF.1-2.*

November 2011 ACC/AHA/SCAI PCI practice guidelines state that “it is only appropriate to consider initiation of a PCI program without on-site cardiac surgical backup if this program will clearly fill a void in the healthcare needs of the community.” *FF 32.* The guidelines note that competition with another PCI program in the same geographic area, particularly an established program with surgical backup, may not be in the best interests of the community.” Lawrence & Memorial Hospital, located in New London County, is geographically isolated in terms of elective PCI accessibility, as there are no facilities that perform elective PCI procedures in Lawrence & Memorial Hospital’s service area or within southeastern Connecticut. *FF. 12.* Specifically, the closest facility offering full cardiac services in Connecticut is 48 miles away from New London. *FF.13.* Thus, the proposed elective PCI program will not duplicate or overlap any of the existing programs in the state.

In addition to geographic isolation, there are several New London County and/or Lawrence & Memorial Hospital service area population characteristics which indicate that such a program would be beneficial to residents. First, New London County residents have high heart disease death and hospitalization rates. *FF 15.* Second, age is a key risk factor for heart disease, and the 2015 rate of growth expected for Lawrence & Memorial Hospital service area’s aging population is significantly higher than for the area as a whole. *FF16.* Third, New London County residents’ smoking, obesity, and preventable hospitalization rates exceed both state and national health rates, according to a 2012 Robert Wood Johnson Foundation study. *FF14.* Furthermore, the ratio of the population to primary care physicians in New London County is high. A high ratio implies reduced ability to meet demand for primary care services, which may negatively affect the health of a community, as treatment for needed services may be delayed or not sought at all. Residents with cardiovascular disease or coronary heart disease may remain undiagnosed without an adequate base of primary care to order diagnostics or refer patients to cardiologists. *FF.14.*

The proposed program would build upon Lawrence & Memorial Hospital’s primary PCI program and would utilize the same experienced cardiac interventionalists, equipment, clinical staff and facilities. *FF.5.* The elective PCI program will be supported by a collaborative relationship with Yale-New Haven Hospital, which is the Lawrence & Memorial Hospital’s primary tertiary cardiac referral site. *FF.3.* Since the establishment of its primary PCI program in 2009, 98% of transfers from Lawrence & Memorial Hospital to other acute care hospitals for advanced cardiac services were to YNH. *FF7.* Lawrence & Memorial Hospital’s projected

volume is reasonable to sustain a quality and safe elective PCI program which is needed for patients residing in southeastern Connecticut. The above facts, coupled with the observation that Lawrence & Memorial Hospital's mortality rate compares favorably to the mortality rate published in the 2011 ACCF/AHA/SCAI guidelines, further support the establishment of an elective PCI program by Lawrence & Memorial Hospital. *FF28.*

This proposal is cost effective, as it will not incur any capital or overhead costs because it will build upon Lawrence & Memorial Hospital's existing primary PCI program as it will utilize the same cardiac interventionalists, equipment, staff and facilities. *FF.34-35.*

Based on foregoing, OHCA has determined that approval of the proposed elective PCI program will improve the accessibility and quality of care for patients residing in southeastern Connecticut. Lawrence & Memorial Hospital's proposal will bring appropriate access to needed elective PCI services within a reasonable travel time and improve the quality of cardiac services in a region that fares worse than the state as a whole in terms of health outcomes, health factors and limited access to primary care.

There is a substantial question as to L&M's emergency transfer protocol's compliance with the Memorandum of Decision for Declaratory Ruling Proceeding Concerning the Provision of Emergency Medical Services (February 14, 2003). Therefore, OHCA is not making any determination as to L&M's emergency transfer protocol in terms of compliance with existing state and federal laws. OHCA is referring the protocol to the Office of Emergency Medical Services for its review and consideration.

ORDER

NOW, THEREFORE, the Department of Public Health, Office of Health Care Access, and Lawrence & Memorial Hospital hereby stipulate and agree to the terms of settlement with respect to establishment an elective angioplasty program without onsite surgical backup at Lawrence & Memorial Hospital, as follows:

Lawrence & Memorial Hospital is required to fulfill the following conditions for the first seven (7) years from commencement of the Elective Angioplasty program. At the end of the 7 year period, the Office of Health Care Access reserves the right to continue requiring any of the listed conditions if Lawrence & Memorial Hospital is not performing total PCI procedures above the minimum recommended volumes prescribed by the America College of Cardiology/American Heart Association at that time.

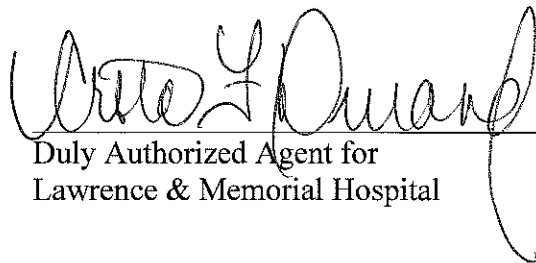
1. Lawrence & Memorial Hospital shall submit on a quarterly basis to OHCA the following reports which must be submitted within thirty (30) calendar days of the end of each quarter:
 - a. Elective and Emergency PCI performed each quarter by town of patient origin, in a format to be specified.
 - b. Elective and Emergency PCI performed each quarter, broken out by inpatient and outpatient, in a format to be specified.
 - c. The number of patients transferred to another hospital for cardiac treatment as a direct result of Emergency and/or Elective PCI at Lawrence & Memorial Hospital. Details to include:
 - i. The cause/reason for transfer;
 - ii. The name of the facility to which the patient was transferred; and
 - iii. The actual time-line beginning with the reason for transfer, including the transportation time and the actual procedure administered at the facility to which the patient was transferred.
2. Reports a through c above shall not include patient identifiable data.
3. Based on OHCA's review of this quarterly data, the Office may request a meeting with Lawrence & Memorial Hospital to discuss the data submitted.
4. If Lawrence & Memorial Hospital does not perform the minimum number of elective PCIs within twelve months of the initiation of the elective PCI program, as recommended by America College of Cardiology/American Heart Association, Lawrence & Memorial Hospital shall submit monthly reports of the number of elective PCIs arrayed by physician to OHCA until such time as these volumes are met by Lawrence & Memorial Hospital or until it meets with OHCA to discuss a plan that will adhere to the quality standards recommended by the American College of Cardiology/American Heart Association.

5. Lawrence & Memorial Hospital shall participate in the ACC National Cardiovascular Database Registry (ACC-NCDR) and report all data including the optional follow-up section. Lawrence and Memorial Hospital shall provide OHCA quarterly data reports from ACC-NCDR. Data must be reported to OHCA thirty (30) calendar days subsequent to Lawrence & Memorial Hospital receiving the reports from ACC. Lawrence & Memorial Hospital is required to comply with the ACC/AHA criteria and standards. If Lawrence and Memorial Hospital determines not to participate in the ACC-NCDR, Lawrence & Memorial Hospital shall notify OHCA immediately, and continue to comply with the ACC/AHA criteria and standards. This condition supersedes Condition 3 of Docket Number 04-30297-CON, as modified by Docket Numbers 06-30297-MDF and 08-30297-MDF
6. The Office of Health Care Access and Lawrence & Memorial Hospital agree that this Agreed Settlement represents a final agreement between the Office of Health Care Access and Lawrence & Memorial Hospital with respect to Docket No. 12-31768-CON. The execution of this Agreed Settlement resolves all objections, claims and disputes, which may have been raised by Lawrence & Memorial Hospital with regard to Docket Number 12-31768-CON.
7. This Agreed Settlement is an order of the Office of Health Care Access with all the rights and obligations attendant thereto, and the Office of Health Care Access may enforce this Agreed Settlement under the provisions of Conn. Gen. Stat. §§ 19a-642 and 19a-653 with all fees and costs of such enforcement being the responsibility of Lawrence & Memorial Hospital.

Signed by CRISTA F. DURAND
(Print name)

VICE PRESIDENT STRATEGIC PLANNING
(Title)

Date 1/31/13


Duly Authorized Agent for
Lawrence & Memorial Hospital

The above Agreed Settlement is hereby accepted and so ordered by the Department of Public Health Office of Health Care Access on February 4, 2013.

2/4/13
Date:

Lisa A. Davis
Lisa A. Davis, MBA, BSN, RN
Deputy Commissioner