Office of Health Care Access
Certificate of Need Application

Agreed Settlement

Applicants:	**Lawrence and Memorial Hospital and Yale-New Haven Hospital**
Docket Number:	**04-30297-CON**
Project Title:	**Establish Primary Interventional Cardiac Service at Lawrence and Memorial Hospital in New London**
Statutory Reference:	**Section 19a-638, Connecticut General Statutes**
Filing Date:	**December 28, 2004**
Hearing Dates:	**March 10, 2005**
Presiding Officer:	**Cristine Vogel, Commissioner**
Decision Date:	**June 1, 2005**
Default Date:	**Not Applicable**
Staff:	**Paolo Fiducia**

Project Description: Lawrence and Memorial Hospital and Yale-New Haven Hospital ("Applicants") propose to establish a primary interventional cardiac service, to be located at Lawrence and Memorial Hospital, at a total capital expenditure of $7,500.

Nature of Proceedings: On December 28, 2004, the Office of Health Care Access ("OHCA") received the Applicants' Certificate of Need ("CON") application seeking authorization to establish a primary interventional cardiac service, to be located at Lawrence and Memorial Hospital. The proposal has a total capital expenditure of $7,500. The Applicants are health care facilities or institutions as defined by Section 19a-630 of the Connecticut General Statutes ("C.G.S.").

A public hearing regarding the CON Application was held on March 10, 2005. The Applicants were notified of the date, time, and place of the hearing and notices to the public were published prior to the hearings in *The Day Publishing Company* (New London). Commissioner Cristine Vogel served as presiding 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 Connecticut General Statutes) and Section 19a-638, C.G.S.

The Presiding Officer heard testimony from the general public, legislators, local officials and witnesses for the Applicants and in rendering this decision, considered the entire record of the proceeding. OHCA's authority to review, approve, modify or deny this proposal is established by Section 19a-638, C.G.S. The provisions of this section, as well as the principles and guidelines set forth in Section 19a-637, C.G.S., were considered by OHCA in its review.

Findings of Fact

Clear Public Need
Impact on the Applicants' Current Utilization Statistics
Proposal's Contribution to Accessibility and Quality of Health Care Delivery in the Region

1. Lawrence and Memorial Hospital ("L&M") is a not-for-profit 280-bed acute care hospital located in New London, Connecticut. L&M currently operates two diagnostic cardiac catheterization laboratories[1]. *(December 28, 2004, CON Application, page 25)*

2. Yale-New Haven Hospital ("YNHH") is a not-for-profit, 944-bed acute care hospital located in New Haven, Connecticut. YNHH is a full service (i.e. cardiac catheterization, angioplasty and open-heart surgery) cardiac provider. *(Department of Public Health License)*

[1] Diagnostic Cardiac Catheterization is a diagnostic procedure in which a catheter, usually inserted into an artery in the groin, is threaded through the circulatory system to the heart to measure electrical activity, blood pressure, and locate blockages.

3. The Applicants propose to establish a primary angioplasty[2] service for acute myocardial infarction ("PAMI") patients at L&M presenting with ST-segment elevation (STEMI) and left bundle branch blockage (LBBB). *(December 28, 2004, CON Application, page 25)*

4. The Applicants have submitted two agreements for the implementation of the proposed PAMI program at L&M, as follows:
   - A Clinical Participant Agreement which states that L&M becomes a clinical participant of the Yale-New Haven Health Services Corporation Network and shall obtain certain services including: training, strategic and service line planning, outcome, and marketing.
   - A Primary Intervention Program Training Agreement which states that YNHH will support the establishment of the primary interventional cardiac services at L&M in a number of ways including: providing or arranging consultative services with respect to the development of proposed care standards, quality assurance programs and policies, procedures and protocols, consulting with respect to the collection and analysis of quality data, and arranging training for nursing and technical staff who will be serving the primary interventional cardiac service.

   (December 28, 2004, CON Application, pages 13, 339 & 340 and Attachment C)

5. The Applicants have had a primary tertiary cardiac referral relationship since 1985. Out of 144 transfers from L&M to other acute care hospitals for advanced cardiac services in FY 2003, 125 were transferred to YNHH. *(December 28, 2004, CON Application, page 27)*

6. The proposed program will be developed and managed by L&M in collaboration with Eastern Connecticut Cardiology Group, PC ("ECCG"), which is the primary cardiology group servicing L&M. ECCG consists of nine board certified cardiologists and one interventional cardiologist with offices in New London and Groton. *(December 28, 2004, CON Application, page 25)*

7. The Hospital stated that ECCG will open a third office in Waterford, CT within the next 12 months and anticipate adding at least one more board certified cardiologist. *(December 28, 2004, CON Application, page 26)*

8. The proposed primary angioplasty service will be performed in L&M's two existing diagnostic cardiac catheterization laboratories by interventional cardiologists on staff at L&M and the Yale School of Medicine. The service will be available twenty-four hours per day, seven days per week. *(December 28, 2004, CON Application, page 25)*

[2] Primary (or 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.

9. The proposed primary angioplasty program will augment existing inpatient and outpatient cardiac services at L&M which include: *(December 28, 2004, CON Application, page 25)*
    - Diagnostic cardiac catheterization
    - 10-bed cardiac care unit
    - 31-bed cardiac step down telemetry unit
    - Direct fiber-optic video link between L&M and YNHH
    - Cardiac Rehabilitation
    - Exercise stress testing
    - Pharmacological and exercise nuclear stress testing
    - Electrocardiograms and holter and event monitoring
    - Echocardiograms
    - Transesophageal echocardiograms
    - Tilt table studies
    - Pacemaker insertions
    - Cardiac homecare
    - Community education programs
    - Paramedic intercept program.

10. The Applicants based the need for the proposed primary angioplasty service at L&M on the following: *(December 28, 2004 CON Application, page 25)*
    - Existing cardiac volume
    - Improved accessibility for patients
    - Reduction in mortality and morbidity in service areas
    - Reduction in time to treatment

11. The Applicants' proposed service areas ("PSA") for the proposed PAMI program consist of the following towns:

Table 1: L&M's Proposed Primary Angioplasty Program's Service Areas

Towns	Primary	Secondary	Total	
	East Lyme	Bozrah	Bozrah	Montville
	Groton	Colchester	Colchester	New London
	Ledyard	Franklin	East Lyme	North Stonington
	Lyme	Griswold	Franklin	Norwich
	Montville	Lisbon	Griswold	North Stonington
	New London	Norwich	Ledyard	Old Lyme
	North Stonington	Preston	Lisbon	Preston
	Old Lyme	Salem		Salem
	Stonington	Voluntown		Stonington
	Waterford			Voluntown
				Waterford
L&M's Share of Area's Inpatient Diagnostic Cardiac Caths	48.8%	5.5%	33.2%	
Area's Share of L&M's Inpatient Diagnostic Cardiac Caths	87.4%	5.5%	92.9%	

Source: Cardiac catheterization volume from *OHCA Acute Care Hospital Inpatient Discharge Database*. Service area from *December 28, 2004 CON Application*, pages 32-33).

12. The demographic characteristics of L&Ms' PSA for the proposed PAMI program are as follows:

Table 2: Demographic Characteristics of L&M's PSA

	Population				
Service Area	**Total**	**Adults (15+)**	**15 – 44 (%)**	**45 – 64 (%)**	**65+ (%)**
Primary	168,400	134,872	43.9	22.9	13.4
Secondary	80,810	63,470	43.4	22.4	12.7
Total	249,210	198,342	43.7	22.7	13.2
Service Area Connecticut	**3,405,565**	**2,696,490**	**42.2**	**23.2**	**13.8**

Source: Census 2000.

13. L&M's historical volume of diagnostic cardiac catheterizations for Fiscal Years ("FY") 2000-2003 is as follows:

Table 3: L&M's Historical Cardiac Catheterization Volume (FYs 2000 – 2003)

CT Service Area	2000	2001	2002	2003*
Inpatient	470	516	420	474
Outpatient	649	675	558	475
Total	1,119	1,191	978	949

***** Diagnostic cardiac catheterization laboratories opened at The William W. Backus Hospital and Westerly Hospital (Rhode Island).

Source**:** *OHCA Acute Care Hospital Inpatient Discharge Database* and self-reported outpatient figures from *CON Application, December 28, 2004 page 40).*

14. In Connecticut from FYs 2000 through 2003, patients 65 years and older received 55% of all inpatient diagnostic cardiac catheterizations and angioplasty procedures. *(OHCA Acute Care Hospital Inpatient Discharge Database)*

15. Physician participation in the primary interventional cardiac service will be strictly limited to experienced interventional cardiologists who meet or exceed the volume standards set forth in the American College of Cardiology ("ACC") and the American Heart Association ("AHA") guidelines. *(September 16, 2004, CON Application, page 25)*

16. The 2001 ACC/AHA Guidelines for PCI recommend criteria and standards for the performance of angioplasty at hospitals without on-site cardiac surgery. These criteria and standards will be utilized by the Applicants and are specified in **Attachment I**. *(June 15, 2001, JACC Vol.37, No. 8, page 2226&2227)*

17. The Atlantic Cardiovascular Patient Outcomes Research Team (C-PORT) Trial's Manual of Operations for the Primary Angioplasty Registry contains patient eligibility and identification criteria, guidelines for clinical care, standards for facilities and care providers and staff training, including care plan and logistics

development and quality and error management. These criteria and standards will be utilized by the Applicants and are specified in **Attachment I**. *(September 3, 2003, The Atlantic C-PORT Trial Primary Angioplasty Registry, Manual of Operations)*

18. The Hospital stated that during FY 2003, sixty-five of the 246 patients with a primary diagnosis of Acute Myocardial Infarction ("AMI") were diagnosed with STEMI. The Chief of Cardiology reviewed the medical records meeting the C-PORT inclusion criteria and determined that all of the patients met the criteria and would have been candidates for primary angioplasty. *(December 28, 2004, CON Application, pages 26&27)*

19. The Hospital stated that the proposed angioplasty service is planned to meet the ACC/AHA practice guidelines and the C-PORT requirements for care standards, staff training and competency, physician competency, surgical back-up logistics, and quality monitoring and reporting. *(December 28, 2004, CON Application, page 54)*

20. The Applicants stated that primary angioplasty would be performed at L&M safely and efficiently by meeting the ACC/AHA criteria and standards and C-PORT guidelines through the following:
    a. Patient entry points (e.g., the Emergency Department) will be continuously staffed by personnel competent in performing electrocardiogram ("ECG"), initial evaluation and treatment of patients with acute ischemic syndromes, including MI and unstable angina. The same personnel will have training in cardiac, monitoring and advanced cardiac life support ("ACLS");
    b. The critical care unit and cardiac service unit will have cardiac monitoring, immediate access to persons trained in ACLS and capabilities for arterial line and pulmonary artery catheter placement, temporary pacemaker replacement, mechanical ventilation and intra-aortic balloon placement;
    c. The specialty care unit and future cardiac services unit will be able to provide continuous ECG monitoring and prompt access to ACLS trained staff;
    d. Nursing staff monitoring post-operative PAMI patients will meet all applicable training requirements;
    e. Credentialing and privileging of interventionalists will be conducted in accordance with the policies and procedures set forth in the Medical Staff Bylaws; and
    f. Nursing and technical staff involved in the PAMI Program will take part in a formal training program arranged through YNHH.
    (December 28, 2004, CON Application, page 107)

22. Numerous studies have demonstrated that primary PCI is a more effective therapeutic alternative to pharmaceutical therapy resulting in lower morbidity and mortality, as follows:
    - PCI for acute myocardial infarction can be performed safely and effectively at a community hospital without on-site cardiac surgical facilities. *(Ting, et.al,Mayo Clinic, 2004, "Percutaneous coronary intervention for ST-segment and non-ST-segment elevation myocardial infarction at hospitals with and without on-site cardiac surgical capability")*

- The C-PORT trial found that community hospitals performing primary angioplasty without cardiac surgical backup had better outcomes based on a six-month composite measure of mortality and adverse outcomes than those who received pharmaceutical therapy. *(Aversano, et.al., "Thrombolytic Therapy vs. Primary Percutaneous Coronary Intervention for Myocardial Infarction in Patients Presenting to Hospitals Without On-site Cardiac Surgery")*

23. The average ischemic heart disease and AMI discharges and deaths in L&M's PSA for FYs 1999-2003 are as follows:

Table 5: Average Annual Ischemic Heart Disease and AMI Discharges and Deaths in L&M's Proposed CT Service Areas, (FYs 2000 – 2003[1])

	Hospital Discharges				Mortality	
	Ischemic Heart Disease[2]		AMI		Ischemic Heart Disease	
Service Area	Discharges	Adult Rate	Discharges	Adult Rate	Deaths	Adult Rate
Primary	1,202	8.9	484	3.6	242	1.8
Secondary	774	12.2	328	5.2	129	2.0
Total Service Area	1,976	10.0	812	4.1	371	1.9
Connecticut	-	**8.2**	-	**3.2**	-	**2.1**

Mortality figures are from CT Department of Public Health Vital Records.
Population figures are from Census 2000.
[1]Deaths were from calendar years 2000 through 2003. AMI discharges were from Hospital Fiscal Years 2000 through 2004 (Hospital Fiscal Year from October 1st through September 30th).
[2]Includes discharges with a primary diagnosis of either coronary atherosclerosis or acute myocardial infarction (AMI).
ICD-9 codes: Ischemic Heart Disease 410 - 414; AMI 410.
ICD-10 codes: Ischemic Heart Disease Mortality I20 – I25.
(Discharges from OHCA Acute Care Hospital Inpatient Discharge Database and MA, NY, and RI Hospital Discharge Databases.)

Note: The adult rate was calculated by dividing the average annual total number of ischemic or AMI discharges or ischemic deaths originating in the service area by the adult population (age 15 and older) in that area and multiplying this by 1,000. Therefore, it is interpreted as the number of discharges or death per 1,000 adults in the service area (e.g. 7.1 ischemic heart disease discharges per 1,000 adults in L&M's total service area).

24. Travel distances from L&M to the nearest existing PAMI and full-service cardiac providers are as follows:

Table 4: Area PAMI and Full-Service Cardiac Providers

Hospital	Miles to L&M Hospital
Hartford	48
St. Francis	49
Yale	49

Source: Travel miles from Yahoo maps.

25. The ACC/AHA guidelines for PCI recommend formalized written protocols in place for immediate (within 1 hour) and efficient transfer of patients to the nearest full-service cardiac center. The ACC/AHA guidelines also state that procedures must be done in a timely fashion (balloon inflations within 90±30 minutes of ED admission). *(JACC, 2001, Vol. 37, No.8, pg. 2239)*

26. The Applicants stated that patients who require CABG or other cardiac surgery will be transferred on an urgent basis to YNNH. The Applicants have executed a transfer agreement. *(December 28, 2004 CON Application, page 334)*

27. The transportation of patients to L&M for PAMI services will be supported primarily by American Ambulance Service. *(December 28, 2004 CON Application, page 52)*

28. L&M will be responsible for the facilities, equipment and day-to-day operations of the PAMI program. YNNH will ensure that all staff are expertly trained in the art of acute coronary interventional procedures and will also provide ongoing training as necessary and appropriate. *(March 3, 2005 Responses to Interrogatories, page 4)*

29. The Applicants project the following number of diagnostic cardiac catheterizations and primary angioplasties in L&M's PSA for FYs 2005, 2006, and 2007: *(December 28, 2004 CON Application, page 45)*

Table 6: Projected Cardiac Volume

Service	FY 2005	FY 2006	FY 2007
Diagnostic Cardiac Catheterizations*	919	928	937
Primary Angioplasties	52	73	77

Projections based on a 4.18% compounded annual growth rate and historical market share.
(December 28, 2004 CON Application, pages 48-50)

30. The Applicants stated that Dr. Fiengo will perform the substantial majority of the 60-70 projected procedures per year, with the remainder provided by Yale affiliated interventional cardiologists. *(December 28, 2004 CON Application, page 51)*

31. The Applicants stated that the proposed PAMI program and call system is staffed by Dr. Fiengo (54% of covered time), the on-site interventional cardiologist from ECCG, and eight interventionalists (46% of covered time) from Yale University School of Medicine, Cardiology Interventional Group ("YSMCG"). The burden of coverage is shared among the nine (9) doctors, and all participants have agreed to the call schedule. *(December 28, 2004 CON Application, page 2)*

32. The Applicants stated that if L&M is approved for PAMI, YSMCG is committed to recruiting an additional interventional cardiologist to help support the L&M program. *(March 3, 2005 Responses to Interrogatories, page 2)*

33. To ensure seven days per week, 24 hours per day program availability, the Applicants have proposed the following operating call schedule:

- Dr. Fiengo would cover Monday, Tuesday, Wednesday day and night, and every third weekend. YSMCG would cover Thursday, Friday, and two out of three weekends.
- Interventionalists from YSMCG will be providing coverage to L&M from their Branford office during the daytime.
- During the nighttime, coverage will be provided from the physician homes. Several of the covering physicians live on the shoreline east of New Haven (two live in Madison and two live in Guilford) and will be readily available to L&M. In addition, L&M will provide one on-site call room for an interventional cardiologist who wants to spend the night at L&M.
- L&M has assured that there will not be delays in treatment when the interventional cardiologist is traveling to L&M as one of the ECCG cardiologists will also be on-call and will be preparing the patient for the angioplasty procedure prior to the arrival of the interventional cardiologist. The ECCG cardiologist will perform the diagnostic catheterization and identify the culprit lesion causing the AMI. By having the ECCG cardiologist on-call in addition to the on-call interventional cardiologist, the care process will be expedited.
  (December 28, 2004 CON Application, page 342 and March 3, 2005 Responses to Interrogatories, page 2)

34. Dr. Henry Cabin from the Yale School of Medicine testified at the hearing on March 10, 2005 to the following:

    - "It takes about 50 minutes from New Haven to L&M.
    - Its about 35 to 40 minutes from Guilford/Madison to L&M".

Financial Feasibility of the Proposal and its Impact on the Applicant's Rates and Financial Condition
Impact of the Proposal on the Interests of Consumers and Payers of Health Care Services

35. The proposal has a total expenditure of $7,500 for medical equipment which will be financed through operating funds. *(December 28, 2004, CON Application, page 67)*

36. L&M projects the implementation of the proposal will result in incremental losses in operations of $(504,082), $(524,171) and $(513,692) for FYs 2005, 2006 and 2007, respectively. *(December 28, 2004, CON Application, page 132)*

37. L&M projects gains in total operations with the project of $762,351, $760,696, and $769,975 for FYs 2005, 2006, and 2007, respectively. *(December 28, 2004, CON Application, page 132)*

38. L&M does not anticipating hiring any additional FTEs as a result of this CON. *(December 28, 2004, CON Application, page 72)*

Consideration of Other Section 19a-637, C.G.S. Principles and Guidelines

The following findings are made pursuant to principles and guidelines set forth in Section 19a-637, C.G.S.:

39. There is no State Health Plan in existence at this time. *(December 28, 2004 CON Application, page 30)*

40. The Applicants have adduced evidence that this proposal is consistent with L&M's long-range plan. *(December 28, 2004 CON Application, page 30)*

41. L&M has improved productivity and contained costs by participating in group purchasing, energy conservation, reengineering and applications of technology. *(December 28, 2004 CON Application, page 64)*

42. The Applicants' proposal will not impact L&M's teaching and research responsibilities. *(December 28, 2004 CON Application, page 65)*

43. There are no distinguishing characteristics of L&M's patient/physician mix. *(December 28, 2004 CON Application, page 65)*

44. The Applicants have sufficient technical, financial and managerial competence to provide efficient and adequate service to the public. *(December 28, 2004 CON Application, page 63 and Attachment VIII)*

Rationale

The Office of Health Care Access ("OHCA") approaches community and regional need for proposed services on a case-by-case basis. Certificate of Need ("CON") applications for cardiac services do not lend themselves to general applicability due to the variety and complexity of factors, which may affect any given proposal; e.g., the characteristics of the population to be served, the nature of the existing services, the specific services proposed to be offered, the current utilization of services, and the financial feasibility of the proposed service. In considering this application even though L&M's service area has a younger population and a lower mortality rate than the Connecticut rate average, OHCA determined that geographic isolation, as well as the high cardiac volume at L&M, are significant factors in determining need.

L&M and Yale-New Haven Hospital ("Applicants") propose to expand the cardiovascular services at L&M to include primary angioplasty for acute myocardial infarction ("PAMI") patients presenting with ST-segment elevation ("STEMI") or left bundle branch blockage ("LBBB"). L&M will be responsible for the day-to-day operations of the PAMI program, including facilities and equipment. YNHH will ensure that all staff are expertly trained in acute coronary interventional procedures and will provide tertiary back-up services as an existing full-service cardiac provider. The service area for the proposed program consists of 18 towns, and L&M is geographically positioned to address the needs of the residents in the proposed service areas.

The Applicants based the need for the proposed primary interventional cardiac service on existing cardiac volume, improved accessibility for patients, reduction in mortality and morbidity in the service area, and reduction in time to treatment. Numerous studies have demonstrated that primary PCI is a more effective therapeutic alternative to pharmaceutical therapy resulting in lower morbidity and mortality. According to medical literature, primary PCI can be performed safely without cardiac surgery when rigorous program criteria are established through the American College of Cardiology/American Heart Association ("ACC/AHA") criteria and standards and C-PORT guidelines, as specified in Attachment I. Current medical literature supports primary angioplasty in community hospitals without on-site cardiac surgery for patients presenting with STEMI or LBBB myocardial infarction.

The ACC/AHA guidelines for PCI recommends that formalized written protocols be in place for immediate (within 1 hour) and efficient transfer of patients to the nearest full-service cardiac center. Currently, residents of L&M's proposed service areas travel over 45 miles to full-service cardiac centers for PAMI services. Out of 144 transfers from L&M to other acute care hospitals for advanced cardiac services in FY 2003, 125 were transferred to YNHH. Implementation of the proposal will allow primary angioplasty procedures to be done in a timely fashion (balloon inflations within 90 ± 30 minutes of admission). Primary intervention will be performed routinely as the treatment of choice around the clock (e.g. 24 hours per day/7 days a week) for a large proportion of patients with AMI, to ensure streamlined care paths and increased case volumes. These are all

salubrious results from improved access to patient care.

The proposal has the potential to improve the quality of care and continuity of cardiac services in the region. Studies have shown that acute infarct PCI can be performed safely and effectively at a community hospital without cardiac surgical capability by following rigorous standards as specified in Attachment I. The Applicants stated that primary angioplasty would be performed at L&M safely and efficiently by meeting the ACC/AHA criteria and standards and C-PORT guidelines through a fully equipped cardiac catheterization laboratory with access to a full range of interventional equipment.

Furthermore, physicians participating in the program will be experienced interventional cardiologists who meet or exceed the minimum volume standards put forth in the ACC/AHA guidelines. The proposed program will be developed and managed by L&M in collaboration with Eastern Connecticut Cardiology Group, which is the primary cardiology group servicing L&M, consisting of nine board certified cardiologists and one interventional cardiologist, Dr. Fiengo. The proposed PAMI program at L&M will be covered by Dr. Fiengo and eight interventional cardiologists from the Yale School of Medicine Cardiology Group ("YSMCG"). YSMCG is committed to recruiting an additional interventional cardiologist to help support the L&M program.

To ensure seven days per week, 24 hours per day program availability at L&M, all nine interventionalists for the PAMI program agreed to an operating schedule at L&M. Dr. Fiengo would cover Monday, Tuesday, Wednesday day and night, and every third weekend. YSMCG would cover Thursday, Friday, and two out of three weekends. Interventionalists from YSMCG will be providing coverage to L&M from their Branford office during the daytime. During the nighttime, coverage will be provided from the physician homes. Several of the covering physicians live on the shoreline east of New Haven and will be readily available to L&M. In addition, L&M will provide one on-site call room for an interventional cardiologist who wants to spend the night at L&M. In addition, L&M has assured that there will not be delays in treatment when the interventional cardiologist is traveling to L&M as one of the ECCG cardiologists will also be on-call and will be preparing the patient for the angioplasty procedure prior to the arrival of the interventional cardiologist. The ECCG cardiologist will perform the diagnostic catheterization and identify the culprit lesion causing the AMI. By having the ECCG cardiologist on-call in addition to the on-call interventional cardiologist, the care process will be expedited.

L&M currently is operating two diagnostic cardiac catheterization laboratories performing 1,119, 1,191, 978 and 949 studies in Fiscal Years ("FY") 2000, 2001, 2002, and 2003, respectively. Based on historical volumes and service area market share rates, OHCA estimates that L&M could potentially perform 52, 73 and 77 PAMIs for FYs 2005, 2006 and 2007, respectively. Dr. Fiengo will perform the substantial majority of the 60-70 procedures per year, with the remainder provided by Yale-affiliated interventional cardiologists. In FY 2003, sixty-five of the 246 patients with a primary diagnosis of AMI at L&M were diagnosed with STEMI. The Chief of Cardiology reviewed the medical records meeting the C-PORT inclusion criteria and determined that

all of the STEMI patients met the criteria and would have been candidates for primary angioplasty. Based on the above, OHCA finds that the proposed PAMI program at L&M would meet or exceed the minimum volume standard of 36 PAMIs per year as stated in the ACC/AHA Guidelines.

Finally, the CON proposal is financially feasible. The proposal has a total expenditure of $7,500 for medical equipment which will be financed through operating funds. L&M projects the implementation of the proposal will result in incremental losses in operations of $(504,082), $(524,171) and $(513,692) for FYs 2005, 2006 and 2007, respectively. However, L&M projects gains in total hospital operations with the project of $762,351, $760,696, and $769,975 for FYs 2005, 2006, and 2007, respectively. L&M's volume and financial projections upon which they are based appear to be reasonable and achievable. Therefore, the CON proposal will not adversely impact the interests of consumers and payers of such services.

The Applicants' proposed primary angioplasty service is differentiated from other cardiac-related proposals in the following ways. First, L&M is located in a geographic pocket or outlying area where its residents have to travel over 45 miles for emergent angioplasty; thereby potentially not meeting the recommended door-to-balloon time of 90-120 minutes and increasing the risk of mortality and morbidity for its population. As a result of this geographic isolation, L&M's area residents are currently not receiving the treatment of choice for its STEMI patients. L&M's proposal will bring appropriate access to high quality cardiac services within a reasonable travel time. Second, L&M currently operates a high volume diagnostic cardiac catheterization program, and currently performs approximately 950 diagnostic cardiac catheterizations per year and is projecting to perform 60-70 PAMIs per year. Additionally, the proposed arrangement between L&M, ECCG, and YSMCG will provide full physician coverage by experienced interventional cardiologists for the PAMI program ensuring seven days a week, 24 hours per day program availability. Therefore, L&M's program will be able to achieve PAMI volumes in excess of those stated in the ACC/AHA Guidelines. Finally, L&M's strong collaborative relationship with YNHH will enhance the accessibility of high quality, community-based medical services offered by L&M. Implementation of the proposal will bring appropriate access to high quality cardiac services to the residents of the service areas within a reasonable travel time. In summary, the proposal will result in enhanced cardiac services in the New London region.

Order

NOW, THEREFORE, the Office of Health Care Access ("OHCA") and Lawrence and Memorial Hospital and Yale-New Haven Hospital ("Applicants") hereby stipulate and agree to the terms of settlement with respect to the Applicants' request to establish a primary interventional cardiac service to be located at L&M at a total capital expenditure of $7,500, as follows:

1. The Applicants' request for a CON to establish a primary interventional cardiac service to be located at L&M at a total capital expenditure of $7,500 is hereby approved.

2. L&M shall complete and submit to OHCA on a quarterly basis the data elements in the Connecticut Cardiac Data Registry (Attachment II). Data should be submitted to OHCA on a computer disk in either an excel workbook or comma-delimited text file in a format specified by OHCA. The most current version of the Connecticut Cardiac Data Registry includes, but may not be limited to, the elements listed in Attachment II. Data must be reported to OHCA thirty (30) calendar days following the end of the quarter. Fiscal Year quarters end December 31st, March 31st, June 30th, and September 30th. Upon receipt, OHCA will check the data's conformance to the required specifications and within ten (10) business days notify L&M in writing of its evaluation. If OHCA finds questionable material, L&M will have fifteen (15) business days from notification by OHCA to submit a revised dataset for evaluation. All patient-level data submitted to OHCA to satisfy this requirement will be subject to the laws and regulations of the state of Connecticut and the Office of Health Care Access regarding its collection, use and confidentiality. If L&M does not submit the above data to the Cardiac Data Registry on a quarterly basis, the primary angioplasty program shall be terminated. In the event of such a termination, L&M shall file a CON for the reinstitution of the program.

3. If L&M and/or the physicians do not perform the ACC/AHA recommended minimum number of annual institutional or operator volumes, as specified in Attachment I within 12 months of commencement of the primary PCI program (first 12-month period), L&M shall submit monthly reports of primary angioplasty volume arrayed by physician to OHCA until such time as the minimum volumes are met by both institution and physician. If by the end of the second 12-month period, the ACC/AHA institutional and operator annual volumes are not met, the Applicants' primary PCI program shall be terminated. In the event of such a termination, L&M shall file a CON for the reinstitution of the program.

4. L&M shall participate in the C-PORT registry and is required to comply with the patient eligibility and identification, guidelines for clinical care, standards for facilities and care providers and staff training, including care plan and logistics

development and quality and error management, as stated in the Manual of Operation. L&M shall provide OHCA quarterly data reports through such registry for the purposes of monitoring and quality assurance. If L&M determines not to participate in the C-PORT registry or the C-PORT registry no longer exists, L&M shall notify OHCA immediately, and continue to comply with the C-PORT guidelines and protocols.

5. L&M shall participate in the ACC National Cardiovascular Database Registry (ACC-NCDR) and report all data including the optional follow-up section. L&M shall provide OHCA quarterly data reports from the ACC-NCDR. These reports shall be submitted to OHCA at the same time that the Connecticut Cardiac Data Registry data is filed. L&M is required to comply with all the ACC/AHA criteria and standards for the performance of angioplasty at hospitals without on-site cardiac surgery. If L&M determines not to participate in the ACC-NCDR, L&M shall notify OHCA immediately, and continue to comply with the ACC/AHA criteria and standards.

6. L&M shall report to OHCA documenting compliance with the ACC/AHA general exclusion criteria for invasive procedures, performance of primary PCI in hospitals without cardiac surgery capabilities, and selection of patients appropriate for primary PCI or transfer to a full-service cardiac center. If the ACC/AHA criteria and standards and/or the C-PORT guidelines are not met, Lawrence and Memorial Hospital's primary PCI program shall be terminated. In the event of such a termination, L&M shall file a CON for the reinstitution of the program.

7. The Applicants will contract with a second on-site interventional cardiologist for the proposed PAMI program who will begin performing PAMIs' at L&M upon Dr. Fiengo performing 70 cumulative angioplasty procedures at L&M. The interventional cardiologist must be fully credentialed and have the following qualifications:
   - Board-Certified in interventional cardiology
   - Maintains a Connecticut license and admitting privileges at both L&M and YNHH
   - Meets or exceeds the AHA/ACC minimum operator volume standards for PCI for the past 2 years.

   The Applicants shall provide the CV of the additional interventional cardiologist prior to performance of primary angioplasties at L&M. OHCA shall acknowledge receipt and acceptance of the CV prior to performance of PAMIs by the physician.

8. The Applicants shall report to OHCA documenting compliance with the operating call schedule. The Applicants shall provide documentation that on call YSMCG cardiologists initiate the procedure within 40 minutes of call.

9. OHCA and L&M and YNHH agree that this Agreed Settlement represents a final agreement between OHCA and L&M and YNHH with respect to this request. The

signing of this Agreed Settlement resolves all objections, claims and disputes, which may have been raised by the Applicants with regard to Docket Number 04-30297-CON.

10. This authorization shall expire on June 1, 2007. Should the Applicants' primary interventional cardiac service not be implemented by that date, the Applicants must seek further approval from OHCA to complete the project beyond that date.

11. 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 pursuant to the provisions of Sections 19a-642 and 19a-653 of the Connecticut General Statutes at L&M's expense, if the Applicants fail to comply with its terms.

May 31, 2005 William T. Christopher

_____ _____

Date Duly Authorized Agent for
Lawrence and Memorial Hospital

June 1, 2005 Kyle Kramer

_____ _____

Date Duly Authorized Agent for
Yale-New Haven Hospital

The above Agreed Settlement is hereby accepted and so ordered by the Office of Health Care Access on June 1, 2005.

Date Signed:
June 1, 2005

Signed by:
Cristine A. Vogel
Commissioner
Office of Health Care Access

CAV:pf