

STATE OF CONNECTICUT
OFFICE OF HEALTH CARE ACCESS

M. JODI RELL
GOVERNOR

CRISTINE A. VOGEL
COMMISSIONER

January 9, 2009

IN THE MATTER OF:

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

**Norwalk Hospital and
Saint Vincent's Medical Center**

Edward Staunton
Director, Service Line Development
Norwalk Hospital
34 Maple Street
Norwalk, CT 06856

Notice of Final Decision
Office of Health Care Access
Docket Number: 08-31079-CON

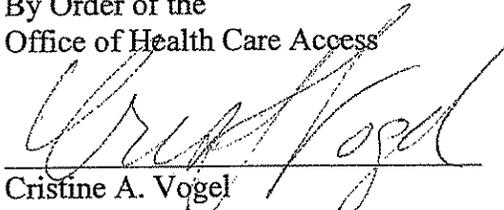
**Establish and Operate a Primary
Angioplasty Myocardial Infarction
(PAMI) Program at Norwalk Hospital**

Susan L. Davis, RN, Ed.D.
President and Chief Executive Officer
Saint Vincent's Medical Center
2800 Main Street
Bridgeport, CT 06606

Dear Mr. Staunton and Dr. Davis:

This letter will serve as notice of the Agreed Settlement between the Office of Health Care Access and Norwalk Hospital and Saint Vincent's Medical Center in the above matter, as provided by Section 19a-638, C.G.S. On January 9, 2009, the Agreed Settlement was adopted as the finding and order of the Office of Health Care Access. A copy of the Agreed Settlement is attached hereto for your information.

By Order of the
Office of Health Care Access


Cristine A. Vogel
Commissioner

Enclosure
CAV:agf



Office of Health Care Access Certificate of Need Application

Agreed Settlement

Applicants: Norwalk Hospital
Saint Vincent's Medical Center

Docket Number: 08-31079-CON

Project Title: Establish and Operate a Primary Angioplasty Myocardial Infarction (PAMI) Program at Norwalk Hospital

Statutory Reference: Section 19a-638, Connecticut General Statutes

Filing Date: October 7, 2008

Hearing Date: December 4, 2008

Presiding Officer: Cristine Vogel, Commissioner

Decision Date: January 9, 2009

Default Date: Not Applicable

Staff: Steven W. Lazarus
Alexis G. Fedorjaczenko

Project Description: Norwalk Hospital and Saint Vincent's Medical Center ("Applicants") propose to establish and operate a Primary Angioplasty Myocardial Infarction (PAMI) program at Norwalk Hospital, with no associated capital expenditure.

Nature of Proceedings: On October 7, 2008, the Office of Health Care Access ("OHCA") received the Applicants' Certificate of Need ("CON") application seeking authorization to establish and operate a Primary Angioplasty Myocardial Infarction (PAMI) program at Norwalk Hospital. The proposal has no associated capital expenditure. The Applicants are health care facilities or institutions as defined by Section 19a-630 of the Connecticut General Statutes ("C.G.S.").

Pursuant to Section 19a-638, C.G.S., three individuals, or an individual representing an entity with five or more people, had until October 28, 2008, the twenty-first calendar day following the filing of the Applicant's CON application, to request that OHCA hold a public hearing on the Applicant's proposal. On October 28, 2008, The Stamford Hospital requested that OHCA hold a public hearing.

Pursuant to Section 19a-638, C.G.S., a public hearing regarding the CON application was held on December 4, 2008. On November 6, 2008, the Applicant was notified of the date, time, and place of the hearing. On November 7, 2008, a notice to the public announcing the hearing was published in *The Connecticut Post* (Bridgeport) and *The Hour* (Norwalk). Commissioner Cristine A. Vogel served as Presiding Officer. 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 these sections, 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

Contribution of the Proposal to the Quality and Accessibility of Health Care Delivery in the Region

Impact on the Applicants' Current Utilization Statistics

1. Norwalk Hospital ("NH" or "Hospital") is a not-for-profit, 328-bed acute care hospital located at 34 Maple Street in Norwalk, Connecticut. (*April 22, 2008, Initial CON Application, pages 7 and 832*)
2. Saint Vincent's Medical Center ("SVMC") is a not-for-profit, 473-bed acute care hospital located in Bridgeport, Connecticut. SVMC is a member of Ascension Health, a not-for-profit Catholic health system. (*April 22, 2008, Initial CON Application, pages 7 and 9; September 12, 2008, Agree Settlement, Docket Number 08-31130*)
3. Norwalk Hospital proposes to expand its current cardiovascular services to include primary angioplasty ("PAMI") for acute myocardial infarction patients presenting with ST-segment elevation ("STEMI") and new left bundle branch blockage ("LBBB"). (*April 22, 2008, Initial CON Application, pages 7-8*)
4. SVMC operates a comprehensive cardiology and cardiothoracic program, including open heart surgical services, and has long been the primary destination for NH patients requiring transfer for PAMI and other cardiac surgical services. (*April 22, 2008, Initial CON Application, pages 7 and 9*)

5. SVMC will serve as the primary surgical back-up hospital for the proposed PAMI program. *(April 22, 2008, Initial CON Application, page 9)*

6. The proposed program will augment NH's existing inpatient and outpatient cardiac services including:
 - Cardiac Catheterization (diagnostic procedures including right and left heart catheterizations);
 - Pacemaker Insertions, Evaluation and Follow-up;
 - Implantable Cardiac Defibrillator (ICD) Insertions, Evaluation and Follow-up;
 - Loop Recorder Insertion and Removal;
 - Stress Testing (Exercise and Pharmacologic);
 - Event Monitoring;
 - Nuclear Cardiac Imaging (Stress and Rest);
 - Cardiac Imaging Services including CT (64 slice scanner) and MRI;
 - Echocardiography (Transthoracic, Transesophageal, Resting, Exercise, and Exercise Dobutamine);
 - 24-hour Holter monitoring;
 - 24-hour Ambulatory Blood Pressure Monitoring;
 - Elective Cardioversions;
 - Tilt Table Testing;
 - EKG Testing;
 - Intra-aortic Balloon Pumping;
 - Vascular and Thoracic Surgical Services;
 - Cardiac Rehabilitation;
 - Coronary Care and Telemetry Units; and
 - Cardiovascular Care and Prevention Programs.*(April 22, 2008, Initial CON Application, page 12)*

7. The Applicants based the need for the proposed PAMI service on the following:
 - A significant number of potential PAMI cases receive their care at Norwalk Hospital because it is their local community hospital; and
 - Patients that present at the NH emergency department ("ED") with STEMI or new LBBB must be transferred, reducing the likelihood of meeting the recognized 90-min door to balloon time standard.*(April 22, 2008, Initial CON Application, page 19)*

8. NH's service area across all service lines consists of the towns in the following chart. Of these towns, the Hospital proposes that the service area for the proposed PAMI program will consist of the primary service area towns of Norwalk, Westport, New Canaan, Wilton, and Weston. This is based on a medical records review indicating that patients from these towns comprise more than 80% of potential PAMI patients.

Table 1a: NH's Service Area

Primary	New Canaan; Norwalk; Westport; Wilton; Weston
Secondary	Bethel; Bridgeport; Darien; Easton; Fairfield; Greenwich; Monroe; Newtown; Redding; Ridgefield; Stamford; Stratford; Trumbull

(April 22, 2008, Initial CON Application, page 28)

Table 1b: Potential PAMI Patients, Town of Origin

		# Potential PAMI Patients	% of Total
PSA	Norwalk	33	53.2%
	Westport	7	11.3%
	Wilton	6	9.7%
	New Canaan	3	4.8%
	Weston	1	1.6%
	Subtotal	50	80.6%
SSA/Other	Derby	1	1.6%
	Fairfield	1	1.6%
	Orange	1	1.6%
	Plantsville	1	1.6%
	Ridgefield	1	1.6%
	Stamford	1	1.6%
	All Other States	3	4.8%
Grand Total	62	100%	

(April 22, 2008, Initial CON Application, page 29)

9. The Hospital indicated that there are no PAMI providers located in the proposed program service. The Hospital noted that existing PAMI providers in the Hospital's SSA include:

Table 2: Existing PAMI Providers in NH's SSA

Hospital	Town
Stamford Hospital	Stamford, CT
Greenwich Hospital	Greenwich, CT
Saint Vincent's Medical Center	Bridgeport, CT
Bridgeport Hospital	Bridgeport, CT

(April 22, 2008, Initial CON Application, pages 30-31)

10. The average annual primary percutaneous coronary interventions ("PCI") and inpatient cardiac catheterization volumes in NH's PSA by area provider for FYs 2005-2007 are as follows:

Table 3: Average Annual Primary PCI and Inpatient Diagnostic Cardiac Catheterization in PSA by Provider, (FYs 2005-2007)

Hospital	Primary PCI		Diagnostic Cardiac Catheterization	
	Procedures	Market Share (%)	Procedures	Market Share (%)
SVMC	56	68%	392.3	47%
NH	n/a	n/a	205.0	25%
Bridgeport	21	26%	122.3	15%
Stamford	1.7	2%	47.3	6%
Yale	2.7	3%	44.9	5%
Other	0.6	1%	20.3	2%
Totals	82.0	100%	831.3	100%

(October 7, 2008, Completeness Response, page 917)

11. The Applicants stated that although hospitals do not generally report door-to-balloon time for transferred PAMI patients, their analysis found that the door-to-balloon time for NH patients who must be transferred for PAMI services exceeds the 90-minute standard. The following tables illustrate this analysis.

Table 4a: Median Time, ED Door to ED Departure at NH

FY	Median Time
2008	70 Minutes
2007	94 Minutes
2006	113 Minutes
2005	115 Minutes

(October 7, 2008, Completeness Response, page 924)

Table 4b: NH's Potential PAMI Patients, Average Door-to-Balloon Time

	Time to SVMC
Phase 1. Presentation at NH's ED to Departure from NH's ED	94 Minutes
Phase 2. Transportation by Ambulance to Receiving Hospital (Average Depending on time of Day)	20 to 34 Minutes
Phase 3. Receiving Hospital Door-to-Balloon Time	45 Minutes
Total Time Elapsed	159 to 173 Minutes

(April 22, 2008, Initial CON Application, pages 22- 25)

12. The five-year average ischemic heart disease and AMI discharges and deaths in NH's PSA and the State of Connecticut are as follows:

Table 5: Average Five-Year Ischemic Heart Disease and AMI Discharges and Deaths in NH PSA and Connecticut

	Discharged from CT Hospitals				Mortality			
	Ischemic Heart Disease		AMI		Ischemic Heart Disease		AMI	
	Discharges	Adult Rate	Discharges	Adult Rate	Deaths	Adult Rate	Deaths	Adult Rate
NH PSA	1031.2	8.66	242.8	2.04	29.4	0.25	23.4	0.20
Connecticut	24198.8	8.87	5059.6	1.85	654.8	0.24	474.8	0.17

Note: Five-year average for FYs 2003-2007

(October 7, 2008, Completeness Response, page 919-20)

13. NH's historical diagnostic cardiac catheterization volume is as follows:

Table 6: Norwalk Hospital's Historical Diagnostic Cardiac Catheterization Volume (FYs 2005 – 2008)

	2005	2006	2007	2008*
Inpatient	180	132	72	92
Outpatient	161	104	67	80
Total	341	236	139	172

ICD-9 codes are 37.21, 37.22, and 37.23

* FY 2008 is annualized based on 6 months of data.

Note: The Applicants indicated that a major contributing factor to the decline in volume was the obsolescence of the cardiac catheterization equipment, and that since replacing the laboratory in January 2008, volume has increased.

(April 22, 2008, Initial CON Application, pages 35-6 and October 7, 2008, Completeness Response, pages 913-4)

14. The Applicants reported performing a review of NH transfer logs to identify patients presenting with either STEMI or new LBBB who would be potential PAMI patients. The findings are presented in the following table

Table 7: Medical Records Review: Potential PAMI Patients Transferred to Other Hospitals, 2005-2008

	2005	2006	2007	2008*
Bridgeport Hospital	5	7	6	3
SVMC	37	36	50	41
Other/Unknown	4	2	6	0
Total	46	45	56	44

* FY 2008 is annualized based on 11 months of data.

Note: The Applicants reported that between FY 2005 and FY 2008, there were 2 patients per year who were transferred from NH to SVMC and ultimately received open heart surgery.

(April 21, 2008, Initial CON Application, pages 20-211 October 7, 2008, Completeness Response, pages 918-9 & 922)

15. Norwalk Hospital projects the following number of diagnostic cardiac catheterizations and primary angioplasties for its PSA for FYs 2008, 2009, 2010, and 2011:

Table 8: Projected Cardiac Volume

Service	2008	2009	2010	2011
Primary Angioplasties	--	56	56	56
Inpatient Cardiac Catheterizations	102	116	116	116
Outpatient Cardiac Catheterizations	88	100	100	100
Total Cardiac Catheterizations	190	216	216	216

(April 22, 2008, Initial CON Application, pages 39-40)

16. Together, NH and SVMC, and their medical staff, have formed a joint PAMI Performance Improvement Committee ("PPIC") for the establishment and ongoing monitoring of the PAMI program at NH. (April 22, 2008, Initial CON Application, page 46)

17. The scope of activity of the PPIC includes the following:
- Develop a common set of credentialing standards for PAMI procedures performed at NH;
 - Develop quality metrics for ongoing competency and re-appointment, including minimum volume and/or CME requirements;
 - Review PAMI volume by physician and appropriateness;
 - Review outcome statistics including infection rates and late complications;
 - Develop physician action plan for improvement, when appropriate;
 - Review American College of Cardiology ("ACC") data submission;
 - Report to the Credentials Committee, Quality Review Committee, Quality Peer Review Committee of the NH Board and, as needed, directly to the Department Chairs and the Medical Executive Committee.
- (April 22, 2008, Initial CON Application, page 815-816)*
18. To support ongoing quality improvement, a web-based application/digital link was developed for the transmission of coronary angiography and angioplasty images between the two hospitals. *(April 22, 2008, Initial CON Application, page 46)*
19. The 2001 American College of Cardiology/American Heart Association ("ACC/AHA") Guidelines for PCI recommend criteria and standards for the performance of angioplasty at hospitals without on-site cardiac surgery. The Applicants have designed the PAMI program at NH to be compliant with the ACC/AHA practice guidelines including, but not limited to, the following:
- Experienced interventionalists, nursing, and technical catheterization laboratory staff with regular training and volume reviews;
 - NH's cardiac and vascular laboratory equipment has recently been upgraded to incorporate the latest technology and includes a digital link to SVMC;
 - An emergency transfer agreement (with SVMC) and an emergency transfer protocol, bumping policy and critical pathway for PAMI have been developed for this program;
 - PAMI will be available 24 hours per day, seven days per week, with care protocols to ensure rapid identification and treatment of all STEMI and new LBBB patients;
 - The Hospital must perform a minimum of 36 primary PCI procedures per year;
 - Case selection guidelines have been developed ; and
 - The PPIC will provide outcomes analysis and implementation support
- (April 22, 2008, Initial CON Application, pages 44-51 and exhibit 10)*
20. NH's Medical Executive committee approved a PAMI physician privileging and credentialing process which requires that physicians apply for PAMI privileges and, once granted privileges, meet certain standards to maintain privileges. The policy specifics that:
- Any physician applying for PAMI privileges must perform a minimum of 75 angioplasty procedures;
 - Physicians will be on supervised status for one year;
 - The Chief of Cardiology or his designee will function as the supervisor;

- Satisfactory performance of at least 75 angioplasty procedures per year is necessary to maintain PAMI privileges; and
- Failure to maintain this volume with satisfactory primary success rates will result in placement of the physician on supervised status.

(October 7, 2008, Completeness Response, page 908)

21. NH stated that nine interventional cardiologists would provide on-call coverage for the proposed PAMI services. The physicians and their affiliations, and their PCI volume, are presented in the following tables.

Table 9a: Proposed Program Interventionalist

Physician	Hospital Affiliation	Practice Affiliation
David P. Lorenz (a)	SVMC TSH NH	Cardiology Associates of Fairfield County, P.C.
Edward Portnay	SVMC TSH NH	Cardiology Associates of Fairfield County, P.C.
Robert Jumper	SVMC TSH NH	Cardiology Associates of Fairfield County, P.C.
Jared Selter	SVMC NH (pending)	Cardiology Associates of Fairfield County, P.C.
Jeffrey Berman	SVMC NH (pending)	Cardiology Associates of Fairfield County, P.C.
Boris V. Sheynberg	BH SVMC NH	Westport Cardiology
Charles Landau	SVMC DH NH	Connecticut Heart and Vascular Center, P.C.
Craig S. Werner	SVMC DH NH	Connecticut Heart and Vascular Center, P.C.
Victor M. Mejia	SVMC DH NH	Connecticut Heart and Vascular Center, P.C.

(a) Dr. Lorenz will function as the Medical Director of the Cardiac and Vascular Laboratory and serve as Clinical PAMI Director. Dr. Lorenz will be onsite not less than three full days per week. The Stamford Hospital ("TSH"); Bridgeport Hospital ("BH"); Danbury Hospital ("DH")
(April 22, 2008, Initial CON Application, pages 37-89; July 18, 2008, Completeness Response, page 878, October 7, 2008, Completeness Response, pages 908-9)

Table 9b: Cardiologists PCI Volume

Physician	2005	2006	2007	2008
1	0	16	60	86
2	229	106	52	50
3	114	82	70	62
4	99	229	186	160
5	504	158	167	174
6	84	155	142	126
7	328	165	87	116
8	229	112	59	106
9	0	14	97	152

*Note: 2008 is annualized based on six months of data.
 (October 7, 2008, Completeness Response, pages 910-11)*

22. The Applicants stated that the LIFENET System is a web server that utilizes the existing 12-lead EKG technology present in each of NH's ambulances by transmitting data to NH's ED and catheterization lab. NH will test the LIFENET System with its own paramedics during the first year of PAMI operations and, assuming its ability to significantly reduce door-to-balloon time, will implement it with NH-sponsored EMS services. *(April 21, 2008, Initial CON Application, page 13; and July 18, 2008, Completeness Response, page 874)*

Financial Feasibility of the Proposal and its Impact on the Applicants' Rates and Financial Condition
Rates Sufficient to Cover Proposed Capital and Operating Costs
Impact of the Proposal on the Interests of Consumers of Health Care Services and Payers for Such Services
Consideration of Other 19a-637, C.G.S. Principles and Guidelines

23. The proposal has no associated capital expenditure, as NH has made all necessary investments in its cardiac and vascular service line including upgrades of both its cardiac catheterization laboratory and its interventional radiology angiography laboratory, and the acquisition and upgrade to a 64-slice CT scanner. *(April 22, 2008, Initial CON Application, pages 12 & 57)*
24. NH's projected incremental net patient and other operating revenue, total operating expense, and gain from operations associated with the CON proposal are as follows:

Table 10: Financial Projections Incremental to the Project

Description	FY 2009	FY 2010	FY 2011
Incremental Net Patient Revenue	\$1,374	\$1,415	\$1,457
Incremental Other Operating Revenue	\$333	\$333	\$333
Incremental Total Operating Expense	\$1,664	\$1,682	\$1,745
Incremental Gain from Operations	\$43	\$66	\$45

*Note: figures are in thousands.
 (October 7, 2008, Completeness Response, page 956)*

25. The Applicants testified that in the fourth year of the project and beyond, any program losses will be made up with gains in other operations, as is done with several areas of clinical services that have negative contribution margins but are important for the citizens of the Norwalk community. *(December 4, 2008, Hearing Testimony of Dan DeBarber)*
26. SVMC projected incremental revenue from operations, total operating expense, and (loss) from operations associated with the CON proposal are as follows:

Table 11: Financial Projections Incremental to the Project

Description	FY 2009	FY 2010	FY 2011
Incremental Revenue from Operations	(\$916)	(\$951)	(\$988)
Incremental Total Operating Expense	(\$655)	(\$683)	(\$713)
Incremental (Loss) from Operations	(\$261)	(\$268)	(\$275)

*Note: figures are in thousands.
 (October 7, 2008, Completeness Response, page 907)*

27. Other than on-call coverage, NH does not anticipate that any additional staff will be required to perform primary angioplasty. *(April 22, 2008, Initial CON Application, page 61)*
28. NH is the entity that will bill for the facility/technical fees associated with the proposed PAMI service. *(April 22, 2008, Initial CON Application, page 57)*
29. There is no State Health Plan in existence at this time. *(April 22, 2008, Initial CON Application, page 18)*
30. The current and three year projected payer mix for NH, based on Gross Patient Revenue, is as follows:

Table 12: Current & Three-Year Projected Payer Mix

Description	Current	Year 1	Year 2	Year 3
Medicare*	46.4%	46.4%	46.4%	46.4%
Medicaid*	10.4%	10.4%	10.4%	10.4%
CHAMPUS and TriCare	--	--	--	--
Total Government	56.8%	56.8%	56.8%	56.8%
Commercial Insurers*	36.4%	36.4%	36.4%	36.4%
Uninsured	5.1%	5.1%	5.1%	5.1%
Workers Compensation	1.8%	1.8%	1.8%	1.8%
Total Non-Government	43.3%	43.3%	43.3%	43.3%
Total Payer Mix	100%	100%	100%	100%

** Includes managed care activity.
 (April 22, 2008, Initial CON Application, page 59)*

31. NH has adduced evidence that this proposal is consistent with its long-range plan. *(April 22, 2008, Initial CON Application, page 18)*
32. NH has improved productivity and contained costs through energy conservation and reengineering. *(April 22, 2008, Initial CON Application, page 53)*

33. The proposal will not result in any change to Norwalk Hospital's teaching and research responsibilities. *(April 22, 2008, Initial CON Application, page 54)*
34. The Hospital stated that there are no characteristics of its patient/physician mix that make the proposal unique. *(April 22, 2008, Initial CON Application, page 54)*
35. The Applicants have sufficient technical, financial, and managerial competence to provide efficient and adequate service to the public. *(April 22, 2008, Initial CON Application, pages 51-2 & exhibit 13)*

Rationale

The Office of Health Care Access ("OHCA") approaches community and regional need for Certificate of Need ("CON") proposals on a case by case basis. CON applications do not lend themselves to general applicability due to a variety 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 types of services proposed to be offered, the current utilization of services and the financial feasibility of the proposal.

Norwalk Hospital ("NH" or "Hospital") is a not-for-profit, 328-bed acute care hospital located at 34 Maple Street in Norwalk. Saint Vincent's Medical Center ("SVMC") is a not-for-profit, 473-bed acute care hospital located in Bridgeport. Norwalk Hospital currently provides a range of inpatient and outpatient cardiac services, and proposes to expand these services to include primary angioplasty ("PAMI") for acute myocardial infarction patients presenting with ST-segment elevation ("STEMI") and new left bundle branch blockage ("LBBB"). Under this proposal, SVMC, which operates a comprehensive cardiology and cardiothoracic program, will serve as the primary surgical back-up hospital for the proposed PAMI program.

The Applicants based the need for the proposed service at Norwalk Hospital on the number of potential PAMI cases that receive their care at Norwalk Hospital but who currently must be transferred to another hospital for PAMI services. The Applicants provided sufficient evidence to support the projected number of potential PAMI patients at Norwalk Hospital, which exceeds the ACC/AHA minimum of 36 procedures per year. Based on the above, OHCA finds that the Applicants' proposal to establish a PAMI program at Norwalk Hospital in Norwalk will improve the overall quality and accessibility of services for acute myocardial infarction patients presenting with ST-segment elevation and new left bundle branch blockage at the Hospital.

The proposal has no associated capital expenditure, as NH has made all necessary investments in its cardiac and vascular service line including upgrades of both its cardiac catheterization laboratory and its interventional radiology angiography laboratory, and the acquisition and upgrade to a 64-slice CT scanner. The Applicants testified that program losses will be made up with other operating revenue. The Applicant's financial projections and volumes upon which they are based appear to be reasonable.

Order

NOW, THEREFORE, the Office of Health Care Access ("OHCA") and Norwalk Hospital ("NH") and Saint Vincent's Medical Center ("SVMC") (together, "Applicants") hereby stipulate and agree to the terms of settlement with respect to the establishment and operation of a Primary Angioplasty Myocardial Infarction ("PAMI") program at Norwalk Hospital, with no associated capital expenditure, as follows:

1. The Applicants' request for a CON to establish and operate a Primary Angioplasty Myocardial Infarction ("PAMI") program at Norwalk Hospital, with no associated capital expenditure, is hereby approved.
2. There is no associated capital expenditure approved. In the event that any of the Applicants learn of potential significant costs associated with start of operations of this program, the Applicants shall notify OHCA in a timely manner.
3. The Applicants agree that NH is required to file with OHCA, an annual utilization report containing specific data and/or information related to the authorized PAMI program in a format to be defined by OHCA subsequent to the execution of this agreement. OHCA will provide NH with the specific format for the annual filing within ninety days of the authorization date of this agreement. OHCA will also set forth the filing schedule related to the annual utilization reporting at that time. NH shall report its operational start date to OHCA within fifteen days of commencement of operations in order for OHCA to determine NH's reporting schedule.
4. The Applicants agree that if NH does not perform the ACC/AHA recommended minimum number of annual institutional volumes for the first full operational year for the program, NH shall then commence submission of monthly reports to OHCA containing PAMI volume figures for each month. Such monthly volume reports shall commence within 30 days subsequent to the end of operational year one. Further, if upon submission of a full year of monthly reports, NH has not achieved the ACC/AHA recommended minimum number of annual institutional volumes for ~~either operational year one or~~ operational year two, the Applicants agree that the NH PAMI program will be considered by OHCA and the Applicants to be terminated. In the event of such termination, NH shall be required to file a Certificate of Need application for any proposed reinstatement of the program.
5. The Applicants agree that it is the intent of NH and SVMC to participate in the American College of Cardiology National Cardiovascular Database Registry (ACC-NCDR). NH and SVMC are required to comply with the ACC/AHA criteria and standards. If NH and SVMC determine not to participate in the ACC-NCDR, the Applicants shall notify OHCA in a timely manner regarding such decision not to participate and shall continue to comply with the ACC/AHA criteria and standards. Further, the Applicants agree that, if NH and SVMC do participate in ACC-NCDR,

*C. Vogel 1/14/09
H. Cole 1/20/09
A. Swartz 1/21/09*

NH and SVMC are required to submit to OHCA any and all Executive Summary pages from the Institutional Outcomes Reports received by the Applicants from ACC-NCDR, such Executive Summary containing the PCI Quality Measures, PCI Utilization Measures, and Diagnostic Cath Quality Measures. All Executive Summaries received by the Applicants during the year, will be due to OHCA at the same time as the annual report specified and agreed upon in Stipulation #3 above. Further, NH and SVMC shall supply to OHCA the detail reports from ACC-NCDR to NH and SVMC, only if OHCA specifically requests such detailed report.

6. The Applicants shall provide OHCA with dated and signed copies of the following, prior to program commencement:
 - a. Service Agreement,
 - b. Transfer Agreement, and
 - c. Memorandum of Understanding.
7. This authorization shall expire on January 15, 2010. Should the establishment of a PAMI program at NH not be completed by that date, the Applicants must seek further approval from OHCA to complete the project beyond that date.
8. Should the Applicants propose any change in the PAMI service, the Applicants shall file with OHCA a Certificate of Need Determination Request or Certificate of Need letter of Intent regarding the proposed service change.
9. OHCA and NH and SVMC agree that this Agreed Settlement represents a final agreement between OHCA and NH and SVMC 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 08-31079-CON.
10. 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 the Applicants' expense, if the Applicants fail to comply with its terms.

January 9, 2009
Date

Tholly F. Cole
Duly Authorized Agent for
Norwalk Hospital

1-9-09
Date

Jesse Davis
Duly Authorized Agent for
Saint Vincent's Medical Center

The above Agreed Settlement is hereby accepted and so ordered by the Office of Health
Care Access on January 9, 2009.

Date

1-9-09

Cristine A. Vogel
Commissioner

