STATE OF CONNECTICUT
OFFICE OF HEALTH CARE ACCESS

M. JODI RELL
GOVERNOR

CRISTINE A. VOGEL
COMMISSIONER

August 25, 2004

IN THE MATTER OF:

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

The Stamford Hospital and New York Presbyterian Healthcare System, Inc.

Notice of Agreed Settlement
Office of Health Care Access
Docket Number 03-30176-CON

Establishment of PAMI program At Stamford Hospital

To: Arthur A. Klein, MD
Chief Operating Officer and
Senior Vice President
New York Presbyterian Healthcare System, Inc.
New York Weill Cornell Medical Center
525 East 68th Street, Box 191
New York, NY 10021

Dear Dr. Klein:

This letter will serve as notice of the Agreed Settlement between the Office of Health Care Access and The Stamford Hospital and New York Presbyterian Healthcare System, Inc. in the above matter, as provided by Section 19a-638, C.G.S. On August 25, 2004, 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

CAV: km

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Establishment of PAMI program At Stamford Hospital

To: David L. Smith
The Stamford Hospital
Shelburne Road at West Broad Street
P.O. Box 9317
Stamford, CT 06904-9317

Dear Mr. Smith:

This letter will serve as notice of the Agreed Settlement between the Office of Health Care Access and The Stamford Hospital and New York Presbyterian Healthcare System, Inc. in the above matter, as provided by Section 19a-638, C.G.S. On August 25, 2004, 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

C: Stephen M. Cowherd, Esquire, Jeffers & Ireland

CAV: km

Office of Health Care Access
Certificate of Need Application

Agreed Settlement

Applicants:	**The Stamford Hospital and New York Presbyterian Healthcare System, Inc.**
Docket Number:	**03-30176-CON**
Project Title:	**Establish Primary Interventional Cardiac Service at The Stamford Hospital in Stamford**
Statutory Reference:	**Section 19a-638, Connecticut General Statutes**
Filing Date:	**April 19, 2004**
Hearing Dates:	**June 10, 2004 and June 16, 2004**
Presiding Officer:	**Cristine Vogel, Commissioner**
Decision Date:	**August 25, 2004**
Default Date:	**Not Applicable**
Staff:	**Kim Martone** **Michael Sabados** **Steven Lazarus** **Paolo Fiducia**

Project Description: The Stamford Hospital and New York Presbyterian Healthcare System, Inc. ("Applicants") propose to establish a primary interventional cardiac service, to be located at The Stamford Hospital, at a capital expenditure of $100,000.

Nature of Proceedings: On April 19, 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 The Stamford Hospital. The proposal has a capital expenditure of $100,000. The Applicants are health care facilities or institutions as defined by Section 19a-630 of the Connecticut General Statutes ("C.G.S."). The Stamford Hospital is organized under the laws of Connecticut, and New York Presbyterian Healthcare System, Inc. is a corporation organized under the laws of the State of New York.

Public hearings regarding the CON Application were held on June 10, 2004 and June 16, 2004. 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 Advocate* (Stamford). Commissioner Cristine Vogel served as presiding officer in this matter. The hearing was conducted as contested cases 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
Impact on the Applicants' Current Utilization Statistics
Proposal's Contribution to Accessibility and Quality of Health Care Delivery in the Region

1. New York Presbyterian Healthcare System, Inc. ("System" or"NYPHS") coordinates a system of hospitals and other healthcare institutions throughout the tri-state area, including The Stamford Hospital ("TSH") and New-York Presbyterian Hospital ("NYPH"). NYPH operates Columbia Presbyterian Medical Center ("CPMC") in affiliation with Columbia University College of Physicians and Surgeons ("CU"), and the New York Weill Cornell Medical Center ("NYWCMC"). *(February 6, 2004, CON Application, page 8)*

2. TSH is a not-for-profit, 305-bed acute care hospital located in Stamford, Connecticut. TSH, as an affiliate member of the System, maintains an educational affiliation with CU. TSH provides a comprehensive array of services including: Medicine, Surgery, Obstetrics/Gynecology, Psychiatry as well as Medical and

Surgical critical care units. *(February 6, 2004, CON Application, page 9)*

3. NYPH has one of the largest cardiac surgery and cardiac catheterization[1] programs in New York; it also provides a full continuum of other cardiac care services, including heart disease prevention, invasive and non-invasive diagnostic testing, arrhythmia control, heart transplants and a variety of rehabilitation programs. *(February 6, 2004, CON Application, page 8)*

4. TSH proposes to expand its current cardiovascular services to include primary angioplasty[2] for acute myocardial infarction ("PAMI") patients presenting with ST-segment elevation (STEMI) and left bundle branch blockage (LBBB). *(February 6, 2004, CON Application, page 7)*

5. The proposed program will augment existing inpatient and outpatient cardiac services including:
   - Cardiac Catheterization
   - Pacemaker Installation
   - Stress Testing
   - Nuclear Cardiac Imaging
   - Resting and Exercise Echocardiography
   - Cardioversions
   - 24-hour holter monitoring
   - 24-hour ambulatory blood pressure monitoring
   - Tilt table studies
   - Pacemaker evaluation and follow-up
   - AICD evaluation and follow-up
   - Cardiac Rehabilitation Program
   - Echocardiography
   - EKG
   - CT scan and MRI services.
   - TSH is also in the process of applying for a CON for the development of a full-service Electrophysiology (EPS) program (Docket Number 03-30159-CON) *(February 6, 2004, CON Application, page 11)*

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[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.

[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.

6. Physicians affiliated with the Columbia University College of Physicians and Surgeons at CPMC will participate on a joint committee which will provide advice regarding clinical and quality matters for the PAMI program. *(February 6, 2004, CON Application, page 8)*

7. NYPHS will support the establishment of the primary interventional cardiac service at TSH in a number of ways, including: providing or arranging consultative services with respect to the development of proposed care standards, risk stratification criteria, quality assurance programs and policies, procedures and protocols, consulting with respect to the collection and analysis of quality data, assisting in its development of physician credentialing criteria, and arranging training for nursing and technical staff who will be serving the primary interventional cardiac service. *(February 6, 2004, CON Application, page 8)*

8. The Applicants based the need for the proposed primary interventional cardiac service on the following:
   - Existing cardiac volume
   - Reduction in mortality and morbidity in service areas
   - Improved accessibility for patients
   - Reduction in need for ambulance transfers
   - Improved continuity of care

   (February 6, 2004 CON Application, page14)

9. TSH's proposed service areas ("PSA") for the proposed program consist of the following towns:

Table 1: Stamford Hospital's PSA

Towns	Primary	Secondary
	Stamford	Darien Greenwich New Canaan Norwalk Westport Wilton
Hospital's Market Share for All Inpatient Cardiac Catheterizations	63.4%	8.3%
Area's Share of Hospital's CT Inpatient Cardiac Catheterizations	79.0%	16.0%

***Source**: February 6, 2004 CON Application, page 16 & CT Office of Health Care Access Acute Care Hospital Inpatient Discharge Database*

10. The demographic characteristics of TSH's PSA are as follows:

Table 2: Demographic Characteristics of TSH PSA

	Population				
Service Area	**Total**	**Adults (15+)**	**15 – 44 (%)**	**45 – 64 (%)**	**65+ (%)**
Primary	117,083	94,819	45.5	21.7	13.8
Secondary	226,436	175,220	38.5	24.9	13.9
Total PSA	343,519	270,039	40.1	23.8	13.8
Connecticut	**3,405,565**	**2,696,490**	**42.2**	**23.2**	**13.8**

***Source**: Census 2000.*

11. TSH used Environmental Systems Research Institute ("ESRI") data to project that in the primary and secondary service areas the 45-64 age cohort would grow by 14.2% and 65 years and older would grow by 1.9% from 2003 to 2008. These projections could not be verified due to the claimed proprietary nature of the information. *(February 6, 2004 CON Application, page 16)*

12. The proposed service will be provided twenty-four hours per day, seven days per week. *(February 6, 2004, CON Application, page 9)*

13. The historical volume of diagnostic cardiac catheterizations is as follows:

Table 3: Stamford Hospital's Historical Diagnostic Cardiac Catheterization Volume (FYs 2000 – 2003)

CT Service Area	2000	2001	2002	2003
Inpatient	391	391	354	352
Outpatient	319	299	328	304*
Total	**710**	**690**	**682**	**656**

*FY2003 outpatient volume based on an average of the prior 3 years.
***Source**: CT Office of Health Care Access Acute Care Hospital Inpatient Discharge Database and self-reported outpatient figures.*

14. Catheterizations and pacemaker implants have been performed in TSH's diagnostic cardiac catheterization laboratory for more than 20 years. The cardiac catheterization laboratory is equipped with optimal imaging systems, resuscitative equipment and other interventional equipment. 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. *(February 6, 2004, CON Application, page 9)*

15. 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)*

16. The Atlantic Cardiovascular Patient Outcomes Research Team (C-PORT) Trial's Manual of Operations for the Primary Angioplasty Registry contains 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. 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)*

17. The Applicants stated that primary angioplasty would be performed at TSH 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 TSH Medical Staff Bylaws; and
    f. TSH nursing and technical staff involved in the PAMI Program will take part in a formal training program arranged through NYPHS.
    (February 6, 2004, CON Application, pages 35 & 36)

18. 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)*

19. 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")*

20. The average ischemic heart disease and Acute Myocardial Infarction (AMI) discharges and deaths in TSH's PSA for FYs 1999-2003 are as follows:

Table 4: Average Annual Ischemic Heart Disease and AMI Discharges and Deaths in PSA, (FYs 1999 – 2003[a])

	Discharged from CT Hospitals				Mortality	
	Ischemic Heart Disease[b]		AMI		Ischemic Heart Disease	
Service Area	Discharges	Adult Rate	Discharges	Adult Rate	Deaths	Adult Rate
Primary	743	7.8	254	2.7	135	1.4
Secondary	1,226	7.0	411	2.3	315	1.8
Total PSA	**1,969**	**7.3**	**665**	**2.5**	**450**	**1.7**
Connecticut	-	**8.2**	-	**3.2**	-	**1.9**

Source: *CT Office of Health Care Access Acute Care Hospital Inpatient Discharge Database,* CT *Department of Public Health Vital Records, and Census 2000 for population figures.*
[a]Discharges were from FYs 2000 through 1st two quarters of FY 2003; Deaths were from calendar years 1999 through 2001.
[b]Includes AMI discharges.
ICD-9 codes: Ischemic Heart Disease 410 – 414; AMI 410.
ICD-10 codes: Ischemic Heart Disease Mortality I20 – I25.

21. The average annual historical and projected PCI volumes for TSH service areas for FYs 2000-2007 are as follows:

Table 5: Average Annual Historical (FYs 2002 – 2003) and Projected (FY 2005 – 2007) PSA Primary PCI Volumes

	FYs 2000-2003		FY 2005		FY 2006		FY 2007	
Service Area	Average PAMIs	Adult Use Rate	Market Share (%)	Projected PAMIs	Market Share (%)	Projected PAMIs	Market Share (%)	Projected PAMIs
Total	89	.3	70%	62	80%	71	90%	80

Note: The market share for FY 2004 was used for FY 2005.
Source: *CT Office of Health Care Access Acute Care Hospital Inpatient Discharge Database, Census 2000 for population figures, and February 6, 2004 CON Application, page 32*

22. The average annual primary PCI and inpatient cardiac catheterization volumes in TSH's PSA by area provider for FYs 2000-2003 are as follows:

Table 6: Average Annual Primary PCI and Inpatient Diagnostic Cardiac Catheterization in PSA by Provider, (FYs 2000– 2003)

	Primary PCI*		Diagnostic Cardiac Catheterization	
Hospital	**Procedures**	**Market Share (%)**	**Procedures**	**Market Share (%)**
Bridgeport	38	42.7	107	9.1
Hartford	-	-	2	.1
John Dempsey	-	-	1	.2
Saint Francis	-	-	1	.1
Saint Raphael's	2	2.2	6	.5
Saint Vincent's	21	23.6	229	19.6
Yale	23	25.8	92	7.8
Danbury	-	-	2	.1
Greenwich	-	-	82	7.0
L & M	-	-	<1	.02
Norwalk	-	-	205	17.5
Stamford	-	-	344	29.4
Out of State	5	5.6	100	8.5
Totals	**89**	**100.0**	**1,171**	**100.0**

Source: *CT Office of Health Care Access Acute Care Hospital Inpatient Discharge Database*
**Primary PCI for FYs 2002 – 2003.*

23. 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)*

24. TSH stated that patients who require CABG or other cardiac surgery will be transferred on an urgent basis to Connecticut Hospitals that offer full-service cardiac programs. TSH has executed transfer agreements with Bridgeport Hospital and St. Vincent's Medical Center in Bridgeport and the Hospital of St. Raphael in New Haven. *(February 6, 2004 CON Application, page 39)*

25. The transportation of patients to TSH for PAMI services will be supported primarily by Stamford Emergency Medical Services ("SEMS"), which operates the ambulance service in the City of Stamford, as well as Darien EMS Post 53 in Darien. All ambulance units are equipped with 12-lead EKG (Lifepak) capabilities. *(February 6, 2004 CON Application, page 39)*

26. TSH will be responsible for the facilities, equipment and day-to-day operations of the PAMI program. The PAMI program will be operated under TSH's license and it will bill all facility/technical fees associated with the service. *(February 6, 2004 CON Application, page 40)*

27. TSH projects the following number of diagnostic cardiac catheterizations and primary angioplasties for its PSA for FYs 2004, 2005, 2006, and 2007: *(February 6, 2003 CON Application, page 36)*

Table 7: Projected Cardiac Volume

Service	FY 2004	FY 2005	FY 2006	FY 2007
Diagnostic Cardiac Catheterizations*	705	780	864	956
Primary Angioplasties	88	102	118	121

* Projections based on a 10.7% compounded annual growth rate over TSH's FY 2003 volume of 637 cases and are based on a study of coronary heart disease prevalence within TSH's PSA. *(February 6, 2004 CON Application, pages 24 & 29)*

28. TSH stated that four interventional cardiologists would provide the PAMI services. The physicians are Drs. Alcan, Charney, Messinger and Jumper.

Table 8: Proposed Program Interventionalists

Physician	Hospital Affiliation	Office	Av. Annual PCIs
Alcan	St. Vincent's Medical Center	Norwalk	340
Charney	NY Presbyterian & Greenwich	New Rochelle	152
Messinger	NY Presbyterian & Greenwich	New Rochelle	91
Jumper	Not Available		

Source: *February 6, 2004 CON Application, page 35 & CT Office of Health Care Access Acute Care Hospital Inpatient Discharge Database.*

29. To ensure seven days per week, 24 hours per day program availability, TSH has proposed the following operating schedule for each interventional cardiologist:

Table 9: Proposed Weekday Coverage Schedule for Each Interventional Cardiologist

9a.m-5p.m.	Monday	Tuesday	Wednesday	Thursday	Friday
Week 1	A	B	A	B	A
Week 2	B	A	B	A	B
Week 3	A	B	A	B	A
Week 4	B	A	B	A	B

Table 10: Proposed Nights, Weekends and Holidays Coverage Schedule for Each Interventional Cardiologist

5p.m.-9a.m.	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
Week 1	A	A	A	A	A	A	A
Week 2	B	B	B	B	B	B	B
Week 3	C	C	C	C	C	C	C
Week 4	D	D	D	D	D	D	D

(Responses to Completeness received on April 19, 2004, page 10)

30. Dr. Steven F. Horowitz, Chief of the Cardiology Department at The Stamford Hospital, testified at the Technical Hearing June 16, 2004 to the following regarding TSH's proposal:

- Nursing and technical staff from the TSH cardiac catheterization laboratory and other necessary departments will rotate through the NYPH or St. Vincent's catheterization laboratory for initial skills training and continuing education on caring for primary angioplasty patients.
- To provide 24-hours per day, 7-days per week service, TSH has entered into coverage arrangements with four experienced and highly-skilled cardiac interventionalists. Each physician exceeds the operator volume requirement of 75 interventions per year that is established by the ACC/AHA Guidelines.
- In FY 2003, the TSH ED transferred 28 patients directly to full-service facilities for primary angioplasty following assessment and treatment. In addition, the ED admitted approximately 200 other patients with a principal diagnosis of AMI. After reviewing the medical records of each patient, Dr. Horowitz determined that 67 of these patients would have been candidates for PAMI if this capability were available at TSH.

31 TSH provided transfer logs for the Access Ambulance Company detailing emergency cardiac transfers originating at the TSH and ending at receiving hospitals in Bridgeport. The log covering the last nine months of FY 2003 shows an average transport time of 1:12 while the calendar year 2003 data shows an average transport time of 1:15. *(June 23, 2004, Late file submission, page 1)*

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

32. The proposal has a total expenditure of $100,000 which is the cost of the medical equipment. *(February 6, 2004, CON Application, page 40)*

33. TSH reported a loss from operations of $(11,823,000) for FY 2003. However, TSH projects a gain from operations of $99,000, without the CON for FY 2004. The Hospital stated that the improvement in income from operations is due to the implementation of various revenue cycle initiatives, staffing changes and non-salary expense management programs. These factors include: managed care contractual allowance increases and other revenue increases that became effective October 1, 2003; increase in outpatient volumes, primarily in radiology and other imaging services; and significant cost savings realized by decreasing consulting and other professional fees. *(April 20, 2004, Responses to Completeness, page 11)*

34. TSH projects the implementation of the proposal will result in incremental gains in operations of $104,000, $ 353,000 and $397,000 for FYs 2004, 2005 and 2006, respectively. *(February 6, 2004, CON Application, page 577)*

35. The Stamford Health System's unaudited income statement reports a gain from operations of $3,420,000 for the first 8 months of FY 2004. *(June 24, 2004, TSH Late File, Exhibit C)*

36. The proposal will be financed from TSH's equity through operations. *(February 6, 2004 CON Application, page 577)*

37. TSH does not anticipating hiring any additional FTEs as a result of this CON. *(February 6, 2004, CON Application, page 44)*

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.:

38. There is no State Health Plan in existence at this time. *(February 6, 2004 CON Application, page 13)*

39. TSH has adduced evidence that this proposal is consistent with THS' long-range plan. *(February 6, 2004 CON Application, page 13)*

40. TSH has improved productivity and contained costs by participating in group purchasing, energy conservation, reengineering and applications of technology. *(February 6, 2004 CON Application, page 38)*

41. TSH's proposal will impact TSH's teaching and research responsibilities. TSH would like to participate in future C-PORT studies concerning the provision of elective angioplasty in hospitals without cardiac surgery back-up. *(February 6, 2004 CON Application, page 39)*

42. TSH states that there are distinguishing characteristics of TSH's patient/physician mix including the older demographic make-up of the service area, ethnically diverse patient population, and medically underserved population of indigent and uninsured patients that rely heavily on TSH's ED. *(February 6, 2004 CON Application, pages 26, 33 and 39)*

43. The Applicants have sufficient technical, financial and managerial competence to provide efficient and adequate service to the public. *(February 6, 2004 CON Application, page 37 and Exhibit 16)*

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, OHCA determined that the Connecticut-based PAMI volume that is already present in The Stamford Hospital's ("TSH") emergency department is a significant factor in determining need, as well as the older demographic make-up of the service area, ethnically diverse patient population, and medically underserved population of indigent and uninsured patients that rely heavily on TSH's ED.

TSH and New York Presbyterian Healthcare System, Inc. ("Applicants") propose to expand the cardiovascular services at TSH to include primary angioplasty for acute myocardial infarction patients presenting with ST-segment elevation ("STEMI") or left bundle branch blockage ("LBBB"). The Applicants based the need for the proposed primary interventional cardiac service on existing cardiac volume, reduction in mortality and morbidity in the service area, improved accessibility for patients, elimination of need for ambulance transfers and improved continuity of care. 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 ACC/AHA criteria and standards and C-Port guidelines, as specified in Attachment I. TSH is geographically positioned to address the needs of the residents in the service areas. The service area for the proposed program includes Stamford, Darien, Greenwich, New Canaan, Norwalk, Westport and Wilton.

In Connecticut from FYs 2000 through 2003, patients 65 years and older received 55% of all inpatient diagnostic cardiac catheterizations and angioplasty procedures. According to the U.S. Census data, the service area population aged 45-64 is older than the Connecticut average.

Current medical literature supports primary angioplasty in community hospitals without on-site cardiac surgery for patients presenting with ST-segment elevation or left bundle branch blockage (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. 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 TSH's cardiac services. 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 TSH 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. Skilled and experienced allied health staff capable of assisting with angioplasty and caring for patients after the procedure will operate the program. The interventional cardiologists are experienced and skilled and exceed appropriate procedural volumes by performing interventional procedures at a tertiary care facility.

TSH and NYPHS have submitted a draft Memorandum of Agreement for the implementation of this program. Under the terms of the agreement, NYPHS will support the establishment of the primary interventional cardiac services at TSH in a number of ways including: providing or arranging consultative services with respect to the development of proposed care standards, risk stratification criteria, quality assurance programs and policies, procedures and protocols, consulting with respect to the collection and analysis of quality data, assisting in its development of physician credentialing criteria, and arranging training for nursing and technical staff who will be serving the primary interventional cardiac service. Physicians participating in the program will be experienced interventional cardiologists who meet or exceed the minimum volume standards put forth in the American College of Cardiology/American Heart Association (ACC/AHA) guidelines. Additionally, TSH will meet the institutional volume standards. TSH is responsible for the day-to-day clinical and operational aspects of the program including oversight of staff and physical plan. Tertiary back-up services will be provided by Bridgeport Hospital, St. Vincent's Medical Center and The Hospital of Saint Raphael.

TSH performed 710, 690, 682 and 656 diagnostic cardiac catheterization studies in FYs 2000, 2001, 2002, and 2003, respectively. Based on historical volumes and service area market share rates, OHCA estimates that TSH could potentially perform 62, 71 and 80 PAMIs for FYs 2005, 2006 and 2007, respectively. In FY 2003 TSH's ED transferred 28 patients directly to full-service facilities for primary angioplasty following assessment and treatment. In addition, approximately 200 additional patients were admitted from the ED with a principal diagnosis of acute myocardial infarction. After reviewing the medical records of each of these patients, Dr. Horowitz determined that 67 of these patients would have been candidates for PAMI had it been available at TSH. Based on historical service area volumes and the projected capture rates, the proposed program would meet or exceed the minimum volume standards as stated in the ACC/AHA Guidelines.

Finally, the CON proposal is financially feasible. The proposal has a total expenditure of $100,000. The proposal will be financed from TSH's equity through operations. TSH projects incremental gains from operations of $104,000 in FY 2004, $353,000 in FY

2005 and $353,000 in FY 2006 as a result of the implementation of the proposal. Although TSH reported a loss from operations of $(11,823,000) for FY 2003, TSH has initiated a number of incentives to remedy this situation and projects a gain from operations of $99,000 in FY 2004. The Hospital stated that the improvement in its financial situation is due to the implementation of various revenue cycle initiatives, staffing changes and non-salary expense management programs. Major factors included managed care contractual allowances increases and other revenue increases, increase in outpatient volumes, primarily in radiology and other imaging services and significant cost savings realized by decreasing consulting and other professional fees. The effectiveness of this financial strategy was buttressed by the eight month unaudited internal financial reports of Stamford Health System for FY 2004, which indicated a gain from operations of $3,420,000. 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. TSH currently operates a high volume diagnostic cardiac catheterization program. The Hospital also experiences a large number of ED visits by AMI patients on an annual basis. Additionally, the interventional cardiologists who will be performing the PAMI procedures are experienced, high volume operators. Therefore, the TSH program will be able to achieve PAMI volumes in excess of those stated in the ACC/AHA Guidelines. Second, TSH's strong collaborative relationship with the NYPHS will enhance the accessibility of high quality, community-based medical services offered by TSH. TSH will utilize the resources of NYPHS to further enhance provision of quality care including access to the expertise, information, and consultative support of a nationally recognized academic healthcare center renowned for the diagnosis and treatment of cardiac disease. Finally, implementation of TSH's proposal will bring appropriate access to high quality cardiac services to the residents of the service area within a reasonable travel time. In summary, the proposal will result in enhanced cardiac services in the Stamford region.

Order

NOW, THEREFORE, the Office of Health Care Access ("OHCA") and The Stamford Hospital and New York Presbyterian Healthcare System, Inc. ("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 Stamford Hospital at a total capital expenditure of $100,000, as follows:

1. The Applicants' request for a CON to establish a primary interventional cardiac service to be located at Stamford Hospital at a total capital expenditure of $100,000 is hereby approved.

2. Stamford Hospital 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 Stamford Hospital in writing of its evaluation. If OHCA finds questionable material, Stamford Hospital 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 Stamford Hospital 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, Stamford Hospital shall file a CON for the reinstitution of the program.

3. If Stamford Hospital 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), Stamford Hospital 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, Stamford Hospital shall file a CON for the reinstitution of the program.

4. Stamford Hospital 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. Stamford Hospital shall provide OHCA quarterly data reports through such registry for the purposes of monitoring and quality assurance. If Stamford Hospital determines not to participate in the C-PORT registry or the C-PORT registry no longer exists, Stamford Hospital shall notify OHCA immediately, and continue to comply with the C-PORT guidelines and protocols.

5. Stamford Hospital shall participate in the ACC National Cardiovascular Database Registry (ACC-NCDR) and report all data including the optional follow-up section. Stamford Hospital 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. Stamford Hospital 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 Stamford Hospital determines not to participate in the ACC-NCDR, Stamford Hospital shall notify OHCA immediately, and continue to comply with the ACC/AHA criteria and standards.

6. Stamford Hospital 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, the Stamford Hospital primary PCI program shall be terminated. In the event of such a termination, Stamford Hospital shall file a CON for the reinstitution of the program.

7. Stamford Hospital shall provide OHCA with a copy of a dated and signed Program Agreement with the System prior to commencement of the authorized PAMI service.

8. Stamford Hospital shall provide a copy of the Curriculum Vitae of Dr. Rob Jumper prior to commencement of the authorized PAMI service and documentation that Dr. Jumper meets the operator criteria specified in Attachment I.

9. OHCA and Stamford Hospital and New York Presbyterian Healthcare System, Inc. agree that this Agreed Settlement represents a final agreement between OHCA and Stamford Hospital and New York Presbyterian Healthcare System, Inc. 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 03-30176-CON.

10. This authorization shall expire on August 23, 2005. 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 Stamford Hospital's expense, if the Applicants fail to comply with its terms.

8/23/04
Date

Duly Authorized Agent for
The Stamford Hospital

8/23/04.
Date

Duly Authorized Agent for
New York Presbyterian Healthcare System, Inc.

The above Agreed Settlement is hereby accepted and so ordered by the Office of Health Care Access on August 23, 2004.

August 25, 2004
Date

Cristine A. Vogel
Commissioner
Office of Health Care Access

CAV:km

Criteria for the performance of Primary Angioplasty at Stamford Hospital without on-site cardiac surgery:

1. The operators must be experienced interventionalists who regularly perform elective intervention at a surgical center (≥75 cases/year). The institution must perform a minimum of 36 primary PCI procedures per year.
2. The nursing and technical catheterization laboratory staff must be experienced in handling acutely ill patients and comfortable with interventional equipment. They must have acquired experience in dedicated interventional laboratories at a surgical center. They participate in a 24-h, 365-day call schedule.
3. The catheterization laboratory itself must be well-equipped, with optimal imaging systems, resuscitative equipment, IABP support, and must be well-stocked with a broad array of interventional equipment.
4. The cardiac care unit nurses must be adept in hemodynamic monitoring and IABP management.
5. The hospital administration must fully support the program and enable the fulfillment of the above institutional requirements.
6. There must be formalized written protocols in place for immediate (within 1 h) and efficient transfer of patients to the nearest cardiac surgical facility which are reviewed/tested on a regular (quarterly) basis.
7. Primary intervention must be performed routinely as the treatment of choice around the clock for a large proportion of patients with AMI, to ensure streamlined care paths and increased case volumes.
8. Case selection for the performance of primary angioplasty must be rigorous. Criteria for the types of lesions appropriate for primary angioplasty and for the selection for transfer for emergent aortocoronary bypass surgery are shown in the next table.
9. There must be an ongoing program of outcomes analysis and formalized periodic case review.
10. Institution should participate in a 3- to 6-month-period of implementation during which time development of a formalized primary PCI program is instituted that includes establishing standards, training≥ staff, detailed logistic development, and creation of a quality assessment and error management system.

Patient selection for Angioplasty and emergency aortocoronary bypass at hospitals without on-site cardiac surgery.

Avoid intervention in hemodynamically stable patients with:

- Significant (≥60%) stenosis of an unprotected left main (LM) coronary artery upstream from an acute occlusion in the left coronary system that might be disrupted by the angioplasty catheter
- Extremely long or angulated infarct-related lesions with TIMI grade 3 flow

- Infarct-related lesions with TIMI grade 3 flow in stable patients with 3-vessels disease (257,266)
- Infarct-related lesions of small or secondary vessels
- Lesions in other than the infarct artery

Transfer for emergent aortocoronary bypass surgery patients with:

- High-grade residual left main or multivessel coronary disease and clinical or hemodynamic instability
  -After angioplasty or occluded vessels
  -Preferably with intraaortic balloon pump support

Patient eligibility and identification

Inclusion Criteria

- Age ›18 years
- Ability to give informed consent
- Acute myocardial infarction with
  1. › 30 mins ongoing ischemic cardiac pain at presentation and
  2. › 0.1 mv ST-segment elevation in 2 or more contiguous ECG leads or new or suspected new LBBB
  3. › 0.1 mv ST-segment depression in V1 and V2 consistent with true posterior infarction

Exclusion Criteria

- Inability to give informed consent
- Treatment with metformin (Glucophage) and known renal failure or creatinine ›1.5 mg/dl for males or ›1.4 mg/dl for females

Patient Identification

Responsibility for identification of patients that may be candidates for the C-PORT trial rests primarily with emergency room staff, both physicians and nurses, although this may vary from institution to institution. Once a patient is identified (meets all inclusion criteria and has no exclusion criteria) that patient is entered into a log to be kept by emergency room staff in a designated area within the emergency room facility. The log will contain the identified patient's name, gender, race, date of birth, hospital number and the date of admission, whether that patient was approached for C-PORT trial and if not, why; and, if approached regarding C-PORT participation, whether the patient was enrolled in C-PORT or not, and if not, why, and condition of discharge (dead or alive).

Connecticut Cardiac Data Registry: Data Elements and Coding Instructions

General: For each patient encounter in the cardiac catheterization laboratory and each open heart surgical encounter, please provide all of the following applicable information. All data elements relating to a single patient encounter should be recorded in a single row. All data elements must be reported in the order listed below according to the specified length, start, and end positions. If reported in excel, each data element must be reported in a single column according to the specified order and length.

Data Element Number	Data Element	Length	Start	End	Data Label	Coding Instructions
	1. Patient Information					
1	Hospital Number	1	1	2	Hosp#	Enter the Hospital Number as shown in Attachment A. *This will be referred to as the* **"Reporting Hospital."**
2	Medical Record Number	20	3	22	MRN	Enter the patient's medical record number. Add leading zeros as necessary to fill all 20 spaces.
3	Admission Date	8	23	30	Admit	Enter the date that the current hospital stay began. Date format: mmddyyyy
4	Admission Source	1	31	31	Asource	Code "1" for MD referral, "2" for Clinic referral, "3" for Transfer from other hospital, "4: for transfer from Skilled Nursing Facility, "5" for transfer from other healthcare facility, "6" for Emergency Department, "7" for transfer from legal or court institution, "8" for HMO referral.
5	Transferring Hospital	2	32	33	Trans_hosp	For Transfers from other hospitals (Asource - Option 3), fill in the Hospital Number (Attachment A) for the transferring facility.
6	Date of Birth	8	34	41	DOB	Enter the patient's date of birth. Date format: mmddyyyy
7	Gender	1	42	42	Gender	Code "1" for male and "2" for female.
8	Ethnicity	1	43	43	Ethnic	Code "1" for hispanic and "2" for non-hispanic. Hispanic includes people of Mexican, Puerto Rican, Cuban, Central and South American, Spanish, or some other Hispanic descent.
9	Race	1	44	44	Race	Code "1" for white,"2" for black and "3" Asian/Pacific Islander, "4" for Native American, "5" for two or more races, and "6" for other. "White" refers to people having their origins in Europe, the Middle East, or North Africa. "Black" refers to people having their origins in any of the Black racial groups of Africa. "Asian/Pacific Islander" refers to people having their origins in the Far East, Southeast Asia, or the Indian Subcontinent including Asian Indian, Chinese, Filipino, Japanese, Korean, Vietnamese, other Asian racial group, native Hawiians and other Pacific islanders. "Native American" refers to American Indians and Alaska Natives, Native Hawaiians and Pacific Islanders, and any other non-White, non-Black racial group, or non-Asian group. "Two or more races" refers to those with more than one racial identity. "Other" refers to those not classified by the other racial definitions.
10	Patient Town	3	45	47	Reside	Enter the town code of the patient's usual address as shown in Attachment B. There are codes for Massachusetts, New York, Rhode Island, other state, and other country residents.
	2. Diagnosis and Catheterization Information					
11	Referring Cardiologist	7	48	54	Card_ref	Enter the CT License Number for the cardiologist that referred the patient for invasive cardiac services.
12	Primary Diagnosis	5	55	59	PDX	Enter primary diagnosis using valid ICD-9-CM code. Primary diagnosis describing the condition established after study to be chiefly responsible for occassioning the admission of the patient for care. Include up to 5 digits, exclude the decimal point. If diagnosis fewer than 5 digits, zero fill at end.
13	Hospital performed Diagnostic Catheterization	2	60	61	CC_hosp	If a diagnostic catheterization was performed, *code the hospital* that did it using Hospital Number in ***Attachment A***. If no catheterization was performed, code "00".
14	Catheterization Status	1	62	62	CC_type	Code "1" if catheterization was performed at reporting hospital on an inpatient basis, "2" if it was performed at reporting hospital on an outpatient basis, and "3" if it was performed at another hospital prior to the patient's admission at reporting facility, and "0" if no catheterization was performed.
15	Catheterization Code	4	63	66	CC_code	If catheterization performed at reporting hospital, code ICD-9-CM procedure code.

Data Element Number	Data Element	Length	Start	End	Data Label	Coding Instructions
16	Primary Physician performing Diagnostic Catheterization	7	67	73	CC_md	If catheterization performed at reporting hospital, enter the CT License Number for the primary physician performing the diagnostic catheterization. If catheterization performed at another hospital, enter "9999999".
17	Thrombolytic Therapy within 7 days	1	74	74	Thromb	Code "1" if patient received thrombolytic therapy such as streptokinase, urokinase, or thromboplastin activator (TPA) for the purpose of dissolving a coronary thrombosis within 7 days prior to PCI. Code "0" if no thrombolytics were administered within 7 days of the PCI.
	3. PCI Specific Information (Only complete if performed at reporting hospital)					
18	Primary Physician Performing PCI	7	75	81	PCI_md	Enter the CT Physician Identifier of the primary physician who performed the PCI.
19	PCI Date	8	82	89	PCI_date	Enter the date on which PCI was performed. Date format: mmddyyyy
20	Primary Procedure, PCI	4	90	93	PCI_px1	Enter the ICD-9-CM code for the primary PCI procedure. Include up to 4 digits, exclude decimal point.
21	Secondary Procedure, PCI	4	94	97	PCI_px2	Enter the ICD-9-CM code for the secondary PCI procedure. Include up to 4 digits, exclude decimal point.
22	Other PCI This Admission	1	98	98	PCI_oth	Code "1" if patient had an additional PCI during this admission, "0" if not. Note: A complete record in the CT Cardiac Data Registry should be filed for each distinct PCI.
23	Date of Other PCI	8	99	106	PCI_odat	Enter date of other PCI. Date format: mmddyyyy
24	Number of lesions attempted	1	107	107	Lsn_att	Record number of lesions where an attempt was made to pass a guidewire, whether successful or not.
25	Number of lesions successfully dilated	1	108	108	Lsn_dlt	Indicate the number of lesions where the residual post intervention stenosis of the arterial luminal diameter, TIMI Flow is 3 and the minimal decrease in stenosis was 20%.
26	Number of stents places	1	109	109	stents	Number of stents placed.
27	Time in Emergency Department	12	110	121	ED_time	Time patient entered emergency deparment. Form hh\mm\dd\mm\yyyy
28	Time of Balloon Inflation	12	122	133	inf_time	Time of first balloon inflation. Form: hh\mm\dd\mm\yyyy
	4. Open Heart Surgery Specific Information (Only complete if performed at reporting hospital)					
29	Primary Physician Performing Surgery	7	134	140	Surg_phys	Enter the CT License Number of the primary physician who performed the surgery.
30	Surgery Date	8	141	148	Surg_dat	Enter the date on which surgery was performed. Date format: mmddyyyy
31	Primary Procedure, Surgery	4	149	152	Surg_px1	Enter the ICD-9-CM code for the primary surgery procedure. Include up to 4 digits, exclude decimal point.
32	Second Surgical Procedure	4	153	156	Surg_px2	Enter the ICD-9-CM code for the second surgical procedure. List secondary procedures in descending Relative Value Unit (RVU) order. Include up to 4 digits, exclude decimal point.
33	Third Surgical Procedure	4	157	160	Surg_px3	Enter the ICD-9-CM code for the third surgical procedure. List secondary procedures in descending Relative Value Unit (RVU) order. Include up to 4 digits, exclude decimal point.
34	Fourth Surgical Procedure	4	161	164	Surg_px4	Enter the ICD-9-CM code for the fourth surgical procedure. List secondary procedures in descending Relative Value Unit (RVU) order. Include up to 4 digits, exclude decimal point.

Data Element Number	Data Element	Length	Start	End	Data Label	Coding Instructions
	5. Risk Factors					
35	Acuity	1	165	165	Priority	Code based upon the following criteria: Code "1", **Elective**: All cases not classified as urgent or emergency as defined below - Code "2". **Urgent**: The patient was too ill or unstable to be discharged from the hospital, but was not classified as emergency as defined below - Code "3". **Emergency**: Patient required emergency procedures due to ongoing, refractory, unrelenting cardiac compromise, with or without hemodynamic instability Typical patient includes those in arrest with CPR administered immediately prior to the procedure, shock, ongoing ischemia including rest angina, acute evolving MI within 24 hours of procedure, and/or pulmonary edema requiring intubation.
36	Height	2	166	167	Height	Enter the patient's height in inches.
37	Weight	3	168	170	Weight	Enter the patient's weight in pounds.
38	ST-Segment Elevation AMI	1	171	171	ST_elev	Code "1" if AMI and ST-segment elevation (New or presumed new ST segment elevation at the J point in two or more contiguous leads with cut-off points ≥0.2mV in leads V1, V2, or V3, or ≥0.1 in other leads; or development of any Q wave in leads V1 through V3, or the development of a Q-wave ≥ to 30 ms (0.03s) in leads I, II, aVL, aVF, V4, V5, or V6 - Q wave changes must be present in any two contiguous leads, and be ≥ to 1 mm in depth). Code "0" if neither AMI or ST-segment elevation AMI.
39	Previous Myocardial Infarction	1	172	172	MI_prior	Code "1" to indicate patient had MI less than 6 hours prior to interventional procedure, code "2" if MI occurred between 6 and 23 hours prior to interventional procedure, code "3" if MI 24 or more hours prior to interventional procedure, or code "0" if no MI.
40	Smoker	1	173	173	Smoker	Code "1" to indicate patient history confirms any form of tobacco use (cigarettes, cigars, chew, etc) in the past , code "0" if not.
41	Diabetes	1	174	174	Diabetes	Code "1" to indicate history of diabetes, regardless of duration of disease or need for anti-diabetic agents, code "0" if not.
42	Hypercholesterolemia	1	175	175	Cholest	Code "1" to indicate patient has a history of hypercholesterolemia diagnosed or treated by a physician, code "0" if not. Please use the following criteria to determine hypercholesterolemia: 1. Total Cholesterol > 200 2. LDL >= 130 3. HDL < 30 4. Admission cholesterol > 200 mg/dl
43	Renal Failure	1	176	176	Renal1	Code "1" to indicate documented history of renal failure, code "0" if not. Code "1" if Creatinine > 2.0. Prior renal transplant patients are not included as pre-op renal failure unless since transplantation their creatinine has been or currently is > 2.0.
44	Hypertension	1	177	177	Hyperten	Code "1" to indicate documented history of hypertension, code "0" if not. Please code "1" if any of the following criteria: 1. Documented history of hypertension diagnosed and treated with medication, diet, and/or exercise. 2. Blood pressure > 140 systolic or > 90 diastolic on at least 2 occasions. 3. Currently on antihypertensive medication.
45	Arrhythmia	1	178	178	arrythma	Code "1" if any of the following arrythmias, code "0" if not: Atrial fibrillation/flutter requiring medication. Atrioventricular block. Ventricular tachycardia, or ventricular fibrillation, requiring cardioversion and or medication.
46	Chronic Lung Disease	1	179	179	CLD	Code "1" to indicate patient has a documented history of chronic lung disease (i.e., chronic obstructive pulmonary disease, asthma, bronchitis) or has recently been treated with pharmacologic therapy, code "0" if not.
47	Peripheral Vascular Disease	1	180	180	PVD	Code "1" to indicate claudication either with exertion or rest; amputation for arterial insufficiency; vascular reconstruction; peripheral vascular bypass surgery or percutaneous intervention to the extremities, aortic aneurysm, positive invasive/non-invasive testing, code "0" if not.
48	Cerebrovascular Disease	1	181	181	CVD	Code "1" to indicate cerebrovascular disease, "0" if not. Please code "1: if any of the following: Unresponsive coma >= 24 hours; Cerebrovascular Accident (symptoms > 24 hours after onset); TIA (recovery within 24 hours); Non-invasive carotid test with > 75% occlusion; RIND (recovery within 72 hours); non-invasive/invasive carotid test with greater than 75% occlusion.

Data Element Number	Data Element	Length	Start	End	Data Label	Coding Instructions
49	Valvular Heart Disease	1	182	182	Valve	Code "1" if patient has history or evidence of valvular heart disease (ICD-9-CM codes 394.00 - 397.99).
50	Congestive Heart Failure	1	183	183	CHF	Code "1" to indicate that within 6 months prior to the procedure, a physician has diagnosed CHF by one of the following, code "0" if not. Criteria: 1. Paroxysmal nocturnal dyspnea (PND). 2. Dyspnea on exertion (DOE) due to heart failure. 3. Chest X-Ray showing pulmonary congestion. Pedal edema or dyspnea alone are NOT diagnostic. Patient should also have received diuretics, digoxin, or vascular therapy such as ace inhibitors. If there is documentation to support coding both "Congestive Heart Failure, Current" and "Congestive Heart Failure, Past" - then CODE BOTH risk factors.
51	Previous Open Heart Surgery	1	184	184	Priorsurg	Code if patient had open heart surgery prior to the current hospitalization. Do not count any operations during this hospital stay, code "0" if not. Range for ICD-9-CM codes: 35.10 - 35.28 & 36.11 - 36.19.
52	Previous PCI, prior admission	1	185	185	Priopci	Code "1" if patient had PCI prior to current hospitalization, code "0" if not. Do not count PCI during this hospital stay. (ICD-9-CM Codes: 36.01 - 36.02 & 36.05 - 36.06).
53	Previous PCI, this admission	1	186	186	Priorpci2	Code if patient had PCI during current hospitalization, code "0" if not. Do not count PCI during prior hospital stays. (ICD-9-CM Codes: 36.01 - 36.02 & 36.05 - 36.06).
54	Left Main Coronary Artery stenosis	1	187	187	LMT_sten	Code "1" if <50%, code "2" if ≥50% & <70%, code "3" if ≥70% & <90%, code "4" if stensosis is >90% or greater.
55	Left Anterior Descending Coronary Artery stenosis	1	188	188	LAD_sten	Code "1" if <50%, code "2" if ≥50% & <70%, code "3" if stensosis 70% or greater.
56	Circumflex Coronary Artery stenosis	1	189	189	Crfx_stn	Code "1" if <50%, code "2" if ≥50% & <70%, code "3" if stensosis 70% or greater.
57	Right Coronary Artery stenosis	1	190	190	Right_stn	Code "1" if <50%, code "2" if ≥50% & <70%, code "3" if stensosis 70% or greater.

Data Element Number	Data Element	Length	Start	End	Data Label	Coding Instructions
	6. Major Events Following Intervention					
	Please Note: A pre-intervention risk factor that persists post-intervention with *NO* increase in severity is not a major event.					
	Unless otherwise specified, major events are **ONLY** reported if they occurred during or after the intervention, but before hospital discharge.					
	6A. Major Events Following PCI (Complete only if PCI performed at reporting hospital)					
58	Stroke	1	191	191	Strk_pci	Code "1" to indicate permanent new focal neurological deficit occurring either during or following PCI, code "0" if not. Exacerbation of a previous CVA with No New Neurological Deficit would NOT be coded. Transient neurological deficits, such as TIA, are NOT reported as a post-op event.
59	Renal Failure	1	192	192	Ren_pci	Code "1" to indicate if creatinine greater than 2.5 mg/dl for more than 7 post-operative days **or** there is a need for temporary or permanent renal dialysis of any type, code "0" if not. ***Do not code this item if Renal Failure was selected as a risk factor.***
60	Acute Occlusion at Site of Intervention	1	193	193	Occlude	Code "1" to indicate acute occlusion, complete or partial, resulting in reduction of flow through the dilated artery, code "0" if not. Usually caused by thrombosis, intimal flap, or dissection. An occlusion which is reopened before the patient leaves the catheterization laboratory and stays open should NOT be reported. An occlusion requiring the patient's return to the catheterization laboratory SHOULD be reported even if vessel is then reopened. If the occlusion is caused by a stent thrombosis, ONLY code the stent thrombosis. Include any occlusion of the targeted or treated vessel, in any location within the vessel or within its significant proximal or distal branches (including the left artery).
61	A/V Injury at Cath Entry Site, requiring intervention	1	194	194	AV_inj	Code "1" to indicate Arterial or Venous injury including, code "0" if not. Please code "1" if any of the following criteria: Those requiring femoral or brachial embolectomy. Evacuation of a hematoma. Repair of false aneurysm, (example: ultrasound guided compressions). Closure of arterial-venous fistula.
62	Emergency Bypass Surgery	1	195	195	Bypass	Code "1" to indicate patient was taken to the operating room due to complications of PCI, code "0" if not.
63	Stent Thrombosis	1	196	196	St_thrm	Code "1" to indicate formation of a blood clot in the stented segment of the artery and/or adjacent area. This usually results in an acute occlusion, chest pain, or development of an acute MI, code "0" if not. Stent thrombosis usually occurs within 30 days following the procedure. **NOTE**: Stent Thrombosis should be reported as a major event even if it does not become apparent until after the patient is discharged from the hospital. It should be reported if apparent up to 6 months post intervention. An occlusion alone or plaque build-up SHOULD NOT be coded. The thrombus needs to be in or around the area that is stented for the major event to be coded.
	6B. Major Events Following Open Heart Surgery					
	Please Note: A pre-intervention risk factor that persists post-intervention with *NO* increase in severity is not a major event.					
	Unless otherwise specified, major events are **ONLY** reported if they occurred during or after the intervention, but before hospital discharge.					
64	Stroke	1	197	197	Strk_sur	Code "1" to indicate permanent new focal neurological deficit occurring either during or following PCI, code "0" if not. Exacerbation of a previous CVA with No New Neurological Deficit would NOT be coded. Transient neurological deficits, such as TIA, are NOT reported as a post-op event.
65	Renal Failure	1	198	198	Ren_surg	Code "1" to indicate if creatinine greater than 2.5 mg/dl for more than 7 post-operative days **or** there is a need for temporary or permanent renal dialysis of any type, code "0" if not. ***Do not code this item if Renal Failure was selected as a risk factor.***
66	Transmural MI (new Q waves)	1	199	199	Trans_MI	Code "1" to indicate if new Q waves and a rise in CK-MB iso-enzyme to a level indicating myocardial infarction, occurring within 48 hours after surgery, code "0" if not.

Data Element Number	Data Element	Length	Start	End	Data Label	Coding Instructions
67	Deep Sternal Wound Infection	1	200	200	Sternal	Code "1" to indicate drainage of purulent material from the sternotomy wound and instability of the sternum, code "0" if not. **DO NOT** code based solely on the following: Debridement secondary to necrosis, with negative (-) infection Or Positive (+) drainage, negative (-) cellulites, sternum was showing NO instability.
68	Bleeding Requiring Reoperation	1	201	201	Bleeding	Code "1" to indicate unplanned return to the operating room within 36 hours post-op for reoperation to control bleeding or evacuate large hematomas in the thorax or pericardium, code "0" if not. The following scenario WOULD NOT be coded because the chest was left open intentionally and therefore does not qualify as a major event: CABG on Day One - chest left open with Evacuate clots on Day Two and back to operating room to close chest on Day Three
69	Sepsis or Endocarditis	1	202	202	Sep_end	Code "1" if either of the following, code "0" if not. **Sepsis**: Fever and positive blood cultures related to the procedure. **Endocarditis**: Two or more positive blood cultures without any obvious source, demonstrated valvular vegetation, or acute valvular dysfunction caused by infection.
70	G-I Bleeding, Perforation, or Infarction	1	203	203	GI_bleed	Code "1" to indicate any positive episode of vomiting blood, gross blood in the stool, perforation or necrosis of the stomach or intestine, code "0" if not. The episode MUST occur post-surgery, but before hospital discharge.
71	Respiratory Failure	1	204	204	Res_fail	Code "1: to indicate pulmonary insufficiency requiring intubation and ventilation for a period of 72 hours or more at any time during the post-operative stay, code "0" if not. For patients who are placed on and taken off ventilation several times, the total of these episodes should be 72 hours or more.
					7. Discharge Information	
72	Discharge Date	8	205	212	Ddat	Enter the date the patient was discharged from the hospital. If the patient died in the hospital, then the hospital discharge date is the date of death. Date format: mmddyyyy
73	Discharge Status	1	213	213	Dstat	Code "1" to home, "2" to hospice, "3" to acute care facility, "4" to skilled nursing facility, "5" to other health care facility, "6" other, "7" expired in hospital, "8" expired during transport to other facility. If the patient came from a prison or correctional facility and was discharged back to the same institution, then "Home" would be checked. If the patient was discharged to sub-acute rehab that is in a skilled nursing facility, then the discharge status would be "Skilled Nursing Home." If it is unknown where the sub-acute rehab facility is located, then the discharge status would be "Other."