



Office of Health Care Access Certificate of Need Application

Agreed Settlement

Applicants: Yale-New Haven Hospital, Bridgeport Hospital, and Greenwich Hospital, d/b/a Yale-New Haven Health Heart Institute

Docket Number: 03-30148-CON

Project Title: Establish Primary Interventional Cardiac Service at Greenwich Hospital in Greenwich

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

Filing Date: March 31, 2004

Hearing Dates: April 28, 2004
May 6, 2004

Presiding Officer: Cristine Vogel, Commissioner

Decision Date: July 8, 2004

Default Date: July 14, 2004 (with 15 day extension)

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Project Description: Yale-New Haven Hospital, Bridgeport Hospital, and Greenwich Hospital, d/b/a Yale-New Haven Health Heart Institute, (“Applicants”) propose to establish primary interventional cardiac service to be located at Greenwich Hospital, at a capital expenditure of \$5,000.

Nature of Proceedings: On March 31, 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 Greenwich Hospital. The proposal has a capital expenditure of \$5,000. The Applicants are health care facilities or institutions as defined by Section 19a-630 of the Connecticut General Statutes (“C.G.S.”).

Public hearings regarding the CON Application were held on April 28, 2004 and May 6, 2004. The Applicants were notified of the date, time, and place of the hearings and notices to the public were published prior to the hearings in the *Greenwich Times* (Greenwich). Commissioner Cristine Vogel served as presiding officer in this matter. The hearings were conducted as a contested case in accordance with the provisions of the Uniform Administrative Procedure Act (Chapter 54 of the Connecticut General Statutes) and Sections 19a-638 and 19a-639, C.G.S.

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

Findings of Fact

Clear Public Need

Impact on the Applicants’ Current Utilization Statistics

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

1. Yale-New Haven Health System (“System”) and Yale-New Haven Health Heart Institute (“YNHHHI”) consist of Yale-New Haven Hospital (“YNHH”), Bridgeport Hospital (“BH”), and Greenwich Hospital (“GH”). (*December 12, 2003 CON Application, page 1*)
2. GH is a not-for-profit 178-bed acute care hospital located in Greenwich, Connecticut. (*July 23, 2003 Letter of Intent, page 2*)
3. BH is a not-for-profit 425-bed acute care hospital located in Bridgeport, Connecticut. (*July 23, 2003 Letter of Intent, page 2*)
4. YNHH is a not-for-profit 944-bed acute care hospital located in New Haven, Connecticut. (*July 23, 2003 Letter of Intent, page 2*)

5. The Applicants propose to expand primary interventional cardiovascular services to certain community hospitals, for patients presenting with ST-segment elevation and left bundle branch blockage (LBBB) myocardial infarction. (*December 12, 2003 CON Application, page 10*)
6. The Applicants seek to initiate this type of network by establishing a primary interventional cardiovascular service at GH in Greenwich, Connecticut. Once the program has been established at GH, the Applicants will seek to expand the network to other appropriate community hospitals. (*December 12, 2003, CON Application, page 8*)
7. GH's Connecticut service area for the proposed program consist of the following towns:

Table 1: Greenwich Hospital's Proposed CT Service Area

Patient Town

Darien
Greenwich
New Canaan
Norwalk
Stamford

(*December 12, 2003 CON Application, pages 18*)

8. GH also includes towns in Westchester County, New York in its service area. However, Sections 19a-634 and 19a-637 of the Connecticut General Statutes specifically mandate that OHCA consider the availability, scope and need for services for the residents of Connecticut. Therefore, OHCA does not consider out-of-state volume in its evaluation of need for the proposed service.
9. The demographic characteristics of GH's Connecticut service areas are as follows:

Table 2: Demographic Characteristics

	Population				
	Total	Adults (15+)	15 – 44 (%)	45 – 64 (%)	65+ (%)
CT Service Area	300,137	237,694	42.1	23.2	13.8
Connecticut	3,405,565	2,696,490	42.2	23.2	13.8

Source: Census 2000.

10. The proposed service will be provided twenty-four hours per day, seven days per week. (*December 12, 2003 CON Application, page 24*)
11. GH has operated a diagnostic cardiac catheterization laboratory for sixteen years. (*December 12, 2003, CON Application, page 8*)

12. The following is an historical account of diagnostic cardiac catheterization services at Greenwich:

- In 1984 Greenwich applied to the Commission on Hospitals and Health Care (“CHHC”), OHCA’s predecessor agency, to reestablish its cardiac catheterization service (it discontinued the service due to physician recruitment issues in 1977) and was denied.
- In 1986, CHHC again denied Greenwich reactivation of its catheterization service due to the concern over not meeting nationally recommended minimum volumes.
- In 1987, CHHC approved Greenwich’s request for reconsideration of the 1986 denial based on additional evidence to address the need for catheterization services in the area.
- In 1988, CHHC approved Greenwich to provide cardiac catheterization services in conjunction with an outpatient cardiac catheterization demo project. Two physicians would perform cardiac catheterization procedures at the hospital (Langou and Seidenstein)
- From 1993 to 1995, Greenwich was approved many time extensions of the date by which the Hospital must submit a CON for permanent diagnostic cardiac catheterization service. However Greenwich was ordered to comply with the protocol for the demo project, which required “A minimum laboratory caseload of 300 studies per year.”
- In 1995, CHHC approved Greenwich’s request to operate the cardiac catheterization service on a permanent basis. The Agreed Settlement ordered the compliance with appropriateness criteria, which included a minimum caseload of 300 per year, as stated in the 1991 ACC/AHA Task Force Guidelines for Cardiac Catheterization Laboratories. Also the Director of the Yale-New Haven cardiac catheterization laboratory and the Director of the Greenwich lab were to collaborate in performing utilization reviews.
(Docket Number 87-535R, 93-516R, 93-522R, 94-525R, 95-515Ra, 95-533, 97-528Ra, 99-558R)

13. The historical CT service area volume for GH is as follows:

Table 3: Average Annual Historical CT Service Area Primary PCI Volume (FY 2002 - 2003)

CT Service Area	2002	2003	Total	Average
Darien	2	2	4	2
Greenwich	14	19	33	16
New Canaan	1	6	7	4
Norwalk	24	9	33	17
Stamford	38	43	81	40
Totals	79	79	158	79

Source: OHCA Inpatient Discharge Database. Primary PCI is DRG 516.

14. The average annual ischemic heart disease and acute myocardial infarction discharges for FYs 1999 to 2003 and ischemic heart disease deaths and rates per 1,000 population in GH's Connecticut service area are shown below:

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

	Hospital CT Discharges				Mortality	
	Ischemic Heart Disease ^b		AMI		Ischemic Heart Disease	
	Discharges	Rate	Discharges	Rate	Deaths	Rate
CT Service Area	1,736	7.3	585	2.5	344	1.7
Connecticut	-	8.2	-	3.2	-	1.9

Source: OHCA Inpatient Discharge Database, CT Department of Public Health Vital Records, MA, NY and RI Hospital Databases, and Census 2000 for population figures.

^aDischarges were from FYs 2000 through 1st two quarters of FY 2003; Deaths were from calendar years 1999 through 2001.

^bIncludes AMI discharges.

ICD-9 codes: Ischemic Heart Disease 410 - 414; AMI 410.

ICD-10 codes: Ischemic Heart Disease Mortality I20 – I25.

15. The average annual inpatient cardiac catheterization angioplasty volume in GH's Connecticut service area for FYs 2000-2003 is as follows:

Table 5: Average Annual Volume of Inpatient Diagnostic Cardiac Catheterizations and Primary Angioplasties in Greenwich Hospital's CT Service Area by Provider, (FYs 2000 – 2003)

Hospital	Average Annual Inpatient Diagnostic Catheterizations			Average Annual Primary Angioplasties		
	Procedures	Market Share (%)	Area Volume as Share of Total Provider Volume (%)	Procedures	Market Share (%)	Area Volume as Share of Total Provider Volume (%)
Bridgeport	78	7.8	6.5	34	43.8	11.3
Hartford	2	.2	.1	-	-	-
John Dempsey	1	.0	.1	-	-	-
Saint Francis	1	.1	.02	-	-	-
Saint Raphael's	5	.5	.3	1	1.3	.5
Saint Vincent's	188	18.2	14.1	17	21.3	12.0
Yale	85	8.3	3.5	22	27.5	5.6
Danbury	1	.1	.1	-	-	-
Greenwich	82	7.9	79.5	-	-	-
Norwalk	163	15.8	69.5	-	-	-
Stamford	343	33.2	92.18	-	-	-
Out of State	86	8.3	-	5	6.3	-
Totals	1,035	100.0	-	79	100.0	-

Note: Outpatient Diagnostic Cardiac Catheterizations by town are not available.

Source: OHCA Inpatient Discharge Database and MA, NY, and RI Hospital Databases.

16. The Applicants have executed a Memorandum of Understanding, which states:
- The YNHHHI will provide medical direction, education, training and ongoing management/oversight to ensure the delivery of the highest quality of care.
 - A Medical Director will be appointed from YNHHHI to oversee the global aspects of the proposed program at GH.
 - The Medical Director will work closely with the Executive Director of the YNHHHI as well as GH's Director, Section of Cardiology and the Program Director for Cardiology and Medicine to ensure the smooth operation of all aspects of the program.
 - Physician participation in the program will be limited to 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.
 - GH is responsible for the day-to-day clinical and operational aspects of the program including oversight of staff and physical plant.
 - YNHH and BH are responsible for providing the clinical oversight to the proposed program and for providing training to GH staff.
 - BH and YNHH agree to provide tertiary back-up services for such patients.
(December 12, 2003, CON Application, pages 764 & 765)
17. The Atlantic Cardiovascular Patient Outcomes Research Team (C-PORT) Trial's Manual of Operations for the Primary Angioplasty Registry contains patient eligibility and identification, 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 have been adopted by the Applicants and are specified in Attachment I. (December 12, 2003, *The Atlantic C-PORT Trial Primary Angioplasty Registry, Manuel of Operations*)
18. The 2001 American College of Cardiology ("ACC") and the American Heart Association ("AHA") Guidelines for Percutaneous Coronary Intervention recommends criteria and standards for the performance of angioplasty at hospitals without on-site cardiac surgery. These criteria and standards have been adopted by the Applicants and are specified in Attachment I. (June 15, 2001, *JACC Vol.37, No. 8, page 2226&2227*)
19. GH offers a wide range of cardiac services including:
- Diagnostic cardiac catheterization;
 - Cardiac ultrasound and trans-esophageal echo (TEE);
 - Cardiac nuclear medicine;
 - Cardiac rehabilitation;
 - Cardiac intensive care and telemetry inpatient nursing units;
 - EKG, holter, signal, tilt table;
 - Pulmonary function testing laboratory;
 - Radiologic cardiac scoring;
 - Pacemaker implantation and follow-up care;

- Stress testing, exercise/pharmacological/echocardiographic; and
- Cardiac home care
(December 12, 2003, CON Application, page 12)

20. GH is the first community hospital being proposed for this YNHHS program expansion. The Applicants state there are a number of reasons to initiate the program at GH including:

- GH is a member of the YNHHS and YNHHSI and is fully integrated with YNHHS key clinical and administrative personnel.
- GH is strategically located at the Connecticut/New York border.
- GH has more than enough patients in need of this service to meet minimum guidelines and support a quality YNHHSI program.
- Traffic delays on the I-95 corridor have increased substantially in recent years due to growing car volume and long-term construction.
- GH has had a diagnostic cardiac catheterization laboratory since 1987.
- GH has recently added five interventional cardiologists to its medical staff. GH also plans to hire a full-time interventional cardiologist for the program.

(December 12, 2003, CON Application, page 17)

21. 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 provided there is a well structured operation with on going training for involved staff and a well documented plan for acute transfer of patients to a full service facility if necessary.

(December 12, 2003, CON Application, page 14)

22. In Connecticut from FY 2000 through 2003, patients 65 years and older received 55% of all inpatient diagnostic cardiac catheterizations and angioplasty procedures. (OHCA Inpatient Discharge Database)

23. Numerous studies have demonstrated that primary PCI is a more effective therapeutic alternative to pharmaceutical therapy resulting in lower morbidity and mortality, as follows:

- Primary PCI is better than thrombolytic therapy in hospitals that perform primary PCI without on-site surgical backup. Emergent hospital transfer is feasible, safe, and associated with improved clinical outcomes when compared with on-site thrombolytic therapy. (Keeley, et.al, *The Lancet*, January 4, 2003, "Primary angioplasty versus intravenous thrombolytic therapy for acute myocardial infarction: a qualitative review of 23 randomized trials")
- A strategy for reperfusion involving the transfer of patients to an invasive-treatment center for primary angioplasty is superior to on-site fibrinolysis, provided that the transfer takes two hours or less. (Andersen, et.al, *The New England Journal of Medicine*, 2003, "A comparison of coronary angioplasty with fibrinolytic therapy in acute myocardial infarction")
- 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

provided 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"*)

24. According to population estimates and projections prepared by Solucient, the total service area population is projected to increase from 351,333 in 2001 to 360,490 in 2006. More than 14% of the population is over the age of 65. The town of Greenwich has an older population than the service area overall with approximately 17% of the population being over 65. These projections could not be verified due to claimed proprietary nature of the information. (*December 12, 2003, CON Application, page 19*)

25. The Applicants based the need for the proposed primary interventional cardiac service on the following:

- Reduction in mortality and morbidity in service areas
- Improved accessibility for patients
- Elimination of need for ambulance transfers
- Improved continuity of care.

(*December 12, 2003, CON Application, page 9*)

26. Diagnostic cardiac catheterization volumes for the past three fiscal years at GH are as follows: (*December 12, 2003, CON Application, page 23*)

Table 6: Historical Diagnostic Cardiac Catheterizations

Fiscal year	2001	2002	2003**
Diagnostic Cath*	272	244	120

*Diagnostic caths include inpatient and outpatients with procedure codes 37.21, 37.22 and 37.23.

**Volume for FY 2003 has been generated by annualizing data from the first six months of that year.

27. Diagnostic cardiac catheterizations and primary angioplasties performed by each interventional cardiologist staffing the proposed program by procedure at Westchester Medical Center in FY 2002 to present are as follows :

Table 7: Annual procedure volume for each cardiologist

MD	PROCEDURE	CY 02	CY 03
C	Diagnostic Cath	678	793
	PCI	459	447
D	Diagnostic Cath	288	281
	PCI	182	184
E	Diagnostic Cath	616	658
	PCI	379	412
F	Diagnostic Cath	359	344
	PCI	135	153
G	Diagnostic Cath	288	251
	PCI	95	91

(*Responses to Completeness received on March 16, 2004*)

28. GH states the diagnostic cardiac catheterization volume has been declining due to the deliberate practice and referral pattern changes by the cardiologists. GH physicians have been transporting emergency department patients who will likely require urgent cardiac catheterization in the event that they also need angioplasty. *(December 12, 2003 CON Application, page 23)*
29. GH transferred 85 patients in FY 2002 and 83 cases in FY 2003 to other hospitals for interventional and cardiac related services. In addition to the inpatient transfers, 12 and 29 suspected acute MI patients presented to the Emergency Department were transferred in FY 2002 and in FY 2003, respectively. *(December 12, 2003 CON Application, page 23)*
30. GH states during FY 2002 and FY 2003 15 and 36 patients, respectively, were transferred out of state from either an inpatient unit or the Emergency Department. *(Responses to Completeness received on March 31, 2004)*
31. The Applicants state the proposed program at GH will provide the necessary capabilities to treat the majority of acute MI patients who require an urgent cardiac catheterization and primary angioplasty in the service area. The presence of a primary angioplasty program will also contribute to increasing diagnostic cardiac catheterization volumes due to the addition of five interventional cardiologists who will be performing both diagnostic catheterizations as well as primary angioplasty cases. *(December 12, 2003, CON Application, pages 23 & 24)*
32. The Applicants project the following number of diagnostic cardiac catheterizations for the proposed Connecticut service area for FYs 2004, 2005, 2006 and 2007:

Table 8: Projected Diagnostic Cardiac Catheterization

Fiscal year	2004	2005* Year 1	2006 Year 2	2007 Year 3
Diagnostic Cath*	151	232	315	402

*Represents the first year that the primary angioplasty program is operational. *(December 12, 2003, CON Application, page 26)*

33. The Applicants project the following number of diagnostic cardiac catheterizations by unique physician identifier for the proposed Connecticut service areas for the first three years of operation:

Table 9: Projected Number of Cardiac Catheterizations by Physician Identifier

MD CODE	YEAR 1 (2005)	YEAR 2 (2006)	YEAR 3 (2007)
MD A	138	150	150
MD B	69	92	115
MD C	15	29	47
MD D		10	25
MD E		10	25
MD F	5	12	20
MD G	5	12	20
TOTAL	232	315	432

(December 12, 2003, CON Application, page 28)

34. The Applicants project the following number of primary angioplasty procedures for the proposed Connecticut service area for FYs 2005, 2006 and 2007:

Table 10: Projected Primary Angioplasty Procedures

Fiscal year	2005* Year 1	2006 Year 2	2007 Year 3
Primary Angioplasty	40	42	44

*Represents the first year that the primary angioplasty program is operational.
 (December 12, 2003, CON Application, page 26)

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

Table 11: Proposed Operating Schedule for Each Interventional Cardiologist

8a.m.- 5p.m.	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
MD B	X	X		X	X	On	On
MD C			X			Call	Call
MD D			X			Rota-	Rota-
MD E			X			Tion	Tion
MD F*							
MD G*							

5p.m.- 8a.m.	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
MD B		On Call			On Call	On	On
MD C	On Call					Call	Call
MD D			On Call			Rota-	Rota-
MD E				On Call		Tion	Tion

*Schedule will vary
 (Responses to Completeness received on March 16, 2004 page 4)

36. The Applicants state that GH's acute MI patients do not currently have rapid access to a full-service Connecticut hospital due to the geographic distance from Bridgeport and severe traffic delays on I-95. (December 12, 2003 CON Application, page 29)

37. According to a traffic study completed by Buckhurst Fish & Jacquemart, Inc.:

- Between noon and midnight the average speed on northbound I-95 is approximately 45 miles per hour.
- In recent years the practical capacity of I-95 has decreased due to the frequent occurrences of bumper-to-bumper traffic.
- Bumper to bumper traffic conditions exist for at least 3 hours per day and up to 6 hours per day on a typical summer Friday from 9 am to 11 pm.
- I-95 hourly traffic flows and speeds tracked in 2001 indicate that average speed on I-95 in Norwalk ranges from 20-49 miles per hour during the hours of 3 pm through 9 pm.

38. Travel times to the two largest providers of primary angioplasty in the Applicant's proposed Connecticut service area are 46 minutes to Bridgeport Hospital and 69 minutes to Yale-New Haven Hospital (Yahoo Maps). Travel minutes are only one factor in the total time to transfer a patient which also includes such things as ambulance response times, time in Greenwich's Emergency Department, and delays relating to patient transfer to current primary angioplasty providers.
39. 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). Minimum travel minutes from GH's Emergency Department to full-service cardiac centers currently exceed the ideal door-to-balloon time. OHCA does not collect patient social security numbers or a unique patient identifier that would allow the agency to distinguish particular patients who had been transferred between acute care hospitals. (*JACC, 2001, Vol. 37, No.8, pg. 2239*)
40. In a 1983 report the "Inter-Society Commission for Health Disease Resources" recommended laboratories performing adult diagnostic studies maintain a minimum caseload of 300 per year to justify the financial outlay.
41. Margaret Martino, Program Director of Cardiology and Medicine at Greenwich Hospital, testified at the Technical Hearing May 6, 2004 to the following regarding the Hospital's proposal:
 - Average transport time from Greenwich Hospital to Valhalla, NY, is One hour and 22 minutes.
 - During FY 2003 GH had 43 Stemis in the ED (includes NY and CT patients).
 - The emergency response system in the town of Greenwich has over 20 defibrillation units, jointly purchased by Greenwich EMS and GH
42. Dr. Harvey Seidenstein, Medical Director of the Cardiac Laboratory at GH, testified at the Technical Hearing May 6, 2004 to the following regarding the Hospital's proposal:
 - Historically the Diagnostic Cardiac Laboratory at GH has been a single operator laboratory to maximize the quality of the studies and minimize complications, which probably impacted on the volume of procedures.
 - In recruiting other applicants the criteria required a total of 1000 cases performed independently or 150 cases per year in order to maintain high quality and high volume for the laboratory.
 - GH has recently established an affiliation with YNHHSI and additionally the relationship with the Westchester Medical Center and Dr. Weiss group has changed.
43. Dr Melvin B. Weiss, Professor of Medicine and Chief, Division of Cardiology at Westchester Medical Center, NY, testified at the Technical Hearing May 6, 2004 to the following regarding the Hospital's proposal:

- His partners Dr. Craig Munson and Dr. Kumar Kalapatapu and him self are all board certified interventional cardiologists and have recently obtained medical staff privileges at GH.
 - Dr. Munson already has regular block time reserved in the Greenwich catheterization lab once a week.
 - He will perform 2-4 diagnostic catheterizations per week.
44. Dr. Barry Zaret, Medical Director of the YNHH Heart Center, testified at the Technical Hearing May 6, 2004 to the following regarding the Hospital's proposal:
- YNHH Heart Center faculty will enhance the program at GH
 - One interventional cardiologist will be on site daily to do primary angioplasty, another cardiologist (Clinical Cardiologist) will be based full time at GH doing diagnostic procedures and office cardiologist.
45. Other neighboring states Massachusetts and New York require a minimum of 1000 and 400 cardiac catheterization procedures per year respectively, before initiating additional cardiac programs. (*Massachusetts Department of Public Health 2000, Instructions for 105 CMR 100.308 Applications for Open Heart Surgery Service and NY Department of Public Health, Section 709.14 – Cardiac Care Services and Cardiac Advisory Committee Guidelines for Cardiac Cath Lab CON Reviews, June 1999*)

**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**

46. The proposal has a total expenditure cost of \$5,000 for medical equipment to be financed through operations.
(*December 12, 2003, CON Application, page 39*)
47. GH projects incremental gains in operations of \$26,000, \$34,000 and \$45,000 for FYs 2005, 2006, 2007, respectively. (*December 12, 2003, CON Application, page 802*)
48. GH proposes the following additional staff, equipment and supplies required to perform primary angioplasty:
- Covering interventional cardiologists
 - On-call technician and nursing catheterization laboratory staff
 - Staff education and training expenses
 - Stents (bare metal)
 - Balloons
 - Guiding Catheters
 - Guide wires
 - Indeflator
 - Contrast
- (*December 12, 2003, CON Application, page 43*)

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.:

49. There is no State Health Plan in existence at this time. *(December 12, 2003 CON Application, page 13)*
50. The Applicants have adduced evidence that this proposal is consistent with the Applicants' long-range plan. *(December 12, 2003 CON Application, page 13)*
51. The Applicants have improved productivity and contained costs by participating in group purchasing and energy conservation. *(December 12, 2003 CON Application, page 36)*
52. The Applicants' proposal will not impact the Applicants teaching and research responsibilities. *(December 12, 2003 CON Application, page 37)*
53. There are no distinguishing characteristics of the Applicants' patient/physician mix. *(December 12, 2003 CON Application, page 37)*
54. The Applicants have sufficient technical, financial and managerial competence to provide efficient and adequate service to the public. *(December 12, 2003 CON Application, pages 34 & 35)*

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.

Yale-New Haven Hospital, Bridgeport Hospital, Greenwich Hospital d/b/a Yale-New Haven Heart Institute ("Applicants") propose to expand primary interventional cardiovascular services at GH for patients presenting with ST-segment elevation and left bundle branch blockage (LBBB) myocardial infarction. The Applicants based the need for the proposed primary interventional cardiac service on the reduction of mortality and morbidity in the service areas, improved accessibility for patients, elimination of the 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. 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. GH is geographically positioned to address the needs of residents in the service areas. The service area for the proposed programs also includes Westchester County, New York; however, OHCA statutorily is mandated to consider the availability, scope and need for services for the residents of Connecticut.

In Connecticut from FY 2000 through 2003, patients 65 years and older received 55% of all inpatient diagnostic cardiac catheterizations and angioplasty procedures. According to population estimates and projections prepared by Solucient, the total service area population is projected to increase from 351,333 in 2001 to 360,490 in 2006. More than 14% of the population is over the age of 65. The town of Greenwich has an older population than the service area overall with approximately 17% of the population being over 65. These projections could not be verified due to the claimed proprietary nature of the information.

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 provided there is a well structured operation with on going training for involved staff and a well documented plan for acute transfer of patients to a full service facility if necessary. The procedures will be done in a timely fashion (balloon inflations within 90 \pm 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.

There is a direct relationship between the time it takes a patient to undergo primary angioplasty and the outcome. Remoteness, road conditions, topography, travel distance and severity of winter weather conditions all impact the service area and increase travel time. Minimum travel minutes from GH's Emergency Department to full-service cardiac centers currently exceed the ideal door-to-balloon time. This does not include any time period for onset of symptoms to seeking medical attention, ambulance dispatch to the nearest ED, ED assessment and treatment, and coordination with a full-service cardiac center. OHCA does not collect patient social security numbers or a unique patient identifier that would allow the agency to distinguish particular patients who had been transferred between acute care hospitals.

Studies have shown that patients whose door-to-balloon time (the time from when a patient arrives at the emergency room to the time he/she begins to undergo angioplasty) exceeded two hours had a 40-60 percent increased risk of mortality in comparison to patients with the ideal door-to-balloon time of less than one hour. The Applicants' proposal will allow patients to be treated within the ideal door-to-balloon time. In summary, the number of ambulance and helicopter transfers and time delays will be reduced. 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 GH'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. The Applicants stated that primary angioplasty would be performed at GH 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 maintain appropriate procedural volumes by performing interventional procedures at a tertiary care facility.

GH is a member of the YNHHS and YNHHSI and is fully integrated with YNHHS key clinical and administrative personnel. The Applicants have executed a Memorandum of Understanding that states that the YNHHSI will provide medical direction, education, training and ongoing management/oversight to ensure the delivery of quality care. A Medical Director will be appointed from YNHHSI to oversee the global aspects of the proposed program at GH. Additionally, physician participation in the program will be limited to 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, GH will meet the institutional volume standards. GH is responsible for the day-to-day clinical and operational aspects of the program including oversight of staff and physical plant. YNHHS and BH are responsible for providing the clinical oversight to the proposed program and for providing training to GH staff and will provide tertiary back-up services for such patients.

GH has continuously operated a diagnostic cardiac catheterization laboratory for sixteen years. In 1988 the Commission on Hospitals and Health Care ("CHHC"), the predecessor agency to OHCA, gave GH authorization to initiate diagnostic cardiac catheterization services that had been terminated in 1977 due to physician recruitment issues. The approval was for a demonstration project utilizing two physicians, Drs. Langou and Seidenstein, who would generate a minimum caseload of 300 studies per year. From 1993 to 1995, Greenwich was granted several time extensions of the date by which the Hospital must submit a CON for permanent diagnostic cardiac catheterization service because GH was unable to meet the minimum caseload specified by the demonstration project. In 1995, CHHC approved GH's request to operate the cardiac catheterization lab service on a permanent basis. The Agreed Settlement ordered the compliance with appropriateness criteria, which included a minimum caseload of 300 per year, as stated in the 1991 ACC/AHA Task Force Guidelines for Cardiac Catheterization Labs. Also the Director of the Yale-New Haven Hospital cardiac catheterization lab and the Director of the Greenwich lab were to collaborate in performing utilization reviews.

Despite the collaborative arrangement with Yale-New Haven Hospital, GH is not in compliance with CHHC's order relating to the utilization of the cardiac catheterization laboratory. Diagnostic laboratory utilization for FYs 2001, 2002 and 2003 was 272, 244 and 120 studies, respectively. Projections for FYs 2004 and 2005 are 151 and 232,

respectively. GH does not anticipate performing 315 diagnostic studies on an annual basis until FY 2005. GH testified that one cardiologist staffs its cardiac catheterization laboratory and that it could not fulfill the utilization requirements of the CHHC order because it could not find another cardiologist performing at a high quality level. Additionally, GH testified that diagnostic cardiac catheterization volume has been declining due to the deliberate practice and referral pattern changes by the cardiologists. GH physicians have been transporting emergency department patients who will likely require urgent cardiac catheterization in the event that they also need angioplasty. OHCA is concerned that despite the collaboration with Yale-New Haven Hospital, GH is not in compliance with the OHCA order or the previous ACC/AHA guidelines. Additionally, it is generally accepted that a cardiac catheterization laboratory should be performing a minimum of 300 diagnostic studies per year. New York requires that hospitals perform a minimum of 400 cardiac catheterizations and Massachusetts requires that hospitals perform a minimum of 1,000 cardiac catheterizations per year.

The Applicants testified that they are committed to meeting the criteria established by the American College of Cardiology and the American Heart Association for the performance of angioplasty at hospitals without on-site cardiac surgery, as specified in Attachment I. GH has recently added five interventional cardiologists to its medical staff, and GH also plans to hire a full-time interventional cardiologist for the program. The interventional cardiologists are experienced and regularly perform more than 75 annual elective interventions at a full-service cardiac center. GH projects that it will perform a minimum of 36 primary PCI procedures per year. The Applicants project 40, 42, and 44 primary angioplasties in FYs 2005, 2006, and 2007.

Finally, the CON proposal is financially feasible. The proposal has a total expenditure cost of \$5,000 for medical equipment to be financed through operations. GH projects incremental gains from operations of \$26,000 in FY 2005, \$34,000 in FY 2006, and \$45,000 in FY 2007. Therefore, the CON proposal will not adversely impact the interests of consumers and payers of such services.

In conclusion, the Applicants' proposed primary angioplasty service is differentiated from other cardiac-related proposals in the following ways. Due to traffic and road conditions, GH patients have to travel an hour or more for emergent angioplasty; minimum travel minutes from GH's Emergency Department to full-service cardiac centers currently exceed the ideal door-to-balloon time. GH area residents are currently not receiving the treatment of choice for its ST-segment elevation acute myocardial infarction patients. The proposed program has a strong collaborative relationship with YNHHS and the YNHS, which should bring appropriate access and high quality cardiac services to the public. However, the low volume of diagnostic catheterization that the cardiac catheterization laboratory has generated since its inception in 1988 is troubling to OHCA, and OHCA seeks assurance that the projected volume of primary angioplasty procedures for the proposed program will be met. The Applicants and members of the Greenwich community presented compelling evidence and testimony to OHCA which demonstrated a clear public need for the primary angioplasty program, however, OHCA desires that the Applicants more fully demonstrate their ability to realize the projected

utilization statistics. Therefore, OHCA concludes that the Applicants should be authorized to offer a primary angioplasty program at Greenwich Hospital for a limited period of three years. The provision of the program for three years will provide the Applicants with adequate time to validate that the program can achieve the utilization that was projected in the proposal. The program will be allowed to continue if the projections are met. If the Applicants are unable to achieve these volumes at the end of three years, the program will be terminated. This approach assures the public of sound professional and clinical expertise. OHCA believes that the phased in approach of this proposal will guarantee the availability of a quality primary angioplasty program for the citizens of the Greenwich area.

Order

NOW, THEREFORE, the Office of Health Care Access (“OHCA”) and Yale-New Haven Hospital, Bridgeport Hospital, and, Greenwich Hospital, d/b/a Yale-New Haven Health Heart Institute (“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 Greenwich Hospital at a total capital expenditure of \$5,000, as follows:

1. The Applicants’ request for a CON to establish a primary interventional cardiac service to be located at Greenwich Hospital at a total capital expenditure of \$5,000 is hereby approved. The primary angioplasty program shall operate 24 hours a day and seven days a week.
2. Greenwich 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 Greenwich Hospital in writing of its evaluation. If OHCA finds questionable material, Greenwich 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 Greenwich Hospital does not submit the above data to the Cardiac Data Registry on a quarterly basis, the primary angioplasty program shall be terminated.

3. OHCA and the Applicants agree that this CON is granted for and in effect for an initial period of three (3) years, starting on the date of the performance of the first primary angioplasty procedure, in order for the Applicants to validate that the program can achieve the utilization that has been projected in the CON proposal. Thereafter, the continuation of this CON shall be governed by Stipulation #6. The Applicants shall schedule quarterly meetings at and with OHCA, regarding the implementation and progress of the primary angioplasty program.
4. The Applicants agree that they must demonstrate that the service is achieving sufficient utilization for the three years of the authorized project period. Sufficient utilization may be defined as achieving, at least:
 - FY 2005 40 Primary Angioplasty Procedures
 - FY 2006 42 Primary Angioplasty Procedures
 - FY 2007 44 Primary Angioplasty Procedures
5. The Applicants agree to file with OHCA at the end of the initial project period, a request for modification of this CON authorization under Docket Number 03-30148 to continue the operation of this program. Such request shall be filed within thirty (30) calendar days subsequent to the end of the third full fiscal year. The request shall be for the continuation of the service with permanent CON authorization status. The Applicants will be allowed to continue the primary angioplasty program until such time as OHCA reviews the request for continuation and takes action upon the request. Continuation of the primary angioplasty program with permanent CON authorization status shall be reviewed and determined based upon the Applicants fully demonstrating to OHCA that the primary angioplasty program is achieving sufficient utilization levels (as identified above in Stipulation #5).
6. Greenwich 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 and as specified in Attachment I. Greenwich Hospital shall provide OHCA quarterly data reports through such registry for the purposes of monitoring and quality assurance. If Greenwich Hospital determines not to participate in the C-PORT registry or the C-PORT registry no longer exists, Greenwich Hospital shall notify OHCA immediately, and continue to comply with the C-PORT guidelines and protocols.
7. Greenwich Hospital shall participate in the ACC National Cardiovascular Database Registry (ACC-NCDR) and report all data including the optional follow-up section. The Applicants 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. Greenwich 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 Greenwich Hospital determines not to

participate in the ACC-NCDR, Greenwich Hospital shall notify OHCA immediately, and continue to comply with the ACC/AHA criteria and standards.

8. Greenwich 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 Greenwich Hospital does not comply with the ACC/AHA criteria and standards and/or the C-PORT guidelines, Greenwich Hospital's primary PCI program shall be terminated.
9. OHCA and Greenwich Hospital, Yale-New Haven Hospital and Bridgeport Hospital agree that this Agreed Settlement represents a final agreement between OHCA and Greenwich Hospital, Yale-New Haven Hospital and Bridgeport Hospital 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 03-30148-CON.
10. This authorization shall expire on July 8, 2005. Should the Applicants' primary interventional cardiac service not be implemented by that date, the Applicants must seek further approval from OHCA to implement 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 the Applicants' expense, if the Applicants fail to comply with its terms.

Date Signed
July 8, 2004

Signed by
Frank A. Corvino
Duly Authorized Agent for
Greenwich Hospital

Date Signed
July 8, 2004

Signed by
Kyle Kramer
Duly Authorized Agent for
Yale-New Haven Hospital

Date Signed
July 8, 2004

Signed by
Robert Trefy
Duly Authorized Agent for
Bridgeport Hospital

The above Agreed Settlement is hereby accepted and so ordered by the Office of Health Care Access on July 8, 2004.

Date Signed
July 8, 2004

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

CV:pf

Primary angioplasty would be performed at GH safely and efficiently by Meeting ACC/AHA criteria and standards and C-PORT guidelines through the following:

- a) All patients entry points (e.g. emergency department) are continuously staffed by personnel competent in performing an ECG, initial evaluation and treatment of patients with acute ischemic syndromes, including acute MI and unstable angina. This includes equipment and training in cardiac monitoring and advanced cardiac life support (ACLS);
- b) The intensive care or cardiac unit will have the following capabilities:
 - Cardiac Monitoring
 - Immediate access to persons trained in ACLS
 - Arterial line and pulmonary artery catheter capabilities
 - Temporary pacemaker placement and mechanical ventilation
 - Continuous vasoactive intravenous infusions
 - Intra-aortic balloon placement facilities
 - Nursing staff must be competent in the recognition and treatment of arrhythmias and evaluation of ischemic symptoms
- c) An intermediate or step-down unit will be able to provide continuous ECG monitoring and prompt access to ACLS trained staff;
- d) On general nursing floors nursing staff must be competent to recognize unstable angina and provide initial management;
- e) Participating interventional cardiologists must perform at least 75 interventional procedures per year and the program must perform at least 36 primary angioplasty procedures per year;
- f) All participating programs must have a diagnostic catheterization laboratory;
- g) Adequate training of catheterization laboratory staff, including nurses and technicians, must be documented;
- h) Documentation of adequate supplies and support facilities is required;
- i) Formal training program for technical and nursing staff must be completed at YNHH and/or BH. This will include familiarization with: angioplasty equipment (guide catheters, guide wires, and angioplasty catheters including balloons and stents), commonly used drugs, assessment and monitoring anticoagulation, use of intra-aortic balloon equipment, patient transfer and a number of items related to patient care before, during and after the procedure;
- j) Pre-procedure, intra-procedure and post-procedure nursing care plans and critical pathways must be in place before primary angioplasty is begun;
- k) Special attention will be given to the following issues:
 - *Primary angioplasty performed within 90 minutes of arrival in the emergency department;*
 - Thrombolytic therapy within approximately 30 minutes of arrival in the emergency department;
 - Mobilization of all necessary staff;
 - Obtaining patient consent; and
 - Emergency patient transfer, if necessary.

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. <i>This will be referred to as the "Reporting Hospital."</i>
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 Hawaiians 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 occasioning 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, <i>code the hospital</i> 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 department. 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						
						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.
35	Acuity	1	165	165	Priority	
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 ≥ 0.2 mV 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 ≥ 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 ≥ 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 \geq 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 arrhythmias, 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 \geq 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 stenosis 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 stenosis 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 stenosis 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 stenosis 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 <i>NO</i> 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 <i>NO</i> 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."