Office of Health Care Access
Certificate of Need Application

Agreed Settlement

Applicants:	**New Britain General Hospital and Hartford Hospital**
Docket Number:	**03-30207-CON**
Project Title:	**Establish Primary Interventional Cardiac Service at New Britain General Hospital in New Britain**
Statutory Reference:	**Section 19a-638, Connecticut General Statutes**
Filing Date:	**July 30, 2004**
Hearing Date:	**September 7, 2004**
Presiding Officer:	**Cristine A. Vogel, Commissioner**
Decision Date:	**October 29, 2004**
Default Date:	**Not Applicable**
Staff:	**Kim Martone** **Michael Sabados** **Steven Lazarus** **Paolo Fiducia**

Project Description: New Britain General Hospital and Hartford Hospital ("Applicants") propose to establish a primary interventional cardiac service, to be located at New Britain General Hospital, at a total capital expenditure of $25,633.

Nature of Proceedings: On July 30, 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 New Britain General Hospital. The proposal has a capital expenditure of $25,633. The Applicants are health care facilities or institutions as defined by Section 19a-630 of the Connecticut General Statutes ("C.G.S.").

A public hearing regarding the CON Application was held on September 7, 2004. The Applicants were notified of the date, time, and place of the hearing and a notice to the public was published prior to the hearing in *The Herald* (New Britain). Commissioner Cristine Vogel served as presiding officer in this matter. The hearing was conducted as a contested case in accordance with the provisions of the Uniform Administrative Procedure Act (Chapter 54 of the Connecticut General Statutes) and Section 19a-638, C.G.S.

The Presiding Officer heard testimony from the general public, legislators, local officials and witnesses for the Applicants and in rendering this decision, considered the entire record of the proceeding. OHCA's authority to review, approve, modify or deny this proposal is established by Section 19a-638, C.G.S. The provisions of 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 Britain General Hospital ("NBGH") is a non-profit community hospital serving patients who may appropriately require tertiary care or Level I trauma services. *(June 28, 2004 Completeness Responses, Attachment H, page 26)*

2. Hartford Hospital is a tertiary care hospital that is a duly designated Level I Trauma Center, and is available as a statewide resource to community hospitals and their patients. NBGH and HH ("Applicants") have a long-standing collaborative relationship through the Hartford Health Care Corporation. *(March 15, 2004 CON Application, Attachment GG, page 598 and June 28, 2004 Completeness Responses, Attachment H, page 26)*

3. The Applicants propose to expand NBGH's current cardiovascular services to include primary angioplasty[1] for acute myocardial infarction ("PAMI") patients presenting with ST-segment elevation (STEMI) and left bundle branch blockage (LBBB). *(March 15, 2004, CON Application, page 7)*

4. NBGH currently offers a comprehensive array of services for patients experiencing cardiac conditions including: emergency services, intensive cardiac care, step-down telemetry unit care, cardiac rehabilitation program, advanced cardiac diagnostic services and health promotion programs. The proposed PAMI program will augment these existing services. *(March 15, 2004, CON Application, pages 6-9)*

5. HH will support the establishment of the primary interventional cardiac service at NBGH in a number of ways, including: participating in the quality improvement activities, assisting in the training of NBGH technicians and nurses at HH, accepting patients in transfer from NBGH for emergency open-heart surgery and failed primary angioplasty, providing competency assessment tools for laboratory personnel and equipment use, and participating in monthly on-site case review conference to monitor clinical performance and outcomes. *(March 15, 2004, CON Application, Attachment GG)*

6. NBGH will acquire, maintain and submit data as required by HH and establish a digital link for transmission of coronary angiography and angioplasty images between NBGH and HH. In the event that simultaneous emergencies for AMI cannot be accommodated by the NBGH cardiac laboratory or if a procedural complication warrants urgent transfer, NBGH will transfer emergency cases from NBGH to an appropriate institution at the discretion of the referring NBGH physician. *(March 15, 2004, CON Application, Attachment GG)*

7. 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.

   (March 15, 2004 CON Application, pages 10-20)

[1] 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.

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

Table 1: New Britain General Hospital's Proposed Service Area (PSA)

	Primary
Towns	Berlin New Britain Newington Plainville Southington
NBGH's Market Share for All Inpatient Cardiac Catheterizations	41%
Primary Towns' Share of NBGH's CT Inpatient Cardiac Catheterizations	87%

***Source**: March 12, 2004 CON Application, page 12 &CT Office of Health Care Access Acute Care Hospital Inpatient Discharge Database*

9. The demographic characteristics of NBGH's PSA are as follows:

Table 2: Demographic Characteristics of NBGH's PSA

	Population				
Service Area	**Total**	**Adults (15+)**	**15 – 44 (%)**	**45 – 64 (%)**	**65+ (%)**
Primary	175,115	141,803	41.5	22.9	16.1
Connecticut	**3,405,565**	**2,696,490**	**42.2**	**23.2**	**13.8**

***Source:** Census 2000.*

10. NBGH currently has in place a dedicated cardiac catheterization laboratory which is staffed and available 24 hours a day, 365 days a year. The proposed PAMI service will utilize the catheterization laboratory's existing facilities, equipment, and staff and will be provided twenty-four hours per day, seven days per week. *(March 15, 2004, CON Application, pages 20&31)*.

11. The NBGH cardiac catheterization laboratory operates side-by-side with its interventional radiology laboratory in the same suite. Staff members at the NBGH Cardiac Cath/Angio Lab are cross-trained and rotate equally in both the catheterization and angiography rooms. *(June 28, 2004 Completeness Responses, page 5)*

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

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

CT Service Area	**2000**	**2001**	**2002**	**2003**
Inpatient	407	456	418	436
Outpatient	562	582	556	565
Total	**969**	**1,038**	**974**	**1,001**

Source: Inpatient figures from *CT Office of Health Care Access Acute Care Hospital Inpatient Discharge Database, self-reported outpatient figures (FYs 2000 – 2002) and FY 2003 outpatient total from March 12, 2004 CON Application, page 18.*

13. NBGH stated that 315 cases with a diagnosis of AMI were treated at the NBGH emergency department ("ED") in Fiscal Year ("FY") 2003. 99 were observed as having STEMI based on the first electrocardiogram taken upon arrival at the ED. 35 additional cases were diagnosed with enzyme elevation myocardial infarction and LBBB. Of these 134 cases, 49 were transferred immediately for PAMI and an additional 28 patients were candidates for PAMI resulting in a total yearly caseload of 77 cases. *(March 15, 2004 CON Application, pages 11,19&24)*

14. The 2001 American College of Cardiology ("ACC") and the American Heart Association ("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)*

15. NBGH stated that all PAMI operators will meet, at a minimum, the ACC/AHA performance standard of 75 cases per year. *(March 15, 2004 CON Application, page 34)*

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. 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)*

18. The average ischemic heart disease and Acute Myocardial Infarction (AMI) discharges and deaths in NBGH'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	1,530	10.8	473	3.3	363	2.6
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.

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

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

	PCIs for AMI patients*		Diagnostic Cardiac Catheterization	
Hospital	**Procedures**	**Market Share (%)**	**Procedures**	**Market Share (%)**
Bridgeport	1	0.5	2	0.2
Hartford	19	17.8	118	12.3
John Dempsey	34	31.8	184	19.3
Saint Francis	36	34.0	130	13.6
Saint Raphael's	15	14.0	108	11.2
Saint Vincent's	0	0.0	2	0.2
Yale	2	1.9	10	1.0
Danbury			1	0.1
Middlesex			1	0.1
New Britain			396	41.4
Saint Mary's			4	0.4
Waterbury			2	0.2
Out of State			1	0.1
Totals	**107**	**100.0**	**959**	**100.0**

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

20. 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)*

21. The proposed PAMI program will use HH as its primary surgical back-up facility. NBGH has developed a Transfer Protocol and Agreement with HH. *(March 15, 2004 CON Application, page 37 and June 28, 2004 Completeness Responses, Attachment H)*

22. NBGH projects the following number of diagnostic cardiac catheterizations and primary angioplasties for its PSA for FYs 2004, 2005, 2006, and 2007:

Table 7: Projected Cardiac Volume

Service	FY 2005	FY 2006	FY 2007
Diagnostic Cardiac Catheterizations*	1,005	1,101	1,010
Primary Angioplasties	38**	77	77

* DCCs are projected to increase by 5, 10, and 10 additional procedures in FYs 2005, 2006, and 2007, respectively due to the affiliation with the PAMI program.

** The PAMI program is projected to begin operation on April 1, 2005. Therefore, the procedure volume shown is for 6 months only. PAMI projections are based on NBGH's actual experience of PAMI transfers, its ED patient population who are potential candidates for PAMI and the demographic characteristics of the PSA.

(March 15, 2004 CON Application, pages 23, 25, &26)

23. NBGH stated that five interventional cardiologists would provide the PAMI services:

Table 7: Proposed Program Interventionalists and Volume (FYs 2000 – 2003)

Physician	Hospital Affiliation(s)	Office	Average Annual PCIs (FY 2002 – 2003)
Borkowski	New Britain, St. Francis, and John Dempsey	New Britain	134
Corcoran	St. Francis	Bloomfield	220
Kudler	Bristol, St. Francis, and New Britain	New Britain	181
Sappington	St. Francis	Hartford	260
Smith	St. Francis	Hartford	149

Source: *June 28, 2004 Completeness Responses, page 3* ***& CT Office of Health Care Access Acute Care Hospital Inpatient Discharge Database.***

24. The interventional cardiologist will be exclusively assigned to NBGH during the week he is scheduled for on-call coverage. He will not be providing coverage at any other facility during that week. *(June 28, 2004, Completeness Response, Page 6)*

25. To ensure seven days per week, 24 hours per day program availability, NBGH established a patient triage policy for the proposed PAMI program and a 52-week on-call schedule for its interventional cardiologists. Angioplasty call is one week at a time starting Monday at 7:00 a.m. *(June 28, 2004 Completeness Responses, page 2 & Attachments B&C)*

26. 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 PTCA is more effective than thrombolytic therapy for the treatment of ST-segment elevation acute myocardial infraction. *(The Lancet 13-20, January 4, 2003, "Primary angioplasty versus intravenous thrombolytic therapy for acute myocardial infraction: a quantitative review of 23 randomised trials")*
    - Primary angioplasty in high-risk acute myocardial infraction patients at hospitals with no surgery on site is safe, effective, and faster than primary angioplasty after transfer to a surgical facility. *(Journal of the American College of Cardiology, Vol. 43, No. 11, 2004, "Primary angioplasty in acute myocardial infraction at hospitals with no surgery on-site (The PAMI-No SOS Study) versus transfer to surgical centers for primary angioplasty")*

27. NBGH conducted a detailed chart review which indicated the patients in a non-outlier group spent an average of 44.7 minutes from the time of their arrival to the time the ambulance was called. This timeframe consisted of 6.6 minutes from arrival to first ECG and 38.1 minutes from electrocardiogram to ambulance call. NBGH stated with the PAMI program:
    - The 38.1 minute period could be reduced by at least 12 minutes since it would not be necessary to locate an outside interventional cardiologist and make arrangements with a receiving hospital.
    - Additional 37.0 minutes could be eliminated which include calling for an ambulance, waiting for the arrival of the ambulance, giving report to the ambulance crew, loading the patients onto the ambulance stretcher with the necessary monitors and IV drips and traveling to the receiving facility. *(September 14, 2004 Applicants' Late File, pages 3-4)*

28. NBGH has developed and implemented a Rapid ECG Rule, specific ED protocols for the treatment of patients with protocols for the treatment of STEMI patients. *(September 14, 2004 Applicants' Late File, page 4)*

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

29. The proposal has a total expenditure of $25,633 which is the cost of the medical and non-medical equipment. *(March 15, 2004, CON Application, page 49)*

30. NBGH projects losses from operations of ($124,600), ($144,162), and ($120,550) incremental to the project for FYs 2005, 2006, and 2007, respectively. However, NBGH projects gains from total hospital operations of $10,400, $23,370, and $20,448 for FYs 2005, 2006, and 2007, respectively. *(June 28, 2004 Completeness Responses, page 8 and Attachment K)*

31. NBGH had reported consistent losses from operations for FY's 1998-2003. *(OHCA Annual Reporting, FY 1998-2003)*

32. NBGH's unaudited statements report a year-to-date gain of $5,402,000 through July 31, 2004. *(September 1, 2004, NBGH Responses to the Interrogatories, page 52)*

33. NBGH notes the following as explanations for the financial turnaround, compared to the previous years:

    (a) Increased Medicaid payments to approximately $1.0 million. The State effective April 1, 2004 approved an increase in the TEFRA rate for NBGH along with other institutions.
    (b) Medicaid Managed Care contracts were adjusted to reflect the increased Medicaid rate changes effective April 1, 2004.
    (c) Increased volume both inpatient and outpatient had a positive impact to the operating margin. Inpatient days increased 2%, Emergency Room visits increased 5% and outpatient volume increased an average of 2%.
    (d) Cost reduction and revenue cycle enhancement initiatives were implemented over the past two years to improve the operating margin:
        (i) FTEs for FY 2002 to FY 2004 have been reduced from 1,906 to 1,786 or 120 FTEs.
        (ii) Several initiative have been implemented to improve revenue realization:
            a. SMART Documentation Review,
            b. Denial Management,
            c. KREG Contract Management,
            d. 3M Billing Edits, and
            e. Commercial Contract Optimization.

    (September 1, 2004, NBGH Responses to the Interrogatories, pages 2&3)

34. The proposal will be financed from NBGH's equity through operations. *(March 15, 2004 CON Application, page 50)*

35. NBGH will hire .94, 1.22, and 1.22 additional FTEs (i.e. technicians and nurses) for the proposed PAMI program. *(June 28, 2004 Completeness Responses, page 22, Attachment F)*

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.:

36. There is no State Health Plan in existence at this time. *(March 15, 2004 CON Application, page 9)*

37. NBGH has adduced evidence that this proposal is consistent with its long-range plan. *(March 15, 2004 CON Application, page 9)*

38. NBGH has improved productivity and contained costs by participating in group purchasing, energy conservation, reengineering and applications of technology. The affiliation of NBGH and Bradley Memorial Hospital and Health Center has resulted in more efficient programs and services and reduced costs (i.e. elimination of duplicative purchases of technology, streamlining administrative functions, etc.) *(March 15, 2004 CON Application, pages 44-46)*

39. NBGH's proposal will impact NBGH's teaching and research responsibilities. NBGH states that this proposal will allow the residents to provide follow up care to post primary angioplasty patients thereby correcting the deficiency noted in the Residency Review Committee's citation. *(March 15, 2004 CON Application, pages 46&47and June 28, 2004 Completeness Responses, Attachment M)*

40. NBGH states that there are no distinguishing characteristics of its patient/physician mix that makes the facility unique. *(March 15, 2004 CON Application, page 47)*

41. The Applicants have sufficient technical, financial and managerial competence to provide efficient and adequate service to the public. *(March 15, 2004 CON Application, pages 40-42 and Attachment Q)*

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 PAMI volume already present in New Britain General Hospital's ("NBGH") emergency department is a significant factor in determining need, as well as the older population and the high rate of mortality due to ischemic heart disease in NBGH's service area.

NBGH and Hartford Hospital ("Applicants") propose to expand the cardiovascular services at NBGH 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, reduction in 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. 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. NBGH is geographically positioned to address the needs of the residents in the service area. The service area for the proposed program includes Berlin, New Britain, Newington, Plainville, and Southington.

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 65 years and older is higher than the Connecticut average.

Current medical literature supports primary angioplasty in community hospitals without on-site cardiac surgery for patients presenting with STEMI or LBBB. The ACC/AHA guidelines for PCI recommend that formalized written protocols be in place for immediate (within 1 hour) and efficient transfer of patients to the nearest full-service cardiac center. 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 NBGH'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. NBGH currently has in place a dedicated cardiac catheterization laboratory which is staffed and available 24 hours a day, 365 days a year. The proposed PAMI service will utilize the catheterization laboratory's

existing facilities, equipment, and staff and will be provided twenty-four hours per day, seven days per week. The NBGH cardiac catheterization laboratory also operates side-by-side with its interventional radiology laboratory in the same suite. Staff members are cross-trained and rotate equally in both the catheterization and angiography laboratories. The interventional cardiologists are experienced and skilled and exceed appropriate procedural volumes by performing interventional procedures at a tertiary care facility.

NBGH and HH have a long-standing collaborative relationship through the Hartford Health Care Corporation. NBGH and HH submitted an executed agreement for the implementation of the PAMI program, as well as a draft Transfer Protocol and Agreement. Under the terms of the agreements, HH will participate in the quality improvement activities, assist in the training of NBGH technicians and nurses at HH, accept patients in transfer from NBGH for emergency open-heart surgery and failed primary angioplasty, provide competency assessment tools for laboratory personnel and equipment use, and participate in monthly on-site case review conference to monitor clinical performance and outcomes. 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. The interventional cardiologists will be exclusively assigned to NBGH during the week he is scheduled for on-call coverage. He will not be providing coverage at any other facility during the week. To ensure seven days per week, 24 hours per day program availability, NBGH established a patient triage policy for the PAMI program and a 52-week on-call schedule for its interventional cardiologists. NBGH is responsible for acquiring, maintaining and submitting data as required by HH, establishing a digital link for transmission of coronary angiography and angioplasty images between NBGH and HH, and transferring emergency cases from NBGH to an appropriate institution in the event of simultaneous emergencies for AMI. HH will be the primary tertiary back-up facility.

NBGH performed 969, 1,036, 974 and 1,001 diagnostic cardiac catheterization studies in FYs 2000, 2001, 2002, and 2003, respectively. NBGH stated that 315 cases with a diagnosis of AMI were treated at the NBGH ED in FY 2003. 99 were observed as having STEMI based on the first electrocardiogram taken upon arrival at the ED. 35 additional cases were diagnosed with enzyme elevation myocardial infarction and LBBB. Of these 134 cases, 49 were transferred immediately for PAMI and 28 were additional candidates from PAMI for a total yearly caseload of 77 cases. Based on historical volumes and service area market share rates, OHCA estimates that NBGH could potentially perform 38 (projected to begin April of 2005), 77and 77 PAMIs for FYs 2005, 2006 and 2007, respectively. The Applicants project 77 PAMIs in the first full year of operation and an additional 10 diagnostic cardiac catheterizations with the PAMI program. Based historical service area volumes and the projected capture rates, the proposed PAMI program would meet or exceed the minimum volume standards as stated in the ACC/AHA Guidelines. Since national data show that 14-20% of all AMIs are eligible for treatment with primary angioplasty, existing providers will continue to have PAMI volume that exceeds national standards.

Finally, the CON proposal is financially feasible. The proposal has a total expenditure of $25,633. The proposal will be financed from NBGH's equity through operations. NBGH projects losses from operations of ($124,600), ($144,162), and ($120,550)

incremental to the project for FYs 2005, 2006, and 2007, respectively. However, NBGH projects gains from total hospital operations of $10,400, $23,370, and $20,448 for FYs 2005, 2006, and 2007, respectively. NBGH has also reported continued losses from operations for FY's 1998-2003 in its annual filings to OHCA. However, NBGH has stated that year-to-date through July 31, 2004, their unaudited statements report a gain of $5,402,000. NBGH contributes its financial turnaround due to increased Medicaid payments, adjustment to Medicaid Managed Care, increased volume both in inpatient and outpatient and several cost reduction and revenue cycle enhancement initiatives implemented over the last two years. 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. The NBGH service area has an older population with a higher rate of ischemic heart disease, AMI discharges and ischemic mortality than the rest of the state. Secondly, NBGH's historical diagnostic cardiac catheterization volume exceeds 1,000 procedures per year. The Hospital 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 NBGH program should be able to achieve PAMI volumes in excess of those stated in the ACC/AHA Guidelines. Finally, NBGH's long-standing collaborative relationship with HH will enhance the accessibility of high quality, community-based medical services offered by NBGH. NBGH will utilize the resources of HH to further enhance provision of quality care including access to the expertise, information, and support of a statewide resource to community hospitals and their patients. In summary, the proposal will result in enhanced cardiac services in the New Britain region.

Order

NOW, THEREFORE, the Office of Health Care Access ("OHCA") and New Britain General Hospital and Hartford Hospital ("Applicants") hereby stipulate and agree to the terms of settlement with respect to the Applicants' request to establish a primary interventional cardiac service to be located at New Britain General Hospital at a total capital expenditure of $25,633, as follows:

1. The Applicants' request for a CON to establish a primary interventional cardiac service to be located at New Britain General Hospital at a total capital expenditure of $25,633 is hereby approved.

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

3. If New Britain General 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), New Britain General 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, New Britain General Hospital shall file a CON for the reinstitution of the program.

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

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

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

7. New Britain General Hospital shall provide OHCA with a copy of a dated and signed Transfer Protocol and Agreement with HH prior to commencement of the authorized PAMI service.

8. OHCA and New Britain General Hospital and Hartford Hospital agree that this Agreed Settlement represents a final agreement between OHCA and New Britain General Hospital and Hartford 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 03-30207-CON.

9. This authorization shall expire on October 29, 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.

10. This Agreed Settlement is an order of the Office of Health Care Access with all the rights and obligations attendant thereto, and the Office of Health Care Access may enforce this Agreed Settlement pursuant to the provisions of Sections 19a-642 and 19a-653 of the Connecticut General Statutes at New Britain General Hospital's expense, if the Applicants fail to comply with its terms.

October 28, 2004

Signed by John Meehan
Duly Authorized Agent for
Hartford Hospital

October 29, 2004

Signed by Lawrence Tanner
Duly Authorized Agent for
New Britain General Hospital

The above Agreed Settlement is hereby accepted and so ordered by the Office of Health Care Access on October 29, 2004.

October 29, 2004

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

ACC/AHA Criteria for the Performance of Primary Angioplasty at Hospitals Without On-Site Cardiac Surgery

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

ACC/AHA 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 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 vessel
- Preferably with intra-aortic balloon pump support

ACC/AHA Recommendation for PCI at Hospitals Without On-Site Cardiac Surgery Class IIb

Patients undergoing primary PCI in facilities without on-site cardiac surgery, but with a proven plan for rapid access (within 1 our) to a cardiac surgery operating room in a nearby facility with appropriate hemodynamic support capability for transfer.

The procedure should be:

- Limited to patients with STEMI or LBBB
- Done in a timely fashion (balloon inflation within 90-120 minutes of admission
- Performed by persons skilled in the procedure (>= 75 PCIs/year)
- Done only at facilities performing a minimum of 36 PCI primary procedures per year

Attachment II

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."