



Office of Health Care Access Certificate of Need Application

Agreed Settlement

Applicants: New Milford Hospital and New York Presbyterian Healthcare System, Inc.

Docket Number: 03-30089-CON

Project Title: Establish a Diagnostic and Interventional Cardiac Catheterization Laboratory at New Milford Hospital in New Milford

Statutory Reference: Sections 19a-638 & 639, Connecticut General Statutes

Filing Date: December 12, 2003

Hearing Dates: January 20, 2004 and February 5, 2004

Presiding Officer: Cristine Vogel, Commissioner

Decision Date: April 21, 2004

Default Date: Not Applicable

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Project Description: New Milford Hospital and New York Presbyterian Healthcare System, Inc. ("Applicants") propose to establish a diagnostic cardiac catheterization laboratory and primary angioplasty service, to be located at New Milford Hospital, at a capital expenditure of \$3,063,900.

Nature of Proceedings: On December 12, 2003, the Office of Health Care Access (“OHCA”) received the Applicants’ Certificate of Need (“CON”) application seeking authorization to establish a diagnostic cardiac catheterization laboratory and primary angioplasty service to be located at New Milford Hospital. The proposal has a capital expenditure of \$3,063,900. The Applicants are health care facilities or institutions as defined by Section 19a-630 of the Connecticut General Statutes (“C.G.S.”). New Milford Hospital, Inc. is organized under the laws of Connecticut, and New York Presbyterian Healthcare System, Inc. is a corporation organized under the laws of the State of New York.

Public hearings regarding the CON Application were held on January 20, 2004 and February 5, 2004. The Applicants were notified of the date, time, and place of the hearing and notices to the public were published prior to the hearings in the *News Times* (Danbury). Commissioner Cristine Vogel served as presiding officer in this matter. The hearing was conducted as contested cases in accordance with the provisions of the Uniform Administrative Procedure Act (Chapter 54 of the Connecticut General Statutes) and 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 Sections 19a-638 and 19a-639, C.G.S. The provisions of these sections, as well as the principles and guidelines set forth in Section 19a-637, C.G.S., were considered by OHCA in its review.

Findings of Fact

Clear Public Need

Impact on the Applicants’ Current Utilization Statistics

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

1. New York Presbyterian Healthcare System, Inc. (“System”) coordinates a system of hospitals and other healthcare institutions in New York, Connecticut, and New Jersey, including New Milford Hospital (“NMH”) and New-York Presbyterian Hospital (“NYPH”). NYPH operates Columbia Presbyterian Medical Center (“CPMC”) in affiliation with Columbia University College of Physicians and Surgeons (“CU”). (*December 12, 2003 Responses to Completeness, Technical Clarification Letter, page 1*)
2. NMH joined the System as an affiliate member in 1997. NMH collaborated with CU on the development of its Regional Cancer Center program. (*December 12, 2003 Responses to Completeness, Technical Clarification Letter, page 3*)

3. NMH is a not-for-profit, 85-bed acute care hospital located in New Milford, Connecticut. NMH, as an affiliate member of the System, maintains an academic affiliation with CU. NMH provides a comprehensive array of services including: Cardiology, Oncology, Diabetes, Radiation Oncology, Obstetrics, Cardiac Rehabilitation, Pain Management, Respiratory Therapy and Surgery. *(December 12, 2003 Responses to Completeness, Technical Clarification Letter, page 1)*
4. NYPH has one of the largest cardiac surgery and cardiac catheterization programs in New York. *(December 12, 2003 Responses to Completeness, Technical Clarification Letter, page 4)*
5. The Applicants propose to establish a diagnostic cardiac catheterization service¹ at NMH, which would evolve upon meeting certain pre-established benchmarks to include primary angioplasty for acute myocardial infarction (percutaneous coronary intervention or PCI²). *(December 12, 2003 Responses to Completeness, Technical Clarification Letter, page 1)*
6. Physician services and clinical oversight for the NMH diagnostic and interventional cardiac catheterization laboratory service will be provided by Connecticut licensed physicians who are faculty members of CU. *(Responses to Completeness, December 12, 2003, Attachment cq-1, page 3)*
7. The System would arrange for consultative services to NMH in the following areas: physician credentialing recommendations; clinical training for professional and technical staff based on CPMC standards; development of NMH's care standards, risk stratification criteria, quality assurance programs, and operational policies and procedures based on CPMC standards and nationally recognized guidelines; clinical guidelines and protocols; collection and analysis of quality data for clinical outcomes and performance monitoring, and recruiting procedures. *(December 12, 2003 Responses to Completeness, Technical Clarification Letter, page 1)*
8. For the first 300 cases, the Applicants stated that both CU physicians at CPMC who are licensed in Connecticut and NMH physicians would consult on the selection decisions for potential catheterization lab candidates. *(December 12, 2003 Responses to Completeness, Technical Clarification Letter, page 8)*

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

² Primary (or Emergent) Percutaneous Coronary Intervention (PCI) or Coronary Angioplasty (PCA) is an interventional procedure whereby a catheter, usually inserted into an artery in the groin, is threaded through the circulatory system to a previously diagnosed blockage in the heart. An expandable balloon is passed to this spot and inflated several times, thereby flattening the blockage-causing plaque, potentially widening the artery, and thus improving blood flow.

9. The consultative services provided by the System in collaboration with NYPH will support the proposed program's transition to the introduction of primary PCI on a 24-hour/7-day basis. (*December 12, 2003 Responses to Completeness, Technical Clarification Letter, page 5 and page 6*)
10. 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 will be utilized by the Applicants and are specified in Attachment I. (*June 15, 2001, JACC Vol.37, No. 8, page 2226&2227*)
11. 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*)
12. The Applicants stated that cardiac catheterizations and primary angioplasty would be performed at NMH safely and efficiently by meeting the ACC/AHA criteria and standards and C-PORT guidelines through the following:
 - a) A fully equipped cardiac catheterization laboratory with access to a full range of interventional equipment;
 - b) Rigorous protocols for selection of appropriate low lesion risk and low clinical risk patients;
 - c) Skilled and experienced allied health staff capable of assisting with angioplasty and caring for patients after the procedure;
 - d) Skilled and experienced interventional cardiologists who maintain appropriate procedural volumes by performing interventional procedures at a tertiary care facility;
 - e) A proven and fail-safe protocol for the rapid ambulance transport of patients with procedural complications requiring emergency cardiac surgery;
 - f) Full commitment from cardiac surgery colleagues at a nearby tertiary facility to ensure immediate access to emergent cardiac surgery;
 - g) Capability to immediately consult with interventional and cardiac surgical colleagues; and
 - h) A formal protocol for data collection and analyses to ensure continuous program review and improvement.(*January 30, 2004, Prefile Testimony, pages 19, 20, 25&26*)
13. 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 do 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"*)
- Low-risk elective and acute infarct PCI can be performed safely and effectively at a community hospital without cardiac surgical capability by following rigorous standards. (*Ting, et.al, American Heart Journal, 2003, "Low-risk percutaneous coronary interventions without on-site cardiac surgery: Two years' observational experience and follow-up"*)
- The C-PORT trial found that community hospitals performing primary angioplasty without cardiac surgical backup had better outcomes based on a six-month composite measure of mortality and adverse outcomes than those who received pharmaceutical therapy. (*Aversano, et.al., "Thrombolytic Therapy vs. Primary Percutaneous Coronary Intervention for Myocardial Infarction in Patients Presenting to Hospitals Without On-site Cardiac Surgery"*)
- Patients whose door-to-balloon time (the time from when a patient arrives at a hospital 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. (*Cannon, et.al., JAMA, 2000, "Relationship of symptom-onset-to-balloon time with mortality in patients undergoing angioplasty for acute myocardial infarction"*)

14. NMH's Connecticut primary service area, secondary service area, and tertiary service area for the proposed program consist of the following towns:

Table 1: NMH's CT Service Areas

	Primary	Secondary	Tertiary
Projected Capture Rate	75%	33%	10%
Towns	Bridgewater	Canaan	Bethlehem
	Brookfield	Litchfield	Colebrook
	Cornwall	Morris	Goshen
	Kent	North Canaan	Norfolk
	New Milford	Salisbury	Southbury
	Roxbury	Sharon	Torrington
	Sherman		Winchester
	Warren		Woodbury
	Washington		

(October 3, 2003 CON Application, pages 26 - 27 and Response to Completeness received on December 12, 2003, page 9)

15. NMH also includes towns in Dutchess 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.

16. There are no providers of cardiac catheterization services or primary angioplasty services in Litchfield County. (*October 6, 2003 CON Application, page 10*)
17. The demographic characteristics of NMH's Connecticut service areas are as follows:

Table 2: Demographic Characteristics

Service Area	Population				
	Total	Adults (15+)	15 – 44 (%)	45 – 64 (%)	65+ (%)
Primary	59,714	46,361	39.2	27.1	11.4
Secondary	21,993	17,793	34.3	28.3	18.2
Tertiary	82,881	66,738	37.4	24.8	18.3
Total	164,588	130,892	37.7	26.1	15.7
Connecticut	3,405,565	2,696,490	42.2	23.2	13.8

Source: Census 2000.

18. The Applicants used 2002 Claritas data to project the total population in NMH's service area to increase by 3.3% by 2007. The service area population over 45 years of age is projected to increase by 10% by 2007. These projections could not be verified. The Applicants claimed that the data was proprietary. (*January 30, 2004, Prefile Testimony, page 11*)
19. The Applicants based the need for the proposed diagnostic and interventional cardiac catheterization laboratory on the following:
- Reduction in mortality and morbidity in service areas
 - Improved accessibility for patients
 - Elimination of need for ambulance and helicopter transfers
 - Improved continuity of care
- (*October 6, 2003 CON Application, pages 5-8*)
20. The projected initial diagnostic cardiac catheterization volume based on the statewide per capita use rate per 1,000 population and the estimated historical CT service area volume are as follows:

Table 3: Projected Diagnostic Cardiac Catheterizations Based Upon Statewide Use Rate* (FY 2003)

CT Service Area	Adults	Use Rate	Procedures	Capture Rate (%)	Projected CT Volume
Primary	44,446	9.19	408	75	306
Secondary	15,058	9.19	138	33	46
Tertiary	66,512	9.19	611	10	61
Total	126,016	9.19	1,158	-	413

Table 4: Average Annual Historical CT Service Area Volume (FY 2000 - 2003)

CT Service Area	Average Annual Historical Volume	Average Annual Use Rate	Capture Rate (%)	Projected CT Volume
Primary	242	5.4	75	182
Secondary	123	8.2	33	41
Tertiary	512	7.7	10	51
Total	877	7.0	-	274

* Source: OHCA Inpatient Discharge Database and Census 2000 for population figures. Estimated historical volume derived by combining actual inpatient diagnostic catheterizations and estimated outpatient diagnostic catheterizations. Outpatient diagnostic catheterizations estimated based upon statewide inpatient to outpatient diagnostic catheterization ratio (37%). For example, primary service area average annual inpatient diagnostic catheterizations: $177 * .37 = 65$; $177 + 65 = 242$.

21. 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 NMH's Connecticut service area are shown below:

Table 5: Average Annual Ischemic Heart Disease and AMI Discharges and Deaths, (FYs 1999 – 2003^a)

CT Service Area	Hospital CT Discharges				Mortality	
	Ischemic Heart Disease ^b		AMI		Ischemic Heart Disease	
	Discharges	Rate	Discharges	Rate	Deaths	Rate
Primary	281	6.1	107	2.3	70	1.5
Secondary	152	8.5	68	3.8	44	2.5
Tertiary	622	9.2	279	4.2	169	2.5
Total	1,055	8.1	454	3.5	283	2.2
Connecticut	-	8.2	-	3.2	-	2.2

Source: OHCA Inpatient Discharge Database, CT Department of Public Health Vital Records, 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.

22. The Applicants estimated the annual cardiac catheterization outmigration from NMH's service area using physician interviews and a physician survey. Through physician interviews and industry data, NMH physicians project that 510 diagnostic cardiac catheterizations and 198 interventional procedures for a total of 708 cardiac catheterizations outmigrated for care from their practices. Through a physician survey, the cardiology and primary care physicians project an annual outmigration of 456 diagnostic catheterizations and 325 PCI procedures. (*October 6, 2003 CON Application, pages 13&33 and Responses to Completeness, December 12, 2003, page 5*)

23. The average annual inpatient cardiac catheterization angioplasty volume in NMH's Connecticut service area for FYs 2000-2003 are as follows:

Table 6: Average Annual Volume of Inpatient Diagnostic Cardiac Catheterizations and Angioplasties in NMH's CT Service Area by Provider, (FYs 2000 – 2003*)

Hospital	Average Annual Inpatient Diagnostic Catheterizations			Average Annual Angioplasties		
	Procedures	Market Share (%)	Area Volume as Share of Total Provider Volume (%)	Procedures	Market Share (%)	Area Volume as Share of Total Provider Volume (%)
Bridgeport	37	5.7	2.3	65	19.2	5.3
Hartford	251	39.2	6.8	144	42.6	11.5
John Dempsey	21	3.3	2.6	14	4.1	2.8
Saint Francis	55	8.7	1.3	22	6.6	1.8
Saint Raphael's	23	3.7	.7	12	3.5	1.4
Saint Vincent's	15	2.3	.8	19	5.6	1.6
Yale	71	11.1	2.2	51	14.9	3.3
Danbury	48	7.5	7.6	-	-	-
New Britain	1	.1	.1	-	-	-
Norwalk	1	.2	.2	-	-	-
Saint Mary's	14	2.2	2.6	-	-	-
Stamford	1	.1	.1	-	-	-
Waterbury	73	11.4	9.3	-	-	-
Out of State	29	4.6	-	12	3.4	-
Totals	640	100.0	-	339	100.0	-

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

Source: OHCA Inpatient Discharge Database.

*1st two quarters of FY 2003.

24. The Applicants estimate approximately 25 emergency helicopter transfers and 25 ambulance transfers for a total of 50 cardiology transfers occur annually from the NMH Emergency Department. (*October 6, 2003 CON Application, pages 13&35*)
25. NMH had over 350 patients present to the Emergency Department with a cardiac related diagnosis for treatment in Fiscal Year ("FY") 2002. Ninety-five of these patients were diagnosed with acute myocardial infarctions. The Applicants stated that approximately 75 primary angioplasty procedures could have been performed at NMH with the proposed service. Fifty (50) MI patients were transferred after assessment to full-service cardiac centers for further treatment and additional patients were subsequently transferred following admission to NMH's ICU/CCU. (*October 6, 2003 CON Application, page 36 and January 30, 2004, Prefile Testimony, page 12*)
26. The Applicants state the proposed program will improve access to cardiac services for residents of the proposed Connecticut service area and northwestern Connecticut in general and reduce hospital-to-hospital transfers of New Milford Hospital's inpatients. (*Response to Completeness received on December 12, 2003, page 8*)

27. The Applicants stated that travel time to full-service cardiac centers ranges from an average of 40 minutes to as long as one hour and 15 minutes (or more) one-way. Remoteness, road conditions, topography, travel distance and severity of winter weather conditions all impact the service area. Direct public transportation is not available to these centers. (*October 6, 2003 CON Application, page 36*)
28. 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 \pm 30 minutes of ED admission). Total minimum travel minutes from towns in NMH's proposed Connecticut service area to NMH and then to full-service cardiac centers currently exceed the ACC/AHA required door-to-balloon time, as seen in Attachment II. 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*)
29. The Applicants presented a comparison of the time lapse between NMH's current situation without a diagnostic cardiac catheterization laboratory or primary angioplasty program and the time lapse with the proposed diagnostic and interventional service, specifically for STEMI patients, as follows:

Table 7: Comparison of Time

	Time Lapse Current Situation*	Time Lapse Proposed Program*	Time Lapse ST-Elevation MI's*
Ambulance Dispatch to Arrival at ED	35 minutes	35 minutes	35 minutes
Average ED Assessment and Treatment	50 minutes	50 minutes	15 minutes
Coordination with Angioplasty Provider	115 minutes	20 minutes	20 minutes
Average	165 minutes	70 minutes	35 minutes
Transportation to Full Service Cardiac Center		0 minutes	0 minutes
Helicopter	30 minutes		
Ambulance	90 minutes		
Average	60 minutes		
Arrival to Angioplasty Lab	20 minutes	5 minutes	5 minutes
Total	280 minutes	110 minutes	75 minutes

* Does not include any time period for onset of symptoms to seeking medical attention

This information could not be verified without transfer data/log from the emergency medical system. (*January 30, 2004, Prefile Testimony, page 7 and February 5, 2004, Public Hearing Presentation*)

30. The Applicants stated that transfer agreements would be executed with NYPH as well as other full-service cardiac centers within Connecticut. Patients and physicians will jointly determine the clinical appropriateness and preference for referral to full-service cardiac centers for ongoing care. Emergency transportation linkages have been well established through access to Hartford Hospital's LIFESTAR program. *(December 12, 2003 Responses to Completeness, Technical Clarification Letter, page 7)*
31. NMH, with consultation from CU physicians at CPMC, would be responsible for recruiting an on-site Medical Director, an interventional cardiologist and member of the active medical staff, who will perform the diagnostic and interventional procedures. The Director of Interventional Cardiology at CPMC will provide additional clinical oversight and quality leadership to the program. *(December 12, 2003 Responses to Completeness, Technical Clarification Letter, page 6 and February 5, 2004, Public hearing, Slide presentation)*
32. The proposed program would also enable a real-time review of images by Connecticut licensed physicians who are faculty members of CU and credentialed at CPMC, in conjunction with NMH based physicians. *(December 12, 2003 Responses to Completeness, Technical Clarification Letter, page 5)*
33. The Applicants project the following number of cardiac catheterizations and primary angioplasties for the Connecticut service areas for FYs 2004, 2005 and 2006: *(October 6, 2003 CON Application, page 36)*

Table 8: Projected CT Cardiac Volume

Service	FY 2004	FY 2005	FY 2006
Diagnostic Cardiac Catheterizations	413	502	550
Primary Angioplasties		53	77

Note: 2004 volumes are based on a 9.19 use rate for Connecticut. Initiation of the primary PCI program is in the 15th month. The rate of primary PCI vs. total PCI is approximately 14% of diagnostic volume. *(October 3, 2003 CON Application, page 41 and Response to Completeness received on December 12, 2003, page 12)*

34. The hours of operation of the diagnostic cardiac catheterization laboratory will be 9 A.M. to 3 P.M., initially scheduled four days per week based on volume, and expanding as volume dictates.

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

35. The Applicants' proposal includes renovating 3,232 square foot of vacant patient care area (2nd floor) in the hospital by New Milford Hospital for a cardiac catheterization laboratory. The area will consist of the following:

- One procedure room,
- An associated technologist control room,
- Equipment room,
- Patient dressing rooms with lockers,
- Pre-procedure room for two patients,
- Recovery/Holding room for four patients with a nursing station,
- Nurse manager office,
- Physician office,
- And support functions including housekeeping, clean utility and storage.

(October 6, 2003, CON Application, page 48)

36. The proposal has a total expenditure cost of \$3,063,900 which consists of the following:

Table 9: Total Capital Expenditure

Description	Cost
Construction/Renovation	\$1,101,243
Other-Total Arch. & Eng. Costs	100,000
Medical Equipment	462,965
Imaging Equipment	1,244,655
Non-Medical Equipment	155,037
Total Capital Expenditure	\$3,063,900

(October 6, 2003, CON Application, page 47)

37. NMH projects incremental gains in operations of \$279,890 in FY 2004 and \$18,930 in FY 2006. However, in FY 2005, NMH projects a loss in operations of \$41,506 due to the initial implementation of the primary angioplasty program. *(January 30, 2004, Prefile Testimony, page 24 and December 12, 2003, Responses to Completeness, page cq R-3)*
38. NMH projects gains in total hospital operations with the project of \$583,649, \$204,442 and \$194,847 for FYs 2004, 2005, 2006, respectively. *(December 12, 2003, Responses to Completeness, Revised Combined Financial Proforma page/attachment Cq O-2)*
39. NMH proposes to hire 3.4, 5.93 and 6.85 Full-Time Equivalent (“FTE”) positions for FY’s 2004, 2005 and 2006, respectively, which include One Cardiac RN, One Procedure RN, One Recovery Room RN, One Supervisor APRN, One Radiology Technician, One Clerical position and One Housekeeping position. *(October 6, 2003, CON Application, page 53 and December 12, 2003, Responses to Completeness, Revised Financial Proforma page/Attachment Cq O-2)*
40. The proposal will be financed from NMH’s equity through operations. The projected Cash Flow provided from operations for FY 2004 totals \$4,419,226. Of this, a total of \$2,945,248 will be used to fund this proposal. The remaining \$118,652 will be funded from NMH’s Cash Balance. *(October 6, 2003 CON Application, page 51 and December 12, 2003, Responses to Completeness, page 15)*

41. The Applicants' proposal will require the establishment of a new cost center for NMH named "Cardiac Catheterization" and the units of service will be "procedures". *(October 6, 2003, CON Application page 47)*
42. NMH projects revenue of \$3,374 per procedure. NMH's rates are sufficient to cover the proposed capital expenditure and operating costs. *(October 6, 2003, CON Application, page 53)*

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.:

43. There is no State Health Plan in existence at this time. *(October 6, 2003 CON Application, page 23)*
44. NMH has adduced evidence that this proposal is consistent with New Milford Hospital's long-range plan. *(October 6, 2003 CON Application, page 23)*
45. NMH has improved productivity and contained costs by participating in group purchasing and applications of technology. *(October 6, 2003 CON Application, page 44)*
46. The Applicants' proposal will not impact NMH's teaching and research responsibilities. *(October 6, 2003 CON Application, page 45)*
47. There are no distinguishing characteristics of NMH's patient/physician mix. *(October 6, 2003 CON Application, page 45)*
48. The Applicants have sufficient technical, financial and managerial competence to provide efficient and adequate service to the public. *(October 6, 2003 CON Application, page 43 and Attachments G&H)*

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.

New Milford Hospital and New York Presbyterian Healthcare System, Inc. (“Applicants”) propose to expand cardiac services at NMH through the implementation of a two-step process. The Applicants will initially establish a diagnostic cardiac catheterization service at NMH. Once the number of diagnostic cardiac catheterizations performed in the laboratory reaches 300 procedures within any 12-month period, the primary angioplasty service for acute myocardial infarction will commence operation. The Applicants anticipate that 300 diagnostic cardiac catheterizations will be achieved 15 months after commencement of the service. The Applicants based the need for the diagnostic and interventional cardiac catheterization laboratory 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. NMH is geographically positioned to address the needs of residents in the service areas. The service area for the proposed programs also includes Dutchess 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. Forty-two percent of NMH’s service area population is residents aged 45 years and older and this age group is projected to increase by 10% by 2007. The projections were developed using 2002 Claritas data. Due to the proprietary nature of the Claritas information, OHCA cannot verify the projected increases in population. OHCA estimates that NMH could potentially perform a minimum of 274 annual cardiac catheterizations on residents of NMH’s Connecticut service area based upon recent utilization patterns. There are no providers of cardiac catheterization services in Litchfield County or the Northwest corridor of the state. The statewide use rate of 9.19 per 1,000 adults is based on the analysis of inpatient discharge data and outpatient data reported by the hospitals. If the use rate were applied to NMH’s Connecticut service areas, NMH would have been expected to perform 413 cardiac catheterizations in FY 2003. Further, the Applicants project utilization of 413, 502, and 550 diagnostic cardiac catheterizations from NMH’s

Connecticut service areas for FYs 2004, 2005, and 2006 based on the statewide use rate. The Applicants project 53 and 77 primary angioplasties in FYs 2005 and 2006.

The Applicants 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. The interventionalists shall be experienced and regularly perform more than 75 annual elective interventions at a full-service cardiac center. NMH will perform a minimum of 36 primary PCI procedures per year. The Applicants project the interventional cardiologists will perform in excess of the ideal recommended volume of primary angioplasties procedures at NMH in FY 2005. There will be formalized written protocols in place for immediate (within 1 hour) and efficient transfer of patients to the nearest full-service cardiac center, which are reviewed/tested on a regular basis. The procedures will be limited to patients with ST-segment elevation myocardial infarction or new left bundle branch block on the electrocardiogram. The procedures will be done in a timely fashion (balloon inflations within 90₊₃₀ minutes of admission). Primary intervention will be performed routinely as the treatment of choice around the clock (e.g. 24 hours per day/7 days a week) for a large proportion of patients with AMI, to ensure streamlined care paths and increased case volumes. New Milford Hospital will execute transfer agreements with NYPH, Hartford Hospital and may do so with other full-service cardiac centers within Connecticut. Patients and physicians will jointly determine the clinical appropriateness and preference for referral to these centers for ongoing care. Emergency transportation linkages have been well established through access to Hartford Hospital's LIFESTAR program.

The proposal will increase accessibility to cardiac catheterization and primary angioplasty services for residents of the proposed Connecticut service area and reduce hospital-to-hospital transfers of NMH's inpatients. From FYs 2000-2003, 39.2% (6.8% of total volume) of inpatient cardiac catheterizations and 42.6% (11.5% of total volume) of angioplasties originating from NMH's Connecticut service areas were performed at Hartford Hospital. Approximately 75 patients were transferred from NMH for a primary angioplasty procedure in FY 2002. An additional fifty (50) MI patients were transferred after assessment to full-service cardiac centers for further treatment and additional patients were subsequently transferred following admission to NMH's ICU/CCU.

There is a direct relationship between the time it takes a patient to undergo primary angioplasty and the outcome. The time that elapses between the onset of symptoms to the initiation of primary PCI is the most important factor in saving heart muscle during a STEMI event. Remoteness, road conditions, topography, travel distance and severity of winter weather conditions all impact the service area and increase travel time. Total minimum travel minutes from towns in NMH's proposed Connecticut service area to NMH and then to the three largest providers of angioplasty services in the service areas exceeds the ACC/AHA required 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. Emergency medical system travel logs could substantiate the current time delays

of four hours or more experienced by residents of NMH's Connecticut service area. 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 reduce total time to treatment and thus, fall within recommended standards for intervention. 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 will improve the quality of care and continuity of NMH's cardiac services. Studies have shown that low-risk elective and 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 cardiac catheterizations and primary angioplasty would be performed at NMH 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. Rigorous protocols for selection of appropriate low lesion risk and low clinical risk patients will be implemented. 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. A proven and fail-safe protocol for the rapid ambulance transport of patients with procedural complications requiring emergency cardiac surgery will be implemented. New Milford Hospital has the full commitment from cardiac surgery colleagues at a nearby tertiary facility to ensure immediate access to emergent cardiac surgery. The NMH physicians will have the capability to immediately consult with interventional and cardiac surgical colleagues. A formal protocol for data collection and analyses will be established with NYPH to ensure continuous program review and improvement.

The System and NYPH will be NMH's academic and clinical sponsors for the proposed service. Physician services and clinical oversight for the NMH catheterization laboratory service will be provided by Connecticut licensed physicians who are faculty members of CU. The System would arrange for consultative services to NMH in the following areas: physician credentialing recommendations; clinical training for professional and technical staff based on CPMC standards; development of NMH's care standards, risk stratification criteria, quality assurance programs, and operational policies and procedures based on CPMC standards and nationally recognized guidelines; clinical guidelines and protocols; collection and analysis of quality data for clinical outcomes and performance monitoring, and recruiting procedures. For the first 300 diagnostic cardiac catheterization cases, the Applicants stated that both CU physicians at CPMC who are licensed in Connecticut and NMH physicians would consult on the selection decisions for potential catheterization lab

candidates. The consultative services provided by the System in collaboration with NYPH will support the proposed program's transition to introduction of primary PCI on a 24-hour/7-day basis. NMH, with consultation from CU physicians at CPMC, would be responsible for recruiting an on-site Medical Director and practicing interventionalist who will perform the diagnostic and interventional procedures. The Director of Interventional Cardiology at CPMC will provide additional clinical oversight and quality leadership to the program. The proposed program would also enable a real-time review of images by Connecticut licensed physicians who are faculty members of CU and credentialed at CPMC, in conjunction with NMH based physicians.

Finally, the CON proposal is financially feasible. The proposal has a total expenditure cost of \$3,063,900, which consists of renovations to 3,232 square foot of vacant patient care area (2nd floor) in the hospital and the acquisition of cardiac catheterization equipment. The proposal will be financed from NMH's equity through operations. \$2,945,248 of the total projected Cash Flow provided from operations for FY 2004 of \$4,419,226 will be used to fund this proposal. The remaining \$118,652 of the capital expenditure will be funded from NMH's Cash Balance; no debt financing will be used. NMH projects incremental gains from operations of \$279,890 in FY 2004 and \$18,930 in FY 2006. However, in FY 2005, NMH projects a loss in operations of \$41,506 due to the initial implementation of the primary angioplasty program. Despite the implementation of the CON proposal, NMH projects gains from total hospital operations with the project of \$583,649, \$204,442 and \$194,847 for FYs 2004, 2005, 2006, respectively. Therefore, the CON proposal will not adversely impact the interests of consumers and payers of such services.

The Applicants' proposed diagnostic cardiac catheterization laboratory and primary angioplasty service is differentiated from other cardiac-related proposals in the following ways. First, NMH is located in a geographic pocket or outlying area where its residents have to travel an hour or more for emergent angioplasty; thereby not meeting the recommended door-to-balloon time of 90-120 minutes and increasing the risk of mortality and morbidity for its population. NMH area residents are currently not receiving the treatment of choice for its ST-segment elevation acute myocardial infarction patients. NMH's proposal will bring appropriate access to high quality cardiac services within a reasonable travel time. Second, NMH will be the first hospital in the state to initially establish a cardiac catheterization service and phase in a primary angioplasty program once acceptable annual volumes are reached. This approach assures the public of the sound professional judgment behind this proposal. Finally, NMH's strong collaborative relationship with the System will enhance the accessibility of high quality, community-based medical services offered by NMH. NMH will utilize the resources of the System to further enhance provision of quality care including access to the expertise, information, and support of a nationally recognized academic healthcare center renowned for the diagnosis and treatment of cardiac disease.

Order

NOW, THEREFORE, the Office of Health Care Access (“OHCA”) and New Milford Hospital and New York Presbyterian Healthcare System, Inc. (“Applicants”) hereby stipulate and agree to the terms of settlement with respect to the Applicants’ request to establish a diagnostic and interventional cardiac catheterization services to be located at New Milford Hospital at a total capital expenditure of \$3,063,900, as follows:

1. The Applicants’ request for a CON to establish a diagnostic cardiac catheterization laboratory and primary angioplasty services to be located at New Milford Hospital, and financed by New Milford Hospital at a total capital expenditure of \$3,063,900, is hereby approved.
2. The Applicants shall establish the diagnostic cardiac catheterization laboratory at New Milford Hospital initially. Once the number of diagnostic cardiac catheterizations exceeds 300 in any consecutive twelve-month period, the Applicants may transition the program to include primary angioplasty services. The primary angioplasty program shall operate 24 hours a day and seven days a week.
3. New Milford Hospital shall not exceed the approved total capital expenditure of \$3,063,900. In the event New Milford Hospital learns of potential cost increases or expects final project costs will exceed those approved, New Milford Hospital shall file with OHCA a request for approval of the revised CON project budget. The source of funding for the project will be New Milford Hospital’s operations and owner equity
4. New Milford Hospital shall complete and submit to OHCA on a quarterly basis the data elements in the Connecticut Cardiac Data Registry (Attachment III). 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 III. Data must be reported to OHCA thirty (30) business days following the end of the quarter. Fiscal Year quarters end December 31st, March 31st, June 30th, and September 30th. 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.
5. If the NMH cardiac catheterization laboratory and/or the physicians do not perform the ACC/AHA recommended minimum number of annual institutional or operator volumes, as specified in Attachment I, New Milford Hospital shall submit monthly reports of cardiac catheterization and 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 volumes are not met, the Applicants' primary PCI program shall be terminated. The Applicants shall file a Certificate of Need application for initiation of the primary PCI program only if volumes are not achieved by the end of the second 12-month period.

6. The Applicants agree that New Milford Hospital shall participate in the C-PORT registry and are 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 Milford Hospital shall provide OHCA quarterly data reports through such registry for the purposes of monitoring and quality assurance. If the Applicants determine not to participate in the C-PORT registry or the C-PORT registry no longer exists, the Applicants shall notify OHCA immediately, and continue to comply with the C-PORT guidelines and protocols.
7. The Applicants agree that New Milford Hospital shall participate in the ACC National Cardiovascular Database Registry (ACC-NCDR) and report all data including the optional follow-up section. New Milford Hospital shall provide OHCA quarterly data reports from the ACC-NCDR. The Applicants are required to comply with all the ACC/AHA criteria and standards for the performance of angioplasty at hospitals without on-site cardiac surgery, as specified in Attachment I. If the Applicants determine not to participate in the ACC-NCDR, New Milford Hospital shall notify OHCA immediately, and continue to comply with the ACC/AHA criteria and standards set forth in Attachment I.
8. New Milford 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, as indicated in Attachment I. If the ACC/AHA criteria and standards and/or the C-PORT guidelines are not met, the Applicants' primary PCI program shall be terminated.
9. New Milford Hospital shall provide OHCA with copies of dated and signed transfer agreements for cardiology services with NYPH and any other full-service cardiac centers sixty (60) days prior to commencement of operation of the diagnostic cardiac catheterization laboratory.
10. New Milford Hospital shall submit documentation of compliance with the fail-safe protocol for the rapid ambulance transport of patients with procedural complications requiring emergency cardiac surgery sixty (60) days prior to commencement of operation of the primary PCI program. This documentation shall include the annual number of STEMI patients transported by hospital and the door-to-balloon time for each patient. OHCA shall review documentation submitted for

compliance and if the ACC/AHA standards and C-PORT protocols are not being met, the Applicants' primary PCI program shall be terminated.

11. New Milford Hospital shall provide OHCA with a copy of a dated and signed Program Agreement with the System prior to commencement of operation of the diagnostic cardiac catheterization laboratory.
12. New Milford Hospital shall provide OHCA with a copy of its transfer log from NMH's emergency department (i.e. patient identifier, date of discharge/transfer, and door-to-balloon time) for the first full year of operation.
13. New Milford Hospital shall establish a digital data link system with Connecticut licensed physicians who are faculty members of CU and credentialed at CPMC, for the real-time review of diagnostic and interventional cardiac catheterization images. New Milford Hospital shall submit to OHCA the implementation date of the system.
14. New Milford Hospital shall obtain all further required approvals of the Department of Public Health and all other local, state and federal agencies governing the licensure and operation of health care facilities, and New Milford Hospital shall report to OHCA upon receiving such approvals.
15. OHCA and New Milford Hospital and New York Presbyterian Healthcare System, Inc. agree that this Agreed Settlement represents a final agreement between OHCA and New Milford Hospital and New York Presbyterian Healthcare System, Inc. with respect to this request. The signing of this Agreed Settlement resolves all objections, claims and disputes, which may have been raised by the Applicants with regard to Docket Number 03-30089-CON.
16. This authorization shall expire on March 29, 2007. Should the Applicants' diagnostic cardiac catheterization laboratory not be completed by that date, the Applicants must seek further approval from OHCA to complete the project beyond that date.
17. 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 Milford Hospital's expense, if the Applicants fail to comply with its terms.

Date Signed:
April 21, 2004

Signed by:
Richard E. Pugh
Duly Authorized Agent for
New Milford Hospital

Date Signed:
April 21, 2004

Signed by:
Arthur A. Klein, M.D.
Duly Authorized Agent for
New York Presbyterian Healthcare System, Inc.

The above Agreed Settlement is hereby accepted and so ordered by the Office of Health Care Access on April 21, 2004.

Date Signed:
April 21, 2004

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

CV:km

ATTACHMENT I

NMH's General Exclusion Criteria for Invasive Cardiac Procedures

Type of Patient	Diagnostic Procedures	Therapeutic Procedures
Adult	<ul style="list-style-type: none"> • Age >75 years • NYHA Class III or IV heart failure • Acute, intermediate, or high-risk ischemic syndromes • Recent MI with post infarction ischemia • Pulmonary edema thought to be caused by ischemia • Markedly abnormal noninvasive test indicating a high likelihood of left main or severe multivessel coronary disease • Known left main coronary artery disease • Severe valvular dysfunction, especially in the setting of depressed left ventricular performance • Patients at increased risk for vascular complications • Complex adult congenital heart disease 	<ul style="list-style-type: none"> • All valvuloplasty procedures • Diagnostic pericardiocentesis when the effusion is small or moderate in size and there is no tamponade • Elective coronary interventions • Therapeutic procedures in adult congenital heart disease
Pediatric	No procedures	No procedures

* Criteria adapted from the Report of American College of Cardiology Task Force on Clinical Expert Consensus Documents, General Exclusion Criteria for Invasive Cardiac Procedures in Settings without Cardiac Surgery

NMH's Risk Stratification Criteria - Primary Angioplasty

Criteria for the Performance of Primary Angioplasty
<ol style="list-style-type: none"> 1. The physicians shall be experienced interventionalists who regularly perform elective intervention at a surgical center (≥ 75 cases/year). NMH 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 of 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).

ATTACHMENT I

9. There shall be an ongoing program of outcomes analysis and formalized periodic case review.
10. NMH 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.

* Criteria adapted from the ACC/AHA Guidelines for Percutaneous Coronary Interventional Procedures (Revision of the 1993 PTCA Guidelines) - Executive Summary (attached to CON Application at A-17), Criteria for the Performance of Primary Angioplasty at Hospitals Without On-Site Cardiac Surgery

NMH's Patient Selection Criteria - Primary Angioplasty/Transfer to Full-Service

Cardiac Center

NMH shall not perform intervention in hemodynamically stable patients with:

- Significant ($\geq 60\%$) stenosis of an unprotected left main (LM) coronary artery upstream from an acute occlusion in the left coronary system that might be disrupted by the angioplasty catheter
- Extremely long or angulated infarct-related lesions with TIMI grade 3 flow
- Infarct-related lesions with TIMI grade 3 flow in stable patients with 3-vessel disease
- Infarct-related lesions of small or secondary vessels
- Lesions in other than the infarct artery

NMH shall transfer patients for emergent aortocoronary bypass surgery when the patient has:

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

* Criteria adapted from the ACC/AHA Guidelines for Percutaneous Coronary Interventional Procedures (Revision of the 1993 PTCA Guidelines) - Executive Summary (attached to CON Application at A-17), Patient Selection for Angioplasty and Emergency Aortocoronary Bypass at Hospitals without On-Site Cardiac Surgery

ACC/AHA Standards and CPORT guidelines – Transition to Primary PCI

- Accepted rate of “normal” cardiac catheterizations within the range of 20% to 27%;
- Accepted outcomes relating to complications for diagnostic catheterization of less than 1%, including:
 - ✓ Mortality rate of 0.08%
 - ✓ Myocardial Infarction rate of 0.03%
 - ✓ Neurological complication rate of 0.06%
 - ✓ Arrhythmia complication rate of 0.33%
- Minimum individual operator procedural volume of 75 interventions per year; and
- Minimum institutional volume of primary angioplasty procedures of 36 per year.

Minimum Travel Minutes within New Milford Hospital's Proposed Service Area to Current Angioplasty Providers¹

Patient Town	To New Milford Hospital	Total minimum travel minutes ² from patient town to New Milford Hospital and then to:		
		Bridgeport Hospital	Hartford Hospital	Yale-New Haven Hospital
Primary Service Area				
Bridgewater	8	83	89	90
Brookfield	17	92	98	99
Cornwall	57	132	138	139
Kent	29	104	110	111
New Milford	-	75	81	82
Roxbury	15	90	96	97
Sherman	15	90	96	97
Warren	26	101	107	108
Washington	20	95	101	102
Secondary Service Area				
Canaan	84	159	165	166
Litchfield	37	112	118	119
Morris	36	111	117	118
North Canaan	86	161	167	168
Salisbury	83	158	164	165
Sharon	64	139	145	146
Tertiary Service Area				
Bethlehem	37	112	118	119
Colebrook	74	149	155	156
Goshen	48	123	129	130
Norfolk	77	152	158	159
Southbury	33	108	114	115
Torrington	47	122	128	129
Winchester	63	138	144	145
Woodbury	32	107	113	114

Source: Yahoo Maps

¹Travel times reported to the three largest current providers of angioplasty services to the residents of the proposed service area: Hartford Hospital (43%), Bridgeport Hospital (19%), and Yale-New Haven Hospital (15%).

²"Total minimum travel" minutes is the sum of travel minutes from the patient town to New Milford Hospital added to the travel minutes from New Milford Hospital to the three largest providers of angioplasty services in the proposed service area: 1) Bridgeport Hospital (75 minutes) 2) Hartford Hospital (81 minutes) 3) Yale-New Haven Hospital (82 minutes).

These are "minimum travel minutes" because they do not include such things as ambulance response times, time in NMH's Emergency Department, and delays relating to patient transfer to current angioplasty providers. The percentage of Myocardial Infarction or primary angioplasty eligible patients brought directly to New Milford Hospital's Emergency Department and those brought there and transferred to other acute care hospitals cannot be reported here because OHCA does not currently have regulations in place to collect Emergency Department data. Furthermore, OHCA does not collect patient social security numbers or a unique patient identifier that would allow it to distinguish particular patients who had been transferred between acute care hospitals.

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.

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.

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.
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.

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.
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."

Attachment A: Hospital Numbers

Hospital	Hospital Number
William Backus	01
Bradley Memorial	02
Bridgeport	03
Bristol	04
Danbury	05
Day Kimball	06
Greenwich	07
Griffin	08
Hartford	09
Charlotte Hungerford	10
Johnson Memorial	11
Lawrence and Memorial	12
Manchester Memorial	13
Middlesex	15
Milford	16
New Britain	18
New Milford	19
Norwalk	20
Rockville	22
Saint Francis	23
Saint Mary's	25
Saint Raphael's	26
Saint Vincent's	27
Sharon	28
Stamford	29
Waterbury	30
Windham	31
Yale-New Haven	34
CT Children's Medical Center	35
MidState Medical Center	36
John Dempsey	37

**Attachment B: Patient
Town Codes**

Patient Town	Code
Andover	401
Ansonia	201
Ashford	301
Avon	402
Barkhamsted	501
Beacon Falls	502
Berlin	403
Bethany	221
Bethel	503
Bethlehem	504
Bloomfield	404
Bolton	439
Bozrah	302
Branford	203
Bridgeport	101
Bridgewater	505
Bristol	406
Brookfield	506
Brooklyn	303
Burlington	407
Canaan	507
Canterbury	304
Canton	408
Chaplin	305
Cheshire	508
Chester	306
Clinton	307
Colchester	308
Colebrook	509
Columbia	309
Cornwall & Warren	510
Coventry	310
Cromwell	311
Danbury	511
Darien	102
Deep River	312
Derby	204
Durham	313
East Granby	409
East Haddam	315
East Hampton	316
East Hartford	410
East Haven	205
East Lyme	317
East Windsor	411
Eastford	314
Easton	103
Ellington	412

Enfield	413
Essex	318
Fairfield	104
Farmington	414
Franklin	319
Glastonbury	415
Goshen	512
Granby	416
Greenwich	105
Griswold & Lisbon	320
Groton	321
Guilford	206
Haddam	322
Hamden	207
Hampton	323
Hartford	417
Hartland	418
Harwinton	513
Hebron	419
Kent	514
Killingly	324
Killingworth	359
Lebanon	326
Ledyard	327
Litchfield	515
Lyme	329
Madison	208
Manchester	420
Mansfield	330
Marlborough	421
Meriden	209
Middlebury	516
Middlefield	331
Middletown	332
Milford	210
Monroe	106
Montville	333
Morris	517
Naugatuck	518
New Britain	422
New Canaan	107
New Fairfield	519
New Hartford	520
New Haven	211
New London	334
New Milford	521
Newington	423
Newtown	522
Norfolk	523
North Branford	212
North Canaan	524
North Haven	213

North Stonington	335
Norwalk	108
Norwich	336
Old Lyme & Lyme	337
Old Saybrook	338
Orange	214
Oxford	222
Plainfield	339
Plainville	424
Plymouth	425
Pomfret	340
Portland	341
Preston	357
Prospect	525
Putnam	343
Redding	526
Ridgefield	527
Rocky Hill	426
Roxbury	528
Salem	358
Salisbury	529
Scotland	345
Seymour	216
Sharon	530
Shelton	217
Sherman	531
Simsbury	427
Somers	428
South Windsor	430
Southbury	532
Southington	429
Sprague	346
Stafford & Union	431
Stamford	109
Sterling	347
Stonington	348
Stratford	110
Suffield	432
Thomaston	533
Thompson	349
Tolland	433
Torrington	534
Trumbull	111
Vernon	434
Voluntown	351
Wallingford	218
Washington	536
Waterbury	537
Waterford	352
Watertown	538
West Hartford	435
West Haven	219

Westbrook	353
Weston	112
Westport	113
Wethersfield	436
Willington	354
Wilton	114
Winchester	539
Windham	355
Windsor	437
Windsor Locks	438
Wolcott	540
Woodbridge	220
Woodbury	541
Woodstock	356
Non-CT Residents	
Massachusetts	600
New York	700
Rhode Island	800
Unknown CT	997
Other State/Country	998
Unknown	999