



Office of Health Care Access Certificate of Need Application

Agreed Settlement

Applicants: The Waterbury Hospital and St. Mary's Hospital Corporation, d/b/a Waterbury Area Heart Center, Inc. and University of Connecticut Health Center/John Dempsey Hospital

Docket Number: 03-30167-CON

Project Title: Establish a Primary and Elective Angioplasty and Open Heart Surgery Program at Waterbury Hospital and St. Mary's Hospital

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

Filing Date: April 20, 2004

Hearing Dates: May 19, 2004 and June 2, 2004

Presiding Officer: DPH Commissioner Robert Galvin, M.D.

Decision Date: July 23, 2004

Default Date: Not Applicable

Project Description: The Waterbury Hospital and St. Mary's Hospital Corporation, d/b/a Waterbury Area Heart Care, Inc and University of Connecticut Health Center/John Dempsey Hospital ("Applicants") proposes to establish a primary and elective angioplasty and open-heart surgery program at St. Mary's Hospital and The Waterbury Hospital, at a total capital expenditure of \$7,181,248.

Nature of Proceedings: On April 20, 2004, the Office of Health Care Access (“OHCA”) received the Applicants’ Certificate of Need (“CON”) application seeking authorization to establish a primary and elective angioplasty and open-heart surgery program at St. Mary’s Hospital and Waterbury Hospital at a total capital expenditure of \$7,181,248. The Applicants are health care facilities or institutions as defined by Section 19a-630 of the Connecticut General Statutes (“C.G.S.”).

Public hearings regarding the CON Application were held on May 19, 2004 and June 2, 2004. The Applicants were notified of the date, time, and place of the hearings and notices to the public were published prior to the hearings in *Waterbury Republican American* (Waterbury). OHCA Commissioner Cristine A. Vogel designated DPH Commissioner J. Robert Galvin, M.D. 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 Sections 19a-638 and 19a-639, C.G.S.

Yale-New Haven Hospital, Bridgeport Hospital, and St. Vincent’s Medical Center petitioned for party or in the alternative intervenor status with the right to present evidence and cross-examine the Applicants. The Presiding Officer granted their requests for intervenor status with the right to present evidence and cross-examine the Applicants.

The Presiding Officer heard testimony from the general public, legislators, local officials and witnesses for the Applicants and Intervenors. In rendering this decision, the presiding officer has 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 this section, as well as the principles and guidelines set forth in Section 19a-637, C.G.S., were considered by OHCA in its review.

Findings of Fact

Clear Public Need

Impact on the Applicants’ Current Utilization Statistics

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

1. St. Mary’s Hospital (“SMH”) is an acute care hospital with 379 acute care beds located at 56 Franklin Street, Waterbury, Connecticut. (*August 25, 2004, Letter of Intent & St. Mary’s Hospital, 2002 Annual Reporting, Schedule 500*)
2. The Waterbury Hospital (“TWH”) is an acute care hospital with 393 acute care beds located at 64 Robbins Street, Waterbury, Connecticut. (*August 25, 2004, Letter of Intent & The Waterbury Hospital, 2002 Annual Reporting, Schedule 500*)
3. University of Connecticut Health Center/John Dempsey Hospital (“UCHC/JDH”) is an acute care hospital with 224 acute care beds located at 263 Farmington Avenue, Farmington, Connecticut. On April 29, 1994, JDH was approved under Docket Number 92-581 for the expansion of its cardiac services through addition of

angioplasty and open-heart surgery service. (*Agreed Settlement, April 29, 1994, DN 92-581*)

4. The University of Connecticut Health Center Finance Corporation (“UCHCFC”) was created by public act to promote maximum flexibility for John Dempsey Hospital and Uncas-on-Thames Hospital to continue to serve effectively as the teaching hospitals of The University of Connecticut and to provide lower cost health care to benefit the people of the state of Connecticut. (*C.G.S. Chapter 187c, Section 10a-251*)
5. Currently, both SMH and TWH offer acute and ambulatory cardiology services, including electrocardiology, echo cardiology, diagnostic cardiac catheterization¹, 24-hour ambulatory ECG monitoring, exercise stress testing with and without thallium, nuclear cardiology and rehabilitation. (*August 25, 2003, Letter of Intent*)
6. The Applicants propose to establish a primary and elective angioplasty² (“PCI”) and open-heart surgery³ (“OHS”) program at St. Mary’s Hospital and Waterbury Hospital. (*December 23, 2003 CON Application, page 28*)
7. The Applicants stated that they will operate a one-stop postoperative model for post procedure care, whereby the patient remains in the same bed while the acuity and nursing care levels are adapted to meet their changing care needs. This model provides seamless patient care, promotes exceptional clinical outcomes and cost efficiencies and is considered patient, family and physician friendly. A post-operative patient will receive his or her post-procedure care from the same staff

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 (Emergent) or Elective (Scheduled) Percutaneous Coronary Intervention (PCI) or Coronary Angioplasty (PCA) is an interventional procedure performed in a catheterization laboratory 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. National data show that 14-20% of all acute myocardial infarctions or heart attacks are eligible for treatment with primary angioplasty. Primary angioplasty is clinically indicated for patients with ST segment elevation MI (STEMI) or left bundle branch block (LBBB) who need immediate intervention to open an occlusion within 90-120 minutes. Recent studies have shown that primary angioplasty can be performed in hospitals without on-site cardiac surgery because the benefit to using primary angioplasty over thrombolytics or clot busting medications outweighs the risk of having a complication that may then require cardiac surgery. Non-ST Segment elevation MI (NSTEMI or high-risk) patients consist of 80% of all MIs and are considered for angioplasty on an elective basis within 72 hours. Performance of elective angioplasty without cardiac surgery back up is not recommended by the American College of Cardiology or the American Heart Association.

³ Open-heart surgery is a surgical intervention performed on the opened heart while the bloodstream is diverted through a heart-lung machine. Cardiac Surgery includes Coronary Artery Bypass Graft (CABG), Valvuloplasty, and Valve Replacement. CABG is where a vein from the chest or leg, or a prosthesis, is grafted onto either side of a blockage in the coronary artery. This reroutes blood flow around the blockage to the heart muscle. Valvuloplasty is where a balloon tipped catheter is inserted into plaque-blocked heart valves to widen and separate them through repeated balloon inflation. A Valve Replacement is a replacement of plaque-blocked heart valves with prosthetic or tissue graft.

members throughout their hospital recovery. (*December 23, 2003 CON Application, Statement of Need, page IV, and May 27, 2004 Responses to the Interrogatories, page 5*)

8. The Applicants propose the establishment of a management services organization to be known as the Waterbury Area Heart Center, Inc. (“WAHC”). The concept of WAHC is as follows:
 - Staff will consist of a heart program administrator, data analyst, and administrative assistant;
 - Responsibilities include program coordination, quality/training coordination, marketing coordination, and community wellness and outreach;
 - Ownership will be 50% for SMH and 50% for TWH;
 - Establishment of an advisory board to oversee WAHC; and
 - UCHC/JDH will supply the cardiac surgeons for the proposed programs, including a Waterbury-based surgeon, who will be responsible for medical directorship and the medical staff members at SMH and TWH.

(*August 25, 2004, Letter of Intent and December 23, 2004, Certificate of Need Application, Statement of Need, page xi*)
9. The proposed PCI and OHS program at SMH and TWH will be jointly managed by both SMH and TWH through WAHC. The provision of PCI and OHS services will be integrated into existing departments at each hospital. (*August 25, 2003, Letter of Intent*)
10. On April 21, 2004, SMH, TWH, University of Connecticut Health Center Finance Corporation signed a clinical oversight agreement for a period of three years with the following recitals:
 - a) Establish a joint PCI and OHS program provided at two sites utilizing existing cardiac catheterization capacity and cardiac operating rooms to be constructed at the two sites.
 - b) WAHC serves as a management services organization to oversee the program providing programmatic, quality, marketing, and community wellness coordination.
 - c) UCHC’s responsibilities include program implementation support, surgical services, perfusion services, staff recruitment/training support and independent oversight for quality assurance for the program. Specifically:
 - i. Provision of cardiac surgery by physicians of Connecticut Cardiothoracic Surgical Associates, LLC (“CCSA”);
 - ii. Consultation with WAHC, TWH, and SMH in the day-to-day administrative and operational management for the PCI and OHS programs at SMH and TWH;
 - iii. Provision of training and instruction at UCHC for Surgical, ICU, Cath Lab, and Inpatient Cardiac Nursing Staff; and
 - iv. Rotation of UCHC staff to TWH and SMH to provide on-site supervision and education of staff.

(*June 9, 2004, Late Files, pages 14-37*)

11. Dr. Bruce Liang, Chair of Cardiology at UCHC/JDH testified that the administration and clinical staff at UCHC/JDH are committed to supporting the training of SMH and TWH staff. *(June 2, 2004, WAHC Presentation)*
12. The Advisory Board will provide the strategic planning direction for the proposed programs, whose members include SMH, TWH, UCHC/JDH administration, clinical leaders, cardiologists, cardiac surgeons and other physicians. Hospital staff at all levels will be involved in the program development and routine management. *(December 23, 2003, Certificate of Need Application, page iii)*
13. CCSA will be the surgical group to provide cardiac surgery services for the OHS programs. CCSA will follow the same surgical coverage model (i.e. time to respond) as currently practiced at JDH and Hartford Hospital. The Applicants and CCSA will ensure the following:
 - a) At least four (4) surgeons facilitating coverage of the four sites (i.e. SMH, TWH, UCHC/JDH, and Hartford Hospital).
 - b) One of the four surgeons will reside in close proximity to Waterbury and is expected to be the “primary” or “lead” surgeon for the proposed OHS programs.
 - c) CCSA will obtain privileges at SMH and TWH.
 - d) The surgeons would develop a rotation schedule identifying the “lead” or “primary” surgeon for each site as well as a “second” surgeon for each facility. This schedule will be distributed to each hospital’s cardiac catheterization laboratory and emergency department.
(April 20, 2004, Certificate of Need Application, page 40 and May 27, 2004 Responses to the Interrogatories, page 5)
14. The Applicants stated that the proposed cardiac surgeons, Drs. Jonathan Hammond, Paul Preissler, David Underhill, and Henry Low are credentialed at both UCONN and Hartford Hospital and performed over 500 cardiac surgeries in 2003. *(May 27, 2004 Responses to the Interrogatories, page 5 and June 2, 2004, WAHC Presentation)*
15. Both SMH and TWH currently have cardiac operating room staff (PA, RN, LPN or CST) in-house 24 hours a day, seven days a week, and 365 days a year. All medical staff and on-call personnel for the proposed program will have a 30-minute arrival to hospital expectation. *(April 20, 2004, Certificate of Need Application, page 30)*
16. The Applicants will develop a cardiac team that will be comprised of surgeons, cardiologists, cardiac physician assistants and other physicians such as intensivists. The City of Waterbury has 14 cardiologists practicing between SMH and TWH. The proposed staffing plan includes 10 physician assistants specializing in cardiac care to provide care at both SMH and TWH and to be recruited upon program approval. *(May 27, 2004, Responses to the Interrogatories, page 4)*
17. Cardiology Associates of Waterbury, P. C. (“CAW”) is a physician practice, which consists of 8 cardiologists, serving the Greater Waterbury Area (“GAW”). Dr. Borkowski, President and CEO of CAW, testified that his practice provides

emergency, urgent, and elective cardiovascular care in the hospitals. (*May 27, 2004, Prefile Testimony, page 8*)

18. The Applicants stated that the interventional cardiologists for the proposed PCI program, Drs. Kevin Kett and Stephen Widman, are members of CAW and performed over 350 angioplasty procedures in 2003, primarily on the residents of the GWA. (*June 2, 2004, WAHC Presentation*)
19. The Applicants stated that they have identified a third interventional cardiologist who will join CAW upon program approval. There are also 12 other cardiologists who currently provide care to patients with cardiovascular disease and will continue to provide support for the proposed PCI program. (*May 27, 2004, Responses to the Interrogatories, page 4*)
20. For the angioplasties, the Applicants have established a call schedule that includes a first call (first responder) and a backup call person who will be called in at the discretion of the first call person. One of the duties of the backup call person would be to respond to the second hospital if the first call person is actively engaged in a procedure at the other hospital. (*May 27, 2004, Responses to the Interrogatories, page 7*)
21. The Applicants' service areas for the proposed program consist of the following Connecticut towns:

Table 1
SMH and TWH PCI and OHS Programs' Proposed Service Areas

Towns	Primary	Secondary
	Beacon Falls	Morris
	Bethlehem	Oxford
	Cheshire	Plymouth
	Middlebury	Seymour
	Naugatuck	Southington
	Prospect	Torrington
	Southbury	
	Thomaston	
	Waterbury	
	Watertown	
	Wolcott	
	Woodbury	
Hospitals Share of Inpatient Cardiac Catheterizations		
St. Mary's	21.9%	1.5%
Waterbury	33.4%	2.4%
Area's Share of Hospital's Inpatient Cardiac Catheterizations		
St. Mary's	95.4%	2.4%
Waterbury	95.5%	2.5%

(*December 23, 2003 CON Application, page 11 and OHCA Acute Care Hospital Inpatient Discharge Database*)

22. The Applicants developed their primary and secondary service areas designated as the Total Cardiovascular Target Market (“TCTM”) based on their review of all cardiovascular admissions to SMH and TWH. (*April 20, 2004, Certificate of Need Application, pages 7-8*)
23. There is no provider of elective PCI or open-heart surgery in the proposed service areas of the proposed programs. The nearest providers of these services to SMH and TWH are in Bridgeport (31 miles) or New Haven (35 miles). (*Yahoo Maps*)
24. The historical diagnostic cardiac catheterization volume for SMH and TWH is as follows:

Table 2
SMH’s Historical Cardiac Catheterization Volume
(FYs 2000 – 2003 1st 2 Quarters)

CT Service Area	2000	2001	2002	2003
Inpatient	300	312	292	153
Outpatient	224	239	243	129
Total	524	551	535	282

Source: OHCA Acute Care Hospital Inpatient Discharge Database and self-reported outpatient figures.

Table 3
TWH’s Historical Cardiac Catheterization Volume
(FYs 2000 – 2003 1st 2 Quarters)

CT Service Area	2000	2001	2002	2003
Inpatient	436	470	451	252
Outpatient	303	277	341	164
Total	739	749	792	416

Source: OHCA Acute Care Hospital Inpatient Discharge Database and self-reported outpatient figures.

25. The Applicants state that there were 570 OHS and 940 PCI cases performed on citizens from the GWA in the one-year period evaluated for the CON application. (*May 27, 2004, Responses to the Interrogatories, pages 1 and 3*)
26. The Applicants based the need for the proposed PCI and OHS program at two sites on the following:
- Historical catheterization and current referral volume
 - Adopting a standard of care that exists in three other large urban areas
 - Improved patient safety by providing service at the time of diagnosis
 - Improved access and availability of cardiac care in regional service area
 - Reduced time from symptom onset to treatment
 - Improved continuity of care
 - Reduction in mortality and morbidity.
- (*December 23, 2003, Certificate of Need Application, Attachment 4, May 27, 2004, Responses to the Interrogatories, June 9, 2004, Closing Statements*)

27. The demographic characteristics of SMH and TWH’s service areas for the proposed program are as follows:

Table 4
Demographic Characteristics of CT Service Areas

Service Area	Population				
	Total	Adults (15+)	15 – 44 (%)	45 – 64 (%)	65+ (%)
Primary	262,773	206,005	41.2	22.6	14.6
Secondary	114,140	91,310	40.1	24.3	14.8
Total PSA	376,913	297,315	41.1	23.1	14.6
Connecticut	3,405,565	2,696,490	42.2	23.2	13.8

Source: Census 2000.

28. The Applicants provided census data from Claritas, Inc., which indicates an increase of 9.2% in the age 45+populations for the WAHC primary TCTM population by the year 2007. The secondary TCTM age 45+populations are estimated to grow by 8.4%. These projections could not be verified due to the claimed proprietary nature of the information. (April 20, 2004, Certificate of Need Application, page 11)
29. On a statewide basis, there was a 12% decline in the number of adult open-heart surgeries and an 8% increase in PCIs from 2000 to 2003, as seen in **Attachment I**.
30. The average annual historical and projected PCI and OHS volumes for the proposed service areas are as follows:

Table 5
**Average Annual Historical and Projected PSA PCI
 and OHS Volumes (FY 2000 - 2003)**

Procedure	FY 2000-2003 Historical Utilization			FY 2005	FY 2006	FY 2007
	Volume	Adult Use Rate	Market Share (%)	Projected Volume	Market Share (%)	Projected Volume
All PCI	973	3.3	38%	370	44%	506
Primary PCI	290	1.0	38%	110	44%	151
Surgery	574	1.9	38%	218	44%	298

Note: The Applicants based the above projected PCI and OHS market share levels on SMH’s and TWH’s current inpatient diagnostic cardiac catheterization market share.

Source: OHCA Acute Care Hospital Inpatient Discharge Database, Census 2000 for population figures, and December 23, 2003 CON Application, page 42 for market share rates).

31. The average annual ischemic heart disease and AMI discharges and deaths in the proposed service areas for the proposed program are as follows:

Table 6
Average Annual Ischemic Heart Disease
and AMI Discharges and Deaths in PSA (FYs 1999 – 2003^a)

Service Area	Discharged from CT Hospitals				Mortality	
	Ischemic Heart Disease ^b		AMI		Ischemic Heart Disease	
	Discharges	Adult Rate	Discharges	Adult Rate	Deaths	Adult Rate
Primary	2,203	10.7	906	4.4	530	2.6
Secondary	897	9.8	333	3.6	213	2.3
Total PSA	3,100	10.4	1,239	4.2	743	2.5
Connecticut	-	8.2	-	3.2	-	1.9

Source: OHCA Acute Care Hospital 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.

32. The average annual PCI and OHS volumes in the proposed service areas for the proposed program are as follows:

Table 7
Average Annual PCI and OHS Volumes in PSA by Provider
(FYs 2000 – 2003)

Hospital	PCIs			Open-Heart Surgeries		
	Procedures	Market Share (%)	Area Volume as Share of Total Provider Volume (%)	Procedures	Market Share (%)	Area Volume as Share of Total Provider Volume (%)
Bridgeport	399	41.0	32.5	40	6.9	11.5
Hartford	94	9.7	7.4	58	10.1	6.4
John Dempsey	39	4.0	19.1	13	2.2	9.0
Saint Francis	52	5.3	4.3	54	9.5	4.3
Saint Raphael's	167	17.2	19.0	269	46.9	34.3
Saint Vincent's	103	10.5	9.0	9	1.5	2.8
Yale	114	11.7	7.3	124	21.6	12.7
Out of State	5	.5	-	8	1.4	-
Totals	973	100.0	-	574	100.0	-

Source: OHCA Acute Care Hospital Inpatient Discharge Database.

33. SMH and TWH will develop additional required guidelines and care pathways during the implementation phase of the project with assistance of UCHC/JDH, cardiologists, cardiac surgeons and other clinical specialists. A Quality Assurance

plan will be developed during the implementation phase. (*December 23, 2003, Certificate of Need Application, page 50*)

34. The Applicants' proposed PCI and OHS program at two sites would follow the American College of Cardiology ("ACC"), American Heart Association ("AHA") and Society of Thoracic Surgeons ("STS") guidelines, as specified in **Attachment II**. The Applicants propose to collect all relevant program information as recommended by the ACC and STS. The Applicants propose to purchase an ACC/STS approved data collection system and to report the information to the national data collection center. (*December 23, 2003, Certificate of Need Application, page 51*)
35. Studies have shown that 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"*)
36. Travel times from SMH and TWH to the three full-service cardiac providers most used by the Applicants' patients in the Applicant's proposed service area are 44 minutes to Bridgeport Hospital, 40 minutes to the Hospital of St. Raphael, and 42 minutes to Yale-New Haven Hospital. Travel minutes are only one factor in the total time to transfer a patient which also includes such things as ambulance response times, time in SMH and TWH Emergency Department, and any other delays relating to patient transfer to current full-service providers. (*Yahoo Maps*)
37. The 2001 ACC and AHA Guidelines for PCI recommend that PCI be performed by higher volume operators (>75 cases/year) with advanced technical skills (e.g. subspecialty certification) at institutions with fully equipped interventional laboratories and experienced support staff. This setting will most often be in a high-volume center (>400 cases/year) associated with an on-site cardiovascular surgical program. Therefore, angioplasty is best done by high-volume operators in high-volume institutions. (*JACC, 2001, Vol. 37, No.8, page 2239*)
38. Numerous studies have indicated that high volume programs and high volume operators have the best outcomes:
 - In the era of coronary stents, Medicare patients treated by high-volume (>60 PCIs) physicians and at high-volume (>160 PCIs) centers experience better outcomes following PCIs. (*McGrath, et al, "Relation Between Operator and Hospital Volume and Outcomes Following Percutaneous Coronary Interventions in the Era of the Coronary Stent", JAMA, 2000;284:3139-3144*)
 - PCI generally should not be conducted in a low-volume hospitals unless there are substantial overriding concerns about geographic or socioeconomic access. (*Jollis and Romano, MDs, "Volume-Outcome Relationship in Acute Myocardial Infarction, JAMA, 2000:284,24*)
 - Patients hospitalized for MI in New England have the highest use of B-Blocker and aspirin therapy, a low use of reperfusion therapy, and the lowest risk-

adjusted 30-day mortality rate of patients nationwide. (*Krumholz, et al, "Regional variation in the treatment and outcomes of myocardial infarction: Investigating New England's advantage", American Heart Journal, August 2003*)

- Risk-adjusted mortality rates for Medicare patients undergoing CABG surgery during 1994 to 1999 were 22% higher in states without CON regulation. (*Vaughan-Sarrazin, PhD, et al, "Mortality in Medicare Beneficiaries Following CABG Surgery in States With and Without CON Regulation", JAMA, October 16, 2002, Vol 228, No. 15*)
39. A recent article by Epstein, et al. found no evidence of higher in-hospital mortality in patients undergoing PCI at medium volume (200-399 cases/year) hospitals compared with patients treated at hospitals with annual PCI volumes of 400 cases or more. Note: The study did not take into account angiographic characteristics or lesion complexity of patients, co-morbidity amongst patient populations, or whether operator volume affects outcome. (*Epstein, et al., "Hospital Percutaneous Coronary Intervention Volume and Patient Mortality, 1998 to 2000", JACC 2004; 43:1755-62 and Editorial Comment*)
40. The ACC/AHA Guidelines for CABG Surgery (1999) state the following:
- a) Studies suggest that survival after CABG is negatively affected when carried out in institutions that perform fewer than a threshold number of cases annually. Similar conclusions have been drawn regarding individual surgeon volumes.
 - b) The ACC/AHA are supportive of a posture of close monitoring of institutions or individuals that perform <100 cases annually.
41. The Guidelines for Standards in Cardiac Surgery by the Advisory Council for Cardiothoracic Surgery and the American College of Surgeons (1996) state the following:
- a) An annual volume of at least 100 to 125 open-heart procedures per hospital is necessary from a quality standpoint and there is a greater variation in adjusted mortality rates for teams doing lower volumes of procedures as compared with those doing a high volume.
 - b) At least 200 procedures per year as previously recommended in the 1975 report of the Inter-Society Commission on Heart Disease Resources are necessary in order for a program to function efficiently.
 - c) A team approach with a minimum of two qualified cardiac surgeons is recommended to provide adequate and continuous perioperative care as well as assistance in the operating room.
42. The Applicants project the following number of primary and elective angioplasties for the first three years of operation as follows:

Table 8
Percutaneous Coronary Interventions
3-Year Volume by Hospital

Hospital	Year One	Year Two	Year Three
St. Mary's Hospital	179	210	247
Waterbury Hospital	179	210	247
WAHC Total	358	420	494

(April 20, 2004, Certificate of Need Application, page 37)

43. The Applicants project the following number of PCIs by cardiologist for the first three years of operation as follows:

Table 9
Percutaneous Coronary Interventions
3 Years by Cardiologist

Cardiologist	Year One	Year Two	Year Three
Dr. Stephen Widman	179	210	247
Dr. Kevin Kett	179	210	247
WAHC Total	358	420	494

(April 20, 2004, Certificate of Need Application, page 38)

44. The Applicants project the following number of open-heart surgeries for the first three years of operation as follows:

Table 10
Open-Heart Surgeries
3-Year Volume by Hospital

Hospital	Year One	Year Two	Year Three
St. Mary's Hospital	107	125	147
Waterbury Hospital	107	125	147
WAHC Total	214	250	294

(December 23, 2003, Certificate of Need Application, page 39)

Note: The projections are based on 3 surgeons providing service at 4 institutions.

45. The Applicants projected PCI and OHS volumes are based on historical inpatient diagnostic cardiac catheterization utilization and market share in the proposed services areas. The Applicants applied a market share of 38% for the first year of operation. *(December 23, 2003, Certificate of Need Application, page 42)*
46. The Applicants testified to the following:
- The PCI and OHS volumes at each site will meet or exceed ACC/AHA guidelines.
 - There will be one group of physicians, one set of clinical protocols, one quality assurance program and one administration for WAHC.
 - 3 interventional cardiologists will perform PCIs at SMH and TWH initially at projected volume. Another interventional cardiologist will be hired as volume and on-call needs dictate.
 - 3-4 cardiac surgeons will perform OHS at SMH and TWH initially with possibly 5-6 as volume and on-call needs dictate.

- e) There will be a cardiac surgeon physically located in the GWA at all times. The “primary” cardiac surgeon will live in the GWA.
- f) CCSA will open an office in the City of Waterbury upon commencement of the program.
- g) CCSA will arrange for sleeping quarters in the City of Waterbury for covering cardiac surgeons upon program approval.
- h) When the “primary” cardiac surgeon is on vacation or unavailable, a covering CCSA cardiac surgeon will physically be present day and night in the City of Waterbury.
- i) It is rare that two emergency OHS occur at the same time. However, if this did occur, another CCSA surgeon would travel to Waterbury to take the 2nd emergency case. Given the amount of time that elapses for cardiac testing and other preparatory work that occurs, the patient will not be in danger of waiting for the surgeon to arrive from outside the Waterbury area.

(May 27, 2004, Prefile Testimony, June 2, 2004, Hearing Testimony, and June 9, 2004, Late Files, page 10)

47. Yale-New Haven Hospital, Bridgeport Hospital, and St. Vincent’s Medical Center testified to the following:

- a) The direct correlation between a hospital’s procedural volume and its quality,
- b) The statewide decline in the number of OHS cases due to advancements in angioplasty,
- c) The flattening of PCI volume due to enhancements in medical therapies and interventional techniques,
- d) Excess capacity and excellent clinical outcomes (i.e. New England Advantage) at existing full-service cardiac providers,
- e) Proliferation of full-service cardiac programs will decrease quality and increase cost to existing programs,
- f) Shift of PCI and OHS volume from existing providers, and
- g) Two low-volume cardiac programs in Waterbury.

(Intervenors Prefile Testimony, May 27, 2004 and Intervenors Testimony at the Technical Hearing, June 2, 2004)

48. Dr. Zarich, Chief of Cardiology at Bridgeport Hospital testified that Bridgeport Hospital experienced a 10.2% decline in OHS volume between FY 2002 and 2003 and a 15% decline for the first six months of FY 2004. He also testified that the quality of Bridgeport’s OHS program has not been affected. *(May 27, 2004, Prefile Testimony and June 2, 2004 Technical Hearing Testimony)*

49. Dr. Zaret, Medical Director of the Yale-New Haven Heart Center, testified that Yale-New Haven Hospital experienced a 9.7% decrease in OHS volume for the first two quarters of FY 2004 compared to the same period last year. He also testified that the quality of the Yale program has not been affected. *(May 27, 2004, Prefile Testimony and June 2, 2004, Technical Hearing Testimony)*

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

50. The total capital expenditure for the proposed project is \$7,181,248, the breakdown is as follows:

**Table 11
St. Mary's Hospital**

Medical Equipment (Purchase)	\$1,960,313
Non-Medical Equipment (Purchase)	\$434,982
Construction/Renovation	\$1,362,900
Total Capital Expenditure	\$3,758,195

Waterbury Hospital

Medical Equipment (Purchase)	\$1,959,964
Non-Medical Equipment (Purchase)	\$356,389
Construction/Renovation	\$1,106,700
Total Capital Expenditure	\$3,423,053

(December 23, 2003, Certificate of Need Application, page 65)

51. The Applicants propose to finance the proposed project through the Applicants' equity, more specifically from the Operating Funds. SMH will fund \$3,758,195 and TWH will fund \$3,423,053. *(December 23, 2003, Certificate of Need Application, page 78)*

52. SMH projects an incremental to the project Loss from Operations for FY 2005 of \$(641,000) and an incremental Gain from Operations for FYs 2006 and 2007 of \$694,000 and \$1,478,000, respectively. *(December 23, 2003, Certificate of Need Application, pages 781-782)*

53. TWH projects an incremental to the project Loss from Operations for FY 2005 of \$(893,000) and an incremental Gain from Operations for FYs 2006 and 2007 of \$201,000 and \$609,000, respectively. *(December 23, 2003, Certificate of Need Application, pages 781-782)*

54. TWH stated that the financial and FTE assumptions are based on the projections made by TWH under Docket Number 03-30135, which was approved by OHCA on January 21, 2004, for replacement of its existing information system. According to TWH, the financial projections used in that docket serve as a basis for the financials projected in this application. TWH stated that this render a historical based statistical trend analysis irrelevant, unless it can be adjusted to include the impact of the project approved under Docket Number 03-30135. *(May 27, 2004, Responses to the Interrogatories, pages 10 and 11)*

55. SMH and TWH stated that currently they have on staff at each hospital 25 Full Time Equivalents ("FTE") of operation room nursing team, an ICU nursing team of 40

FTEs and an emergency department staff that includes 15 physicians and 40 nurse FTEs at each facility. (June 9, 2004, Applicants' Late File, page 8)

56. The following chart presents the additional incremental FTEs for the proposed programs:

Table 12
Additional Incremental FTE's

	FY 2005	FY 2006	FY 2007
St. Mary's Hospital	29.5	32.0	33.5
Waterbury Hospital	29.5	32.0	33.5
Total Incremental FTE's	59.0	64.0	67.0

Note: The staffing required for each hospital was based on the Applicants' analysis of the volume projections, the physical plant capability, and consideration of program start up efficiency factors. The staff for the catheterization labs and OR are in addition to current staff and staff for the Cardiovascular

Unit is new to each hospital. (December 23, 2003, Certificate of Need Application, pages 781-783 and May 27, 2004, Responses to the Interrogatories, page 10))

57. The Applicants propose minor renovations to the Operating Rooms and Post-Operations Units at both hospitals, as well as renovations to the Catheterization Laboratory at TWH. (December 23, 2003, Certificate of Need Application, pages 66-71)
58. The Applicants propose the following square footage and cost associated with the proposed renovations at both SMH and TWH:

Table 13
Proposed Renovation Square Footage by Hospital

Hospital	Square Feet	Cost
St. Mary's Hospital	5,603	\$1,362,900
The Waterbury Hospital	5,354.	\$1,106,700
Total	10,857	\$2,469,600

(December 23, 2003, Certificate of Need Application, pages 69-70)

59. SMH reported a loss from operations of \$(5,295,000), \$(17,926,000) and \$(3,874,000) for FYs 2001, 2002 and 2003, respectively. (St. Mary's Hospital Audited Financial Statements for FY's 2001, 2002 and 2003, on file with OHCA)
60. TWH reported a loss from operations of \$(1,125,627), \$(4,527,195) and \$(11,073,733) for FYs 2001, 2002 and 2003, respectively. (The Waterbury Hospital Audited Financial Statements for FY's 2001, 2002 and 2003, on file with OHCA)
61. SMH submitted unaudited consolidated statement of revenues and expenses, in which SMH indicated that through seven months of FY 2004, SMH recorded operating revenues of \$98,541,000, which annualized would result in a positive operating gain for SMH. (Responses to the Interrogatories, May 27, 2004, pages 21 and Attachment D-5)
62. TWH submitted unaudited consolidated Internal Income Statement, in which the TWH indicated that through seven months of FY 2004, TWH has gain from

operations of \$3,967,614, which annualized would result in a positive operating gain for TWH. *(June 9, 2004, Applicants' Late File, pages 2-7)*

63. SMH stated that it is engaged in a financial turnaround strategy with the objective to achieve rapid and significant improvement in its financial performance. SMH stated that it has taken the following actions:

- Recruitment of a new management team with substantial turnaround and performance improvement experience;
- Development of a comprehensive turnaround plan;
- Review of its plan by an external consultant;
- Review of its financial forecast by an external financial advisor;
- Ongoing reviews of its financial results and its financial forecast with bondholders and other interested parties;
- Conducted a comprehensive assessment of its operations and implemented interventions designed to increase revenues and/or decrease expenses; and
- Currently, implementing a Performance Improvement Plan with the objective of increasing SMH's operating margin to the 4% range.

(May 27, 2004, Responses to the Interrogatories, pages 14 and 151)

64. TWH presented the following "key" factors as part of their financial turnaround strategy, specifically over the last year:

- Net contracted revenue has increased over 10% compared to last year;
- According to the "Key Indicator Report" the FTEs have dropped to 1,550 due to layoffs last summer, especially in management positions;
- A 23.48% decrease in purchase services compared to last year;
- Medical supplies decreased by 1% over last year;
- The \$27.5 million cash balance as of April 2004, has increased by \$5.7 million since September 2003; and
- TWH has approximately \$35 million of investments at one of their affiliates (included in system wide), which combined with the \$27.5 million cash balance, gives THW over \$60 million in total reserve cash.

(June 9, 2004, Applicants' Late File, page 2)

65. JDH will facilitate the training of TWH and SMH staff and cardiologists by having them perform angioplasties and CABG at JDH during a transition period prior to implementation of the program at SMH and TWH. This will impact JDH only during FY 2005. The impact will be as follows:

Table 14
Additional Cases at JDH
During Transition Phase

Procedure	Cases
Angioplasty	175
CABG	40

Table 15
JDH FTE's
During Transition Phase

Staff Category	FTE	Period
RN	9	7 Months
Other	3	7 Months
RN manager	0.5	12 Months

(March 5, 2004, Responses to the Completeness Letter, page 14)

66. Due to the seven-month transition period during FY 2005, JDH will have an incremental Gain from Operations of \$569,781 during FY 2005.

(March 5, 2004, Responses to the Completeness Letter, page 14)

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.:

67. There is no State Health Plan in existence at this time. *(December 23, 2003 CON Application, page 4)*
68. The Applicants have adduced evidence that this proposal is consistent with the Applicants' long-range plans. SMH and TWH stated that their long-range plans include a shared vision of collaboration and affiliation strategies in an effort to enhance health care services for the shared communities they serve. *(December 23, 2003 CON Application, page 5)*
69. The Applicants have improved productivity and contained costs by participating in group purchasing, energy conservation, reengineering and applications of technology. *(December 23, 2003 CON Application, page 55)*
70. The Applicants' proposal will not impact the Applicants' teaching and research responsibilities. Both SMH and TWH have medical teaching programs that are involved with the current cardiovascular disease patients and this is expected to continue and advance with the proposed programs. There will be an opportunity for CV surgery rotations with the addition of OHS. Research opportunities with UCHC have been discussed. *(December 23, 2003 CON Application, page 56)*
71. The Applicants stated that the number of cardiologists that live and practice in the GWA is significant and are fully supportive of the development of the proposed programs. *(December 23, 2003 CON Application, page 57)*
72. The Applicants have sufficient technical, financial and managerial competence to provide efficient and adequate service to the public. *(December 23, 2003 CON Application, page 52 and Exhibit 3)*

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 older population and the high rate of mortality due to ischemic heart disease were significant factors in determining need.

The Waterbury Hospital (“TWH”) and St. Mary’s Hospital (“SMH”) (collectively known as “Hospitals”), d/b/a the Waterbury Area Heart Center, Inc. (“WAHC”), and the University of Connecticut Health Center/John Dempsey Hospital (“UCHC/JDH”) (collectively known as “Applicants”) propose to expand the cardiac services delivered at the Hospitals to include primary and elective angioplasty services and open heart surgery. The Applicants also propose to operate a one-stop postoperative model for post procedure care. OHCA anticipates this model will provide seamless patient care, improve clinical outcomes, and result in cost efficiencies. The expanded cardiac services will be managed by WAHC, a management services organization established by the Hospitals and UCHC/JDH. The Advisory Board will provide the strategic planning direction for the proposed expanded cardiac services whose members will include SMH, TWH, UCHC/JDH administration, clinical leaders, cardiologists, cardiac surgeons and other physicians. Hospital staff at all levels will be involved in the program development and routine management.

The Applicants based the need for the angioplasty and open heart surgery programs on historical catheterization and current referral volume, adopting a standard of care that exists in three other large urban areas, improving patient safety by providing services at the time of diagnosis, improved access and availability of cardiac care in the service area, reduction in time from onset to treatment, improved continuity of care and reduction in mortality. Recent studies have shown the benefit to using primary angioplasty over thrombolytics and the direct correlation between volume and quality. The Applicants’ primary and secondary service area consists of 18 towns in the greater Waterbury region. The Applicants’ primary and secondary service areas have an older population and a higher proportion of senior citizens than the state as a whole. The primary and secondary service areas had higher adult per capita rates of ischemic heart disease and AMI discharges and ischemic mortality as compare to the state as a whole. The Hospitals are geographically positioned to address the needs of residents in the Hospitals’ Connecticut service areas. There are no providers of elective PCI or OHS in the Hospitals’ service areas.

The Hospitals combined volume of cardiac catheterizations performed in FYs 2000, 2001, 2002, and 2003 (1st 2 quarters) was 1263, 1300, 1327 and 698, respectively.

OHCA estimates in Table 5, that the Hospitals combined could potentially perform a minimum of 428 annual PCIs and 253 OHS cases on residents of the service areas in FY 2006 based upon historical catheterization volume and market share. OHCA also estimates that 110 primary PCI procedures will be performed in FY 2005, 128 in FY 2006 and 151 in FY 2007. On a statewide basis, there is a 12% decline in the number of adult open-heart surgeries and an 8% increase in the number of PCIs from 2000 to 2003. There was no indication of a decline in the quality of OHS at existing providers. The existing full service cardiac providers continue to have cardiac volumes that exceed national standards.

Based on the current cardiology market share levels identified in Finding of Fact #45, the Hospitals project utilization of 214, 250, and 294 OHS cases and 358, 420, and 494 PCIs from the service areas for first three years of operations, to be distributed equally between both Hospitals. Based upon historical inpatient diagnostic cardiac catheterization volume and market share, the expanded cardiac program located at each Hospital would exceed institutional minimum volumes recommended by the ACC/AHA for PCI (200) and the American College of Surgeons–Advisory Council for Cardiothoracic Surgery for open-heart surgery (100–125). It must be noted that the American College of Surgeons–Advisory Council for Cardiothoracic Surgery also recommends that at least 200 open-heart surgical procedures per year be performed in order for a program to function efficiently.

There is a direct relationship between the time it takes a patient to undergo primary angioplasty and the outcome. Studies have shown that patients whose door-to-balloon time (the time from when a patient arrives at a hospital's 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. Remoteness, road conditions, topography, travel distance and severity of winter weather conditions all impact the service area and increase travel time. Current door-to-balloon time to existing full service cardiac providers exceeds the ideal door-to-balloon time of less than one hour. Travel minutes are only one factor in the total time to transfer a patient which also includes such things as ambulance response times, time in the Hospital's Emergency Department, and any other delays relating to patient transfer to current full service providers. 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. The Applicants' proposal will reduce total time to treatment for STEMI patients thus meeting ideal and recommended standards for intervention. The NSTEMI or high-risk patients are considered for angioplasty on an elective basis within 72 hours. Therefore, door-to-balloon time does not apply. These are all salubrious results from improved access to patient care resulting in a reduction in morbidity and mortality.

The Hospital's proposal will increase accessibility to PCI and OHS services for residents of the proposed service areas. The proposed programs will have one group of physicians, one set of clinical protocols, one quality assurance program and one administration. The Hospitals will develop a cardiac team that will be comprised of surgeons, cardiologists,

cardiac physicians and intensivists. UCHC/JDH will provide on-site training at UCHC/JDH for nurses who seek advanced education in cardio-thoracic surgery. Both existing staff and additional specialized staffing will operate the proposed programs. All medical staff and on call personnel will have a 30 minute arrival to hospital expectation. WAHC will serve to coordinate and manage the program and guarantee that staffing levels, utilization and quality guidelines are met and maintained. Cardiology Associates of Waterbury ("CAW") will provide the angioplasty service. Currently, Dr. Stephen Widman and Dr. Kevin Kett of CAW perform all angioplasty procedures, the majority of which are performed on residents of the greater Waterbury area. Connecticut Cardiothoracic Surgical Associates, LLC ("CCSA") will be the surgical group that provides cardiac surgery services at both Hospitals. There will be at least four surgeons involved; the fourth, newly recruited cardiac surgeon will be Waterbury based. In order to provide appropriate back up coverage, CCSA will open an office in Waterbury with sleeping quarters for the covering surgeon. The proposal will improve the quality of care and continuity of the Hospital's cardiac services.

Finally, the CON proposal is financially feasible. The proposal has a total expenditure cost of \$7,181,248, which consists of renovations to 5,603 Square Feet ("SF") of renovation at SMH and 5,354 SF of renovation at TWH for a total of 10,857 SF. SMH reported a loss from operations in their audited financial statements of \$(5,295,000), \$(17,926,000) and \$(3,874,000) for FYs 2001, 2002 and 2003, respectively. TWH reported a loss from operations \$(1,125,627), \$(4,527,195) and \$(11,073,733) for FYs 2001, 2002 and 2003, respectively. SMH and TWH are attempting to remedy this situation and each hospital provided OHCA with a copy of their individual strategic approach to regaining a sound financial position. The effectiveness of each hospital's financial strategy was buttressed by the seven month unaudited internal financial reports for FY 2004, which indicated a reversal in financial position of each hospital. SMH and TWH each propose to hire 29.5, 32.0, and 33.5 FTE positions for FYs 2005, 2006, and 2007 respectively. John Dempsey Hospital is projecting an incremental gain from operations of \$569,781 for FY 2005. JDH will be facilitating the training of TWH and SMH nursing staff and physicians will be performing angioplasties and CABGs at JDH during a seven-month period in FY 2005. This proposal will be financed by SMH and TWH from their equity through operations. SMH will fund \$3,423,053 and TWH will fund \$3,758,195. SMH projects an incremental loss from operations from FY 2005 of \$(641,000). However, SMH projects incremental gain from operations for FYs 2006 and 2007 of \$694,000 and \$1,478,000, respectively. Likewise TWH, projects an incremental loss from operations for FY 2005 of \$(893,000). However, TWH projects an incremental gain from operations for FYs 2006 and 2007 of \$201,000 and \$609,000, respectively. Therefore, the CON proposal will not adversely impact the interests of consumers and payers of such services.

The Applicants' proposed cardiac service is differentiated from other cardiac-related proposals in the following ways. The combined historical diagnostic cardiac catheterization volumes for SMH and TWH exceed 1,200 procedures per year. The Waterbury 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. As a result,

residents of the greater Waterbury area are transferred to full service cardiac facilities for further treatment, with a resultant disruption in continuity of care. Waterbury area residents are currently not receiving the treatment of choice for its ST-segment elevation acute myocardial infarction patients. The Applicants are proposing to address this situation by establishing a full service cardiac program to be located at St. Mary's Hospital and Waterbury Hospital. The cardiac program is being developed in collaboration with UCHC/JDH and will be managed by WAHC. UCHC/JDH will provide program implementation support, surgical services, perfusion services, staff recruitment/training support and independent oversight for quality assurance. This approach assures the public of sound professional judgment behind this proposal. Additionally, the Applicants will contract with high volume, experienced interventional cardiologists who perform most of their procedures on residents of the Waterbury area and cardiac surgeons who will be dedicated to the Applicants' program. The Applicants have brought together a team of highly experienced physicians and professionals who will develop an advanced cardiac care solution for Waterbury.

The Applicants have projected overall reasonable interventional and surgical volumes for a full-service cardiac program. However, Waterbury Hospital currently has 60% of the cardiac market share and St. Mary's Hospital has 40% market share. The Applicants are projecting a 50/50 split of volume following the implementation of the proposal, while providing no explanation for the shift in market share. Given the existing market share, OHCA is concerned that each Hospital might not achieve sufficient utilization to ensure that projected volumes for each site are met. The Applicants and members of the Waterbury community presented compelling evidence and testimony to OHCA which demonstrated a clear public need for the elective and primary angioplasty and OHS program, however, OHCA requires that the Applicants more fully demonstrate their ability to realize the projected utilization statistics for each Hospital. Therefore, OHCA concludes that the Applicants should be authorized to offer expanded cardiac services delivered at each Hospital to include primary and elective angioplasty and open-heart surgery for a limited period of three years. The provision of the expanded services for three years will provide the Applicants with adequate time to validate that the program can achieve sufficient utilization. The expanded cardiac program, or portions of the program (i.e., services at each Hospital), will be allowed to continue if sufficient utilization is met. If the Applicants are unable to achieve sufficient utilization at the end of three years, the program, or portions of the program that are not achieving sufficient utilization, will be terminated. This approach assures the public of sound professional and clinical expertise. OHCA believes that the demonstration approach of this proposal will guarantee the availability of a quality primary and elective angioplasty and open-heart surgery service for the citizens of the GWA.

Order

NOW, THEREFORE, the Office of Health Care Access (“OHCA”) and The Waterbury Hospital and St. Mary’s Hospital Corporation, d/b/a Waterbury Area Heart Center, Inc. and the University of Connecticut Health Center/John Dempsey Hospital (“Applicants”) hereby stipulate and agree to the terms of settlement with respect to the establishment of a primary and elective angioplasty and open-heart surgery program at St. Mary’s Hospital and The Waterbury Hospital, at a total capital expenditure of \$7,181,248, as follows:

1. The Applicants’ request for a CON to establish a primary and elective angioplasty and open-heart surgery program to be located at St. Mary’s Hospital and at The Waterbury Hospital at a total capital expenditure of \$7,181,248, is hereby approved.
2. WAHC shall complete and submit to OHCA on a quarterly basis the data elements in the Connecticut Cardiac Data Registry (**Attachment III**) for the cardiac services located at St. Mary’s Hospital and the Waterbury Hospital with separate data provided for services provided at each Hospital. 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) 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 WAHC in writing of its evaluation. If OHCA finds questionable material, WAHC 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 WAHC does not submit the above data to the Cardiac Data Registry on a quarterly basis, the primary and elective angioplasty and open-heart surgery program located at St. Mary’s Hospital and the Waterbury Hospital may be terminated. In the event of such termination, the Applicants shall file a CON for the reinstatement of the program.
3. As to PCI, OHCA and the Applicants agree that this CON is granted for and in effect for an initial period of three (3) years, starting on the date of the performance of the first elective or primary angioplasty procedure, but in no event later than July 23, 2005, in order for the Applicants to validate that the program can achieve the utilization that has been projected in the CON proposal. The Applicants agree that they must demonstrate that the service is achieving sufficient utilization for each of the three years of the authorized project period at St. Mary’s Hospital and at the Waterbury Hospital. Sufficient utilization is defined as achieving 200 angioplasty procedures at each site for each of the first three years. The Applicants shall

schedule quarterly meetings at and with OHCA, regarding the implementation and progress of the PCI program.

4. As to OHS, OHCA and the Applicants agree that this CON is granted for and in effect for an initial period of three (3) years, starting on the date of the performance of the first open heart surgical procedure, but in no event later than July 23, 2005, in order for the Applicants to validate that the program can achieve sufficient utilization. The Applicants agree that they must demonstrate that the service is achieving sufficient utilization for each of the three years of the authorized project period at St. Mary's Hospital and at the Waterbury Hospital. Sufficient utilization is defined as achieving open-heart surgical procedures of 125, 150 and 200 at each site for the first three years, respectively. The Applicants shall schedule quarterly meetings at and with OHCA, regarding the implementation and progress of the OHS program.
5. The Applicants agree to file with OHCA at the end of the initial project period, a request for modification of this CON authorization under Docket Number 03-30167 to continue the operation of the expanded cardiac services at St. Mary's Hospital and at Waterbury Hospital. Such request shall be filed within thirty (30) calendar days subsequent to the end of the third full operational year. The request shall be for the continuation of the service with permanent CON authorization status. The Applicants will be allowed to continue the elective and primary angioplasty and open-heart surgery program until such time as OHCA reviews the request for continuation and takes action upon the request, subject to the provisions of Stipulation #2. Continuation of the elective and primary angioplasty and open-heart surgery program with permanent CON authorization status shall be reviewed and determined based upon the Applicants fully demonstrating to OHCA that the elective and primary angioplasty and open-heart surgery program has achieved sufficient utilization levels (as identified above in Stipulations #3 and #4) for each of the three years.
6. The Applicants shall identify a fourth cardiac surgeon and identify which one of the four cardiac surgeons will reside in the primary service area and who will be the primary surgeon. The surgeon must be fully credentialed and have the following qualifications:
 - Board-Certified in cardiac surgery
 - Maintains a Connecticut license and admitting privileges at both Hospitals
 - Has performed OHS procedures at a cardiac surgical center that meets or exceeds the annual ACCS/ACS minimum institutional volume standard for CABG for the past 5 years.

The Applicants shall provide to OHCA the Curriculum Vitae ("CV") of the fourth cardiac surgeon sixty (60) days prior to commencement of the open-heart surgery program. The open heart surgery program shall not commence operation until OHCA acknowledges receipt of the CV and that the Applicants comply with this Order.

7. The Applicants will contract with three dedicated interventional cardiologists and one interventional cardiologist to serve as back up for the proposed PCI program. The interventional cardiologists must be fully credentialed and have the following qualifications:
 - Board-Certified in interventional cardiology
 - Maintains a Connecticut license and admitting privileges at both Hospitals
 - Meets or exceeds the AHA/ACC minimum operator volume standards for PCI for the past 2 years.

The Applicants shall provide the CVs of the interventional cardiologists sixty (60) days prior to commencement of the PCI program. The angioplasty program shall not commence operation until OHCA acknowledges receipt of the CVs and that the Applicants comply with this Order.

8. The Applicants shall provide the CVs of each of the cardiac operating room nurses, Board-certified cardiac anesthesiologists, intensivists, and perfusionists for the authorized OHS program sixty (60) days prior to commencement of the OHS program. Fifty percent (50%) of each of the core OR staff mentioned above must be trained in OHS prior to commencement of the OHS program. The OHS program shall not commence operation until OHCA acknowledges receipt of the CVs and that the Applicants comply with this Order.
9. St. Mary's Hospital shall not exceed the approved total capital expenditure of \$3,758,195 and Waterbury Hospital shall not exceed the approved total capital expenditure of \$3,423,053. In the event that either of the Hospitals learns of potential cost increases or expects final project costs will exceed those approved, the Applicants shall file with OHCA a request for approval of the revised CON project budget. The source of funding for the project will be St. Mary's Hospital's and Waterbury Hospital's Operating Funds.
10. St. Mary's Hospital and Waterbury Hospital shall participate in the Society of Thoracic Surgeons Database (STS-DB) database and the ACC National Cardiovascular Database Registry (ACC-NCDR) and report all data including the optional follow-up section. WAHC shall provide OHCA quarterly data reports from STS-DB and ACC-NCDR. Data must be reported to OHCA thirty (30) calendar days subsequent to the Hospitals receiving the reports from the STS and ACC. The Hospitals are required to comply with the STS and ACC/AHA criteria and standards. If the Hospitals determine not to participate in the STS-DB or ACC-NCDR, the Hospitals shall notify OHCA immediately, and continue to comply with the STS and ACC/AHA criteria and standards set forth in **Attachment III**.
11. The Applicants shall submit copies of guidelines, care pathways, and the Quality Assurance Plan that are developed for the expanded cardiac program. Copies of these documents shall be submitted sixty (60) days prior to the performance of any angioplasty procedure or open heart procedure. The Applicants shall have the same Quality Assurance program for both sites. Any changes shall be implemented at

both sites and approved by WAHC.

12. OHCA and St. Mary's Hospital Corporation and The Waterbury Hospital, d/b/a Waterbury Area Heart Center, Inc and University of Connecticut Health Center/John Dempsey Hospital agree that this Agreed Settlement represents a final agreement between OHCA and St. Mary's Hospital Corporation and The Waterbury Hospital, d/b/a Waterbury Area Heart Center, Inc. and University of Connecticut Health Center/John Dempsey 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 03-30167.
13. This Agreed Settlement is an order of the Office of Health Care Access with all the rights and obligations attendant thereto, and the Office of Health Care Access may enforce this Agreed Settlement pursuant to the provisions of Sections 19a-642 and 19a-653 of the Connecticut General Statutes at the Applicants' expense, if the Applicants fail to comply with its terms.

Date

Duly Authorized Agent for
Waterbury Hospital

Date

Duly Authorized Agent for
St. Mary's Hospital

Date

Duly Authorized Agent for
University of Connecticut Health Center/
John Dempsey Hospital

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

Date

J. Robert Galvin, M.D., M.P.H.
Presiding Officer

Recommendations for PCI Institutional and Operator Volumes at Centers With On-Site Cardiac Surgery (21, 186)

	<u>Minimum Institutional Volume</u>	<u>Optimal Institutional Volume</u>
<u>Operator Volume</u>	<u>Institutions performing 200-400 procedures annually</u>	<u>Institutions performing >400 procedures annually</u>
Low (<75 procedures annually)	<p>Class IIb</p> <p>PCI done by low-volume operators (<75) at low-volume centers (200-400).*</p> <p><i>(Level of Evidence: C)</i></p> <p><i>Note: An institution with a volume <200 procedures/year, unless in a region that is underserved because of geography, should carefully consider whether it should continue to offer the service.</i></p>	<p>Class IIa</p> <p>PCI done by low-volume operators (<75) at high-volume centers (>400).*</p> <p><i>(Level of Evidence: C)</i></p> <p><i>Note: Ideally, operators with annual procedure volume <75 should only work at institutions with an activity level of >600 procedures/year.</i></p>
Acceptable (≥75 procedures annually)	<p>Class IIa</p> <p>PCI done by operators with acceptable volume (≥75) at low-volume centers (200-400).</p> <p><i>(Level of Evidence: C)</i></p>	<p>Class I</p> <p>PCI done by operators with acceptable volume (≥75) at high-volume centers (>400).</p> <p><i>(Level of Evidence: B)</i></p>

*Note: Operators who perform <75 procedures/year should develop a defined mentoring relationship with a highly experienced operator who has an annual procedural volume ≥150 procedures/year.