



## **Office of Health Care Access Certificate of Need Application**

### **Agreed Settlement**

**Applicants:** The Waterbury Hospital and St. Mary's Hospital Corporation d/b/a Heart Center of Greater Waterbury and John Dempsey Hospital

**Docket Number:** 08-31202-CON

**Project Title:** Establish Permanent Primary and Elective Angioplasty and Open Heart Surgery Programs at The Waterbury Hospital and Saint Mary's Hospital

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

**Filing Date:** September 15, 2008

**Hearing Dates:** October 30, 2008 and December 18, 2008

**Commissioner & Presiding Officer:** Cristine A. Vogel

**Decision Date:** January 21, 2009

**Default Date:** Not Applicable

**Staff:** Alexis G. Fedorjaczenko  
Steven W. Lazarus  
Sharon Malinowski

**Project Description:** The Waterbury Hospital ("TWH") and Saint Mary's Hospital ("SMH") d/b/a Heart Center of Greater Waterbury ("HCGW") and John Dempsey Hospital ("JDH") (herein referred to as "Applicants") propose to establish permanent primary and elective angioplasty and open-heart surgery programs at SMH and TWH, with no associated capital expenditure.

**Nature of Proceedings:** On September 15, 2008, the Office of Health Care Access (“OHCA”) received the Applicants’ Certificate of Need (“CON”) application seeking authorization to establish permanent primary and elective angioplasty and open-heart surgery programs at SMH and TWH, with no associated capital expenditure. The Applicants are health care facilities or institutions as defined by Section 19a-630 of the Connecticut General Statutes (“C.G.S.”).

Pursuant to Section 19a-638, C.G.S., a public hearing regarding the CON application was held on October 30, 2008. On October 9, 2008, the Applicants were notified of the date, time, and place of the hearing. On October 10, 2008, a notice to the public announcing the hearing was published in the *Republican American*. On November 28, 2008, OHCA informed the Applicants of its intention to reconvene the hearing on December 16, 2008 and on December 10, 2008, OHCA informed the Applicants of the change in date and time of the reconvened hearing from December 16, 2008 to December 18, 2008. On December 18, 2008, OHCA reconvened the hearing, originally convened on October 30, 2008. Commissioner Cristine A. Vogel served as Presiding Officer. The hearing was conducted as a contested case in accordance with the provisions of the Uniform Administrative Procedure Act (Chapter 54 of the Connecticut General Statutes) and Section 19a-638, C.G.S.

OHCA’s authority to review and approve, modify or deny the CON application is established by Section 19a-638, C.G.S. The provisions of this section, as well as the principles and guidelines set forth in Section 19a-637, C.G.S., were fully 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 347 acute care beds and 32 bassinets located at 56 Franklin Street, Waterbury, Connecticut. (*July 8, 2008, Letter of Intent & St. Mary’s Hospital, 2007 Annual Reporting, Schedule 400*)
- 2) The Waterbury Hospital (“TWH”) is an acute care hospital with 357 acute care beds and 36 bassinets located at 64 Robbins Street, Waterbury, Connecticut. (*July 8, 2008, Letter of Intent & The Waterbury Hospital, 2007 Annual Reporting, Schedule 400*)
- 3) John Dempsey Hospital (“JDH”) is an acute care hospital with 204 acute care beds and 20 bassinets 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, Letter of Intent and John Dempsey Hospital, 2007 Annual Reporting, Schedule 400*)

- 4) On July 23, 2004, under Office of Health Care Access (“OHCA”) Agreed Settlement, Docket No: 03-30167-CON, TWH, SMH and JDH, together as Applicants were approved to establish a primary and elective angioplasty<sup>1</sup> (“PCI”) and open heart surgery<sup>2</sup> (“OHS”) program at TWH and SMH, at a total capital expenditure of \$7,181,248. (*July 8, 2008, Agreed Settlement, Docket No.: 03-30167-CON*)
- 5) Under Agreed Settlement, Docket No.: 03-30167-CON, OHCA and the Applicants agreed to the following:
  - a) The CON would be 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 or open heart surgical procedure, but in no event later than July 23, 2005, in order to validate that the program can achieve the utilization that has been projected in the CON proposal;
  - b) The Applicants 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 The Waterbury Hospital. Sufficient was defined as:

**Table 1: Required Minimum Utilization Under Docket No.: 03-31067**

PCI	Achieving 200 angioplasty procedures at each site.
OHS	125, 150 and 200 OHS procedures at each site for the first three years, respectively.

(*July 8, 2008, Agreed Settlement, Docket No.: 03-30167-CON*)

<sup>1</sup> 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. (Source: MedicineNet.com, AHA & ACC)

<sup>2</sup> 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. (Source: MedicineNet.com, AHA & ACC)

- 6) On September 11, 2008, under CON Modification, Docket No.: 03-30167-MD2, OHCA approved the Applicants' request to extend the initial period for the authorized demonstration project from three years to three and one-half years or until January 19, 2009. *(September 11, 2008, OHCA CON Modification, Docket No.: 03-30167-MD2)*
- 7) Under this CON proposal, TWH, SMH and JDH ("Applicants") propose to establish permanent PCI and OHS at SMH and TWH. The programs will be known as the Heart Center of Greater Waterbury ("HCGW"). *(September 15, 2008, CON Application, pages 2-33)*
- 8) The proposed cardiac services were designed as one program at the two hospital sites (TWH & SMH) due to its cost effectiveness. SMH and TWH initially invested approximately \$7 million and currently the program offers identical catheterization laboratories, operating rooms suites and cardiovascular intensive care unit models. It also has single care-giving teams of cardiologists, interventional cardiologists, cardiothoracic surgeons, cardiac anesthesiologists, perfusionists and registered nurses. *(September 15, 2008, CON Application, page 16)*
- 9) According to the Applicants, they considered alternatives to the one program at two site model, including models such as primary angioplasty only at two campuses and full service advanced cardiac services jointly managed at one campus. The Applicants identified the one program at both campuses approach as being the most practical and cost effective way to provide advanced cardiac care services to the citizens of greater Waterbury. *(September 15, 2008, CON Application, pages 16-19)*

10) The proposed primary service area ("PSA") and secondary service area ("SSA") are based on the three year historical volume of the HCGW, as illustrated in the following table:

**Table 2: Proposed PSA & SSA Towns**

<b>TOWN</b>	<b>2005</b> <i>% of Total</i>	<b>2006</b> <i>% of Total</i>	<b>2007</b> <i>% of Total</i>	<b>2008 YTD</b> <i>% of Total</i>
Beacon Falls	0.65	.025	1.28	1.31
Bethlehem	1.94	1.64	1.66	2.10
Cheshire	1.94	2.64	2.04	1.31
Middlebury	3.23	2.77	2.68	2.89
Naugatuck	11.61	12.70	11.86	12.34
Oakville	4.52	3.52	4.97	5.25
Prospect	2.58	4.40	2.81	3.41
Southbury	3.87	4.15	3.95	3.94
Thomaston	2.58	3.65	3.19	3.15
Waterbury	44.52	41.26	42.73	40.42
Watertown	6.45	5.41	5.74	5.77
Wolcott	5.16	7.17	5.74	4.20
Woodbury	4.52	3.52	3.44	3.67
<b>PSA Total</b>	<b>93.55</b>	<b>93.08</b>	<b>92.09</b>	<b>89.76</b>
Morris	0.0	0.13	0.13	0.0
Oxford	0.0	0.88	0.38	0.26
Plantsville	0.0	0.0	0.89	0.0
Plymouth	0.0	0.25	0.64	0.0
Seymour	0.0	0.50	0.13	0.79
Southington	0.0	0.25	0.77	0.79
Terryville	0.65	0.50	0.89	0.79
Torrington	0.65	0.25	0.51	2.10
<b>SSA Total</b>	<b>1.29</b>	<b>2.77</b>	<b>4.34</b>	<b>4.72</b>
<b>Total Service Area</b>	<b>94.84</b>	<b>95.85</b>	<b>96.43</b>	<b>94.49</b>
<b>Other</b>	<b>5.16</b>	<b>4.15</b>	<b>3.57</b>	<b>5.51</b>

Note: Applicants Source: CHIME Decision Support Tool

Data includes patient origin of patients admitted to SMH and TWH for the following:  
 Valve surgeries: DRGs: 105&105,  
 OHS: DRGs: 106, 547-550, and  
 Angioplasties: DRGs: 518, 555-558.

Fiscal year 2008 YTD data represents October 2007-March 2008  
 (September 15, 2008, CON Application, page 34)

11) SMH and TWH currently provide the following cardiac related services:

- a) Non-Invasive Cardiology:
  - i) EKG testing with extensive database of historic EKG tests,
  - ii) Holter monitor testing,
  - iii) Echocardiography including Trans Esophageal Echocardiography with extensive database of historic test,
  - iv) Stress Testing (treadmill, pharmacologic), and
  - v) Cardiology dedicated dual head nuclear cameras.
  
- b) Invasive Cardiology:
  - i) Diagnostic Cardiac Catheterizations,
  - ii) Single room with Biplane imaging,
  - iii) Intra-aortic balloon pump placement,
  - iv) Implants Pacemaker, and
  - v) Implants Defibrillators.
  
- c) Cardiology Clinics:
  - i) Pacemaker Clinic.
  
- d) Cardiac Rehab:
  - i) Phase I,
  - ii) Phase II, and
  - iii) Phase III.
  
- e) Peripheral Vascular:
  - i) Interventional and diagnostic procedures,
  - ii) Minimally Invasive Abdominal Aneurysm Endovascular procedures,
  - iii) CT/MRI angiography,
  - iv) Endovascular and traditional open vascular surgery, and
  - v) Peripheral angioplasty.
  
- f) Critical Care Units:
  - i) Critical care units directed by Board Certified Intensivists,
  - ii) Cardiovascular unit-one stop post operative model for interventional cardiology patients,
  - iii) Ongoing nursing education in collaboration with Advanced Practice Nurses,
  - iv) High percentage of RON and CCRN certification,
  - v) Telemetry and hemodynamic units available, and
  - vi) 24 hour physician unit, coverage provided by on-site surgical and medical residency program.
  
- g) Emergency Department:
  - i) Cardiac care protocols, and
  - ii) Cardiac monitors available in treatment rooms.

- h) Other:
  - i) CT calcium scoring, and
  - ii) CT angiography.
  
- i) Advanced Cardiac Services\* :
  - i) Elective angioplasty,
  - ii) Primary angioplasty, and
  - iii) Open heart surgery.

*\*Approved provisionally under CON Agreed Settlement 03-31067-CON (September 15, 2008, CON Application, pages 11-12)*

12) The Applicants based the need for the proposal on the three year historical volume of elective and primary angioplasty and OHS, as well as on the quality of the programs over the three years of operation as a demonstration project.  
*(September 15, 2008, CON Application, page 29)*

13) The Applicants provided the three year historical volume by hospital as follows:

**Table 3: Historical Utilization**

	FY 2005				FY 2006				FY 2007				FY 2008 (YTD)			
	A	B	C	D	A	B	C	D	A	B	C	D	A	B	C	D
<b>TWH</b>	8	59	23	147	50	331	118	632	60	341	120	893	42	241	112	631
<b>SMH</b>	5	58	20	117	49	260	70	485	46	211	108	512	29	186	70	480
<b>HCGW Total</b>	<b>13</b>	<b>117</b>	<b>43</b>	<b>267</b>	<b>99</b>	<b>591</b>	<b>188</b>	<b>1,117</b>	<b>106</b>	<b>552</b>	<b>228</b>	<b>1,105</b>	<b>71</b>	<b>427</b>	<b>182</b>	<b>1,111</b>
<b>JDH</b>	-	540	160	561	-	419	123	469	-	356	74	459	-	391	79	487

Note: Cardiac service legend: A: Primary Angioplasty, B: Elective Angioplasty, C: Open Heart Service, and D: Cardiac Catheterizations. JDH unable to separate primary and elective angioplasty.  
*(September 15, 2008, CON Application, page 42 and November 14, 2008, Applicants' Late-File, page 1283)*

14) According to the Applicants, the three years of historical advanced cardiac services at HCGW involved the following:

- a) Over 2,400 patients have had these services;
  - b) 1,800 out of 2,400 patients had angioplasty;
  - c) 300 of the 2,400 patients received primary angioplasty;
  - d) 88% of patients requiring acute (primary) angioplasty are treated in 90 minutes or less, compared to the American College of Cardiology ("ACC") goal of 75%; and
  - e) 600 out of the 2,400 patients had OHS.
- (September 15, 2008, CON Application, pages 31-32)*

15) According to the Applicants, the cardiac services at both hospitals are currently capturing 80% of the market share for angioplasty, 84% of the market share for Coronary Artery Bypass Graft ("CABG") surgery, and 65% market share for heart valve surgery in the proposed PSA. *(September 15, 2008, CON Application, page 80)*

16) According to the Applicants, the following illustrates the actual and projected market share:

**Table 4: Projected Market Share by Service**

<b>Service</b>	<b>Actual FY 2008</b>	<b>Projected FY 2009</b>	<b>Projected FY 2010</b>	<b>Projected FY 2011</b>
<b>PCI</b>	80.5%	80.5%	80.5%	80.5%
<b>OHS</b>	75.8%	80.5%	80.5%	80.5%
<b>I/P Cath</b>	71.7%	71.7%	71.7%	71.7%
<b>O/P Cath</b>	49.3%	49.3%	49.3%	49.3%

Note: The Applicants project the market share from FY 2008 will remain constant for all services through FY 2011 except for OHS. According to the Applicants, the historical OHS market share has grown 58.6%, 68.3% and 75.8% for FYs 2006-2008, respectively. *(September 15, 2008, CON Application, page 63)*

17) SMH and TWH currently have 17 cardiologists including five (5) interventional cardiologists, four (4) cardiothoracic surgeons and four (4) cardiac anesthesiologists, all of whom actively practice at both hospitals.  
*(September 15, 2008, CON Application, page 12)*

18) The Applicants noted for the record that the historical individual operator volume for each interventional cardiologist has exceeded the recommended volume of 75 per year. *(September 15, 2008, CON Application, page 29)*

19) According to the Applicants, over the last three years, the number of community based dedicated cardiologists has grown from 14 to 17 and a new practice has opened, Naugatuck Valley Cardiology Associates ("NVCC").  
*(September 15, 2008, CON Application, page 100)*

20) According to the Applicants, the number of physicians residing in the Waterbury area has grown and includes the following:  
a) Four (4) interventional cardiologists;  
b) Four (4) cardiothoracic surgeons; and  
c) Four (4) cardiac anesthesiologists.  
*(September 15, 2008, CON Application, page 100)*

21) According to the Applicants, JDH has been an active and formal participant in administrative, clinical and quality activities for HCGW sine July 2004. After the initial assistance and guidance in the development of the advanced cardiac program including input on protocols, staff training and equipment purchases, the relationship with JDH has evolved into a collegial partnership of shared learning. JDH continues to act in an advisory capacity in all aspects of the advanced cardiac program. In 2007 and 2008, the agreements between the SMH, TWH and JDH were formally renewed. *(September 15, 2008, CON Application, page 102)*

22) JDH's role is described as follows:

- JDH provides cardiothoracic surgical services and perfusion services via contract;
- JDH's director of cardiology is a member of HCGW Advisory Board, and as such has been involved in review and discussion of quality data.
- JDH participates in joint clinical case discussions held monthly at one of the partner hospitals;
- JDH's chief of cardiothoracic surgery is also the chief of cardiothoracic surgery for HCGW;
- The chief and his team review the HCGW program data, clinical processes and overall areas of improvement;
- The JDH and HCGW chief of perfusion also practices in these quality review committees; and
- JDH personnel continue to provide guidance to the HCGW as it relates to new technology (i.e. Robotics), equipment (i.e. new balloon pump), supplies and possible purchases related to these technologies.  
*(September 15, 2008, CON Application, pages 102-103)*

23) The Applicants are projecting the following utilization for each hospital by cardiac service:

**Table 5: Projected Utilization**

	FY 2009			FY 2010			FY 2011		
	A	B	C	A	B	C	A	B	C
<b>TWH</b>	327	134	624	316	129	638	316	129	638
<b>SMH</b>	240	81	472	232	78	481	232	78	481
<b>HCGW Total</b>	567	215	1,097	548	207	1,119	548	207	1,119

Note: Cardiac service legend: A: Total Angioplasties, B: Open Heart Service, and C: Cardiac Catheterizations. The Applicants based the projected volumes on the historical volumes at each hospital.  
*(September 15, 2008, CON Application, pages 62-63)*

24) According to the ACC/AHA guidelines, monitoring should occur for hospitals or individuals performing less than 100 cases per year.

*(American College of Cardiology [www.acc.org], September 15, 2008, CON Application, page 29)*

25) The following table provides the number of patients that were treated monthly at each hospital for cardiac services, from October 2007 to September 2008.

**Table 6: Cardiac Patients per Month for the period October 2007 to September 2008**

	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sept	Total
<b>TWH</b>													
OHS	4	14	9	14	10	11	14	10	16	10	9	17	<b>138</b>
Angioplasty	34	29	26	39	27	28	20	21	30	29	30	33	<b>346</b>
Cardiac Cath	58	57	43	54	46	46	49	52	50	57	48	71	<b>631</b>
<b>SMH</b>													
OHS	10	4	6	6	6	6	5	6	12	9	7	7	<b>84</b>
Angioplasty	24	27	15	16	21	31	22	22	20	17	28	15	<b>258</b>
Cardiac Cath	52	31	25	34	38	40	39	44	53	42	37	45	<b>480</b>

(October 24, 2008, Interrogatories, page 1240)

26) Out of the 357 licensed beds at TWH and 347 licensed beds at SMH, the following table provides the beds available by major service line.

**Table 7: Beds by Major Service Line**

	Physical Beds	Net Clinically available Beds *	Budgeted Staffed Beds **	Maximum staffed Beds ***
<b>TWH</b>				
ICU	20	20	16	20
CVU	8	8	6	8
Telemetry	20	20	18	20
Med-Surg	119	114	114	119
<b>Total</b>	<b>167</b>	<b>162</b>	<b>154</b>	<b>167</b>
<b>SMH</b>				
ICU	16	15.5	12	16
CVU	8	8	4	8
Telemetry	20	20	19	20
Med-Surg	103	100	97	103
<b>Total</b>	<b>147</b>	<b>143.5</b>	<b>132</b>	<b>147</b>

\* Net Clinically Available Beds: Due to the lack of private room availability, semi-private rooms are converted to private rooms routinely to accommodate isolation patient needs. This number reflects average impact; the range can be as high as 10 beds closed due to private room isolation needs.

\*\* Budgeted Staffed Beds: Each Hospital budgets for a number of beds to staff.

\*\*\* Maximum staffed beds: If the census requires, and the private room availability allows, staffing is provided for this maximum number of beds.

(October 24, 2008, Interrogatories, page 1233)

27) The average occupancy rate for each unit is presented in the table below. The Applicants stated that this average does not reflect fluctuations in the census and provided data to show that the SMH CVU was at maximum capacity 1 day in FY 2008, at near-maximum capacity (6-7 patients) 39 days in FY 2008, and that TWH CVU was at maximum capacity 41 days in FY 2008.

**Table 8: Average Occupancy Rate by Unit**

	Occupancy FY 2006	Occupancy FY 2007	Occupancy FY 2008
<b>TWH</b>			
ICU	75%	75%	85%
CVU	63%	63%	63%
Telemetry	90%	90%	90%
Med-Surg	95%	90%	90%
<b>Total</b>	<b>87%</b>	<b>84%</b>	<b>86%</b>
<b>SMH</b>			
ICU	80%	81%	74%
CVU	40%	51%	43%
Telemetry	84%	85%	86%
Med-Surg	93%	94%	87%
<b>Total</b>	<b>88%</b>	<b>89%</b>	<b>84%</b>

(October 24, 2008, Interrogatories, pages 1233-1239)

28) The following tables provide the number and percentage of cardiac-related emergency department visits broken down by method of arrival and by hospital.

**Table 9: Emergency Department Cardiac Related Population (By Number & Percentage)**

	FY 2006		FY 2007		FY 2008	
	TWH	SMH	TWH	SMH	TWH	SMH
Personal Transport	3,682	4,874	3,938	5,372	3,703	5,278
Ambulance Transport	2,916	2,028	2,974	1,752	2,796	1,647
Helicopter	0	1	0	0	0	2
Police	0	35	0	37	0	23
Unknown	437	41	445	205	419	258
<b>Cardiac-Related Emergency Department Visits</b>	<b>7,215</b>	<b>6,984</b>	<b>7,357</b>	<b>7,366</b>	<b>6,918</b>	<b>7,208</b>

	FY 2006		FY 2007		FY 2008	
	TWH	SMH	TWH	SMH	TWH	SMH
Personal Transport	51%	70%	0%	73%	54%	73%
Ambulance Transport	40%	29%	40%	24%	40%	23%
Helicopter	0%	0%	0%	0%	0%	0%
Police	0%	1%	0%	1%	0%	0%
Unknown	6%	1%	6%	3%	6%	4%
<b>Cardiac-Related Emergency Department Visits</b>	<b>100%</b>	<b>100%</b>	<b>100%</b>	<b>100%</b>	<b>100%</b>	<b>100%</b>

(October 24, 2008, Interrogatories, page 1229)

29) The HCGW physician team is made up of 4 cardiothoracic surgeons, 3 surgical physician assistants, 4 cardiothoracic anesthesiologists, 5 interventional cardiologists, and 12 cardiologists. The entire team has privileges and practices at both TWH and SMH. (October 24, 2008, Interrogatories, page 1231)

- 30) The HCGW perfusion team is made up of 4 perfusionists. The entire team has privileges and practices at both TWH and SMH. *(October 24, 2008, Interrogatories, page 1231)*
- 31) The HCGW team of 5 registered nurses (“RNs”) provides perioperative and intraoperative support to the cardiac anesthesiologist in the cardiovascular operating room. All of these RNs work at each campus based on the operating room schedule and the needs of the patient. *(October 24, 2008, Interrogatories, page 1231)*
- 32) The physician, perfusion, and nurse teams have on-call schedules that cover at each hospital regardless of which campus care needs to be provided. *(October 24, 2008, Interrogatories, page 1231)*
- 33) TWH and SMH each have a dedicated 8-bed intensive care Cardiovascular Unit (“CVU”) used to provide inpatient care to post cardiac procedure patients receiving advanced cardiac services (angioplasty and open heart surgery). Each CVU is in space that was newly renovated when the program commenced in July 2005. *(October 24, 2008, Interrogatories, page 1225)*
- 34) Stephen Widman, M.D., director of interventional cardiology at the HCGW, testified that both catheterization laboratories are identically equipped and staffed, and that the post angioplasty recovery areas are identical. *(October 24, 2008, Pre-File Testimony, page 1185)*
- 35) The Applicants provided the following information regarding the cardiac operating room usage at TWH and SMH.

**Table 10: Cardiac Operating Room Usage**

	FY 2005	FY 2006	FY 2007	FY 2008
<b>Simultaneous Use (1)</b>	--	0	3	8
<b>Two or more per day (2)</b>	7	9	38	33

*(1) Simultaneous Use refers to both operating rooms being used at the same time;*

*(2) Two or more per day reflects days that two or more individuals received open heart surgery between both campuses.*

*Note: 88% of the multiple surgeries were for urgently or emergently providing open heart surgery, rather than for elective surgery.*

*(October 24, 2008, Interrogatories, page 1228)*

- 36) Dr. Widman testified that the program’s mortality and procedural complications match or exceed the ACC standards in all areas, despite intervening on an older more urgent patient population and higher risk lesion subset. *(October 24, 2008, Pre-File Testimony, page 1184)*
- 37) Henry Borkowski, M.D., Medical Director of the HCGW, testified to the following with regard to the program’s quality:
- The angiographic success is at or above the ACC mean of 99.3%;
  - The risk adjusted mortality is lower than the ACC mean of 1.23%, ranging from 0.67% to 1.05%;

- The Door to Balloon time (time from arrival at the hospital to PCI) is at an average of 67 minutes, superior to the average of 2.5 to 4 hours+ hours that existed prior to July 2005; and
- Approximately 88% of patients arriving at SMH or TWH EDs are being treated with emergency angioplasty in less than 90 minutes, significantly better than the national target of 75% and the ACC mean of 72%.  
*(October 24, 2008, Pre-File Testimony, pages 1180-1181, "Door-to-Balloon" definition source: Circulation (American Heart Association). 2006; 113:1079-1085.)*

38) Dr. Widman testified that the HCGW's four interventional cardiologists each average approximately 150 cases per year; far exceeding the ACC recommended 75 cases per year. *(October 24, 2008, Pre-File Testimony, page 1184)*

39) David Underhill M.D., board certified cardiothoracic surgeon, testified that:

- Both Hospitals conformed to the Society of Thoracic Surgeons ("STS") standards in all categories assessed, and fell within the group of hospitals in the United States (77%) that are considered "equal" in performance and outcomes in their open heart surgical results;
- The actual mortality rate was far lower than the expected based on EuroSCORE rating; and
- Based on a comparison to the State of New York Adult Surgery Report published by the New York State Department of Health, outcomes are comparable to several of the higher and the lower volume programs in this neighboring state.  
*(October 24, 2008, Pre-File Testimony, pages 1191-1196)*

40) Dr. Underhill testified that each surgeon is considered to be a "high volume practitioner" and provided summaries of recent studies that suggest the importance of surgeon - procedure volume. *(October 24, 2008, Pre-File Testimony, page 1201)*

41) Chad Wable, CEO and President of SMH testified that the HCGW was established based on need, however, the way the cardiac program has been structured there have been cost savings as a result of the one program, two campus approach, which are made up of three parts:

- i) Clinical: There is one perfusion team, one medical director, one anesthesia contract, one surgical chief and one chief of interventional laboratory, leading to approximately \$1 million in annual savings.
- ii) Administrative: There is one database, instead of two databases and two information technology support structures at two individual hospitals. Also, cost savings in the support infrastructure, which has led to approximately \$300,000 in annual savings.
- iii) Any changes to the structure of the existing cardiac program, i.e., moving to a full service advanced cardiac program jointly managed at one campus, would lead to the following:

- (a) Extensive renovations to an emergency department to accommodate the additional patient volume, which would cost several million dollars,
- (b) Another cardiac catheterization laboratory at one of the hospitals would cost an additional \$2-3 million,
- (c) Another cardiovascular operating room at one of the hospitals, which would cost approximately, \$2-3 million,
- (d) There would be other administrative support required, leading the total cost to be upwards of \$10-\$20 million.

*(December 18, 2008, Hearing Testimony of Mr. Chad Wable, President and CEO of Saint Mary's Hospital)*

42) John Tobin, President and CEO of TWH testified to the following:

- a) Any changes in the existing structure of the existing cardiac program may also involve costs related to duplication of services but the biggest savings is in the quality of care and accessibility, and
- b) SMH and TWH are required to file cardiac related data to ACC and STS individually but can also file it collectively.

*(December 18, 2008, Hearing Testimony of Mr. John Tobin, President and CEO of The Waterbury Hospital)*

43) Chad Wable testified to the following regarding the quality of HCGW:

- a) The existing cardiac program (HCGW) has an advisory board that monitors quality of the program;
- b) The Applicants submit data to STS and ACC, which is utilized as a tool to monitor quality,
- c) The Applicants are also reviewed by Connecticut's Department of Public Health and also by the Commission on the Accreditation of Healthcare Organizations and Connecticut Medical Society, and
- d) The Applicants contend that the internal program (self) monitoring through the physicians should continue.

*(December 18, 2008, Hearing Testimony of Mr. Chad Wable, President & CEO of Saint Mary's Hospital)*

**Financial Feasibility of the Proposal and its Impact on the Applicants'  
Rates and Financial Condition  
Impact of the Proposal on the Interests of Consumers of Health Care  
Services and Payers for Such Services  
Consideration of Other Section 19a-637, C.G.S. Principles and Guidelines**

- 44) The Waterbury Hospital's originally projected three-year incremental revenue from operations, total operating expense and losses/gains from operations associated with the implementation of the new unit are presented in the table below:

**Table 11: Waterbury Hospital's Original Incremental Financial Projections**

Description	FY 2009	FY 2010	FY 2011
Incremental Revenue from Operations	\$11,318,005	\$11,346,526	\$11,800,387
Incremental Total Operating Expense	\$9,023,156	\$9,049,510	\$9,411,490
<b>Incremental Gain from Operations</b>	<b>\$2,292,850</b>	<b>\$2,297,016</b>	<b>\$2,388,897</b>

*(September 15, 2008, Certificate of Need, page 1146)*

- 45) The Waterbury Hospital's revised projected three-year incremental revenue from operations, total operating expense and losses/gains from operations associated with the implementation of the new unit are presented in the table below:

**Table 12: Waterbury Hospital's Revised Incremental Financial Projections**

Description	FY 2009	FY 2010	FY 2011
Incremental Revenue from Operations	\$11,546,632	\$11,579,673	\$12,042,860
Incremental Total Operating Expense	\$5,684,232	\$5,882,323	\$6,058,793
<b>Incremental Gain from Operations</b>	<b>\$5,684,232</b>	<b>\$5,697,350</b>	<b>\$5,984,067</b>

*(November 14, 2008, Applicant's late file, page 1287)*

- 46) Saint Mary's Hospital's originally projected three-year incremental revenue from operations, total operating expense and losses/gains from operations associated with the implementation of the new unit are presented in the table below:

**Table 13: Saint Mary's Hospital's Original Incremental Financial Projections**

Description	FY 2009	FY 2010	FY 2011
Incremental Revenue from Operations	\$7,462,000	\$7,520,000	\$7,820,000
Incremental Total Operating Expense	\$6,089,000	\$6,156,000	\$6,405,000
<b>Incremental Gain from Operations</b>	<b>\$1,373,000</b>	<b>\$1,364,000</b>	<b>\$1,415,000</b>

*(September 15, 2008, Certificate of Need, page 1150)*

- 47) Saint Mary's Hospital's revised projected three-year incremental revenue from operations, total operating expense and losses/gains from operations associated with the implementation of the new unit are presented in the table below:

**Table 14: Saint Mary's Hospital's Revised Incremental Financial Projections Project**

Description	FY 2009	FY 2010	FY 2011
Incremental Revenue from Operations	\$7,462,000	\$7,520,000	\$7,820,000
Incremental Total Operating Expense	\$5,092,000	\$5,183,000	\$5,339,000
<b>Incremental Gain from Operations</b>	<b>\$2,370,000</b>	<b>\$2,337,000</b>	<b>\$2,481,000</b>

(November 14, 2008 Applicant's late file, page 1294)

- 48) The following chart presents the original incremental FTEs for the proposed program:

**Table 15: Original additional Incremental FTEs**

Description	FY 2009	FY 2010	FY 2011
Waterbury Hospital	41.8	41.9	43.6
Saint Mary's Hospital	16	16	16
<b>Total Incremental FTEs</b>	<b>57.8</b>	<b>57.9</b>	<b>59.6</b>

(September 15, 2008, Certificate of Need, pages 1146 and 1150)

- 49) The following chart presents the revised incremental FTEs for the proposed programs:

**Table 16: Revised additional Incremental FTEs**

Description	FY 2009	FY 2010	FY 2011
Waterbury Hospital	23.8	23.0	23.0
Saint Mary's Hospital	20.3	20.3	20.3
<b>Total Incremental FTEs</b>	<b>44.1</b>	<b>43.3</b>	<b>43.3</b>

(November 14, 2008 Applicant's late file, pages 1289 and 1296)

- 50) The Waterbury Hospital's payer mix with the CON proposal is as follows:

**Table 17: Three-Year Projected Payer Mix with the CON Proposal**

Total TWH	Current Payer Mix	FY 2009 Payer Mix	FY 2010 Payer Mix	FY 2011 Payer Mix
Medicare	40.7%	40.7%	40.7%	40.7%
Medicaid (including other medical assistance)	21.3%	21.3%	21.3%	21.3%
TRICARE	.2%	.2%	.2%	.2%
<b>Total Government</b>	<b>62.2%</b>	<b>62.2%</b>	<b>62.2%</b>	<b>62.2%</b>
Commercial Insurers	33.1%	33.1%	33.1%	33.1%
Self Pay	2.5%	2.5%	2.5%	2.5%
Workers Compensation	2.2%	2.2%	2.2%	2.2%
<b>Total Non-Government</b>	<b>37.8%</b>	<b>37.8%</b>	<b>37.8%</b>	<b>37.8%</b>
Uncompensated Care	0%	0%	0%	0.0%
<b>Total Payer Mix</b>	<b>100%</b>	<b>100%</b>	<b>100%</b>	<b>100.0%</b>

(September 15, 2008, Initial CON Application, page 105)

51) Saint Mary's Hospital's payer mix with the CON proposal is as follows:

**Table 18: Three-Year Projected Payer Mix with the CON Proposal**

<b>Total SMH</b>	<b>Current Payer Mix</b>	<b>FY 2009 Payer Mix</b>	<b>FY 2010 Payer Mix</b>	<b>FY 2011 Payer Mix</b>
Medicare	46.7%	46.7%	46.7%	46.7%
Medicaid (including other medical assistance)	16.8%	16.8%	16.8%	16.8%
TRICARE	0.0%	0.0%	0.0%	0.0%
<b>Total Government</b>	<b>63.5%</b>	<b>63.5%</b>	<b>63.5%</b>	<b>63.5%</b>
Commercial Insurers	32.2%	32.2%	32.2%	32.2%
Self Pay	2.9%	2.9%	2.9%	2.9%
Workers Compensation	1.4%	1.4%	1.4%	1.4%
<b>Total Non-Government</b>	<b>36.5%</b>	<b>36.5%</b>	<b>36.5%</b>	<b>36.5%</b>
Uncompensated Care	0%	0%	0%	0%
<b>Total Payer Mix</b>	<b>100%</b>	<b>100%</b>	<b>100%</b>	<b>100%</b>

*(September 15, 2008, Initial CON Application, page 105)*

52) Bob Halko, CFO of SMH testified to the following:

- a) For FY 2008, Saint Mary's Health System had a \$4.3 million gain of which \$3.5 million was a grant from the State's hardship fund. Without this grant the gain would only have been approximately \$800,000;
- b) For FY 2007, Saint Mary's Health System had a \$6.1 million gain of which \$5.5 million was a grant from the State's hardship fund. Without this grant the gain would only have been approximately \$600,000;
- c) For FY 2009, Saint Mary's Health System is projected to have a gain from operations of \$175,000 and revenue in excess of expenses of \$2.3 to \$2.4 million. This takes into consideration changes such as Connecticut Children's Medical Center's pediatric department at SMH and associated renovations;
- d) Pension funding for FY 2008 was approximately \$3 million and for FY 2009 will be \$5 million. The \$5 million funding for FY 2009 was mandated; and
- e) As of September 30, 2008, the unfunded portion of the pension plan was approximately \$60 million.

*(December 18, 2008, Hearing Testimony of Mr. Bob Halko, CFO of Saint Mary's Hospital)*

53) Colleen Scott, CFO of TWH testified that for FY 2008, Waterbury Hospital had a loss of \$9 million and the Health System had a total loss of \$17 million.

*(December 18, 2008, Hearing Testimony of Ms. Colleen Scott, CFO of Waterbury Hospital)*

## Rationale

The Office of Health Care Access ("OHCA") approaches community and regional need for Certificate of Need ("CON") proposals on a case by case basis. CON applications do not lend themselves to general applicability due to a variety 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 types of services proposed to be offered, the current utilization of services and the financial feasibility of the proposal.

Saint Mary's Hospital ("SMH") is an acute care hospital located at 56 Franklin Street, Waterbury. The Waterbury Hospital ("TWH") is an acute care hospital located at 64 Robbins Street, Waterbury. John Dempsey Hospital ("JDH") is an acute care hospital located at 263 Farmington Avenue, Farmington. SMH, TWH, and JDH currently operate a primary and elective angioplasty ("PCI") and open heart surgery ("OHS") program at TWH and SMH as a demonstration project. Under this CON proposal, TWH, SMH and JDH (together, "Applicants") propose to establish permanent PCI and OHS programs at SMH and TWH.

The proposed cardiac services currently operate at two hospital sites, TWH and SMH. The cardiac services located at each hospital include catheterizations laboratories, operating rooms suites, and cardiovascular intensive care unit models that are identically equipped and staffed, along with single care-giving teams of cardiologists, interventional cardiologists, cardiothoracic surgeons, cardiac anesthesiologists, perfusionists and registered nurses which all have privileges and practice at both TWH and SMH. The on-call schedules of the care giving teams cover the program regardless of which campus may need care to be provided.

The Applicants provided facts to support their assertion that the OHS and PCI services cannot be accommodated solely at one location without significant renovations or construction of new space. OHCA has reviewed the financial situation at both organizations and concludes that neither hospital has the financial ability nor the access to capital that would be required to renovate and accommodate the entire service.

This CON proposal was presented to OHCA as one program; however, OHCA concludes that apart from the single clinical team model and the management of the services, the hospitals remain independent from each other in all other aspects. The Applicants did provide evidence that utilizing a single clinical team is cost-effective in a "two-hospital" scenario. Both SMH and TWH stated that having the capability to offer such services independently at each hospital does provide a financial gain.

There may be a point in time where the duplication of clinical space at each facility becomes less cost-effective especially if procedure volume remains steady or declines. Intuitively, having one appropriately-sized cardiac program at one location would appear to be most cost-effective and deliver the ideal continuity of care. It is reasonable to assume that the community would learn which facility offers inpatient cardiac services,

much like the hospitals' assertion with inpatient pediatric services being located at only one of the hospitals.

The Applicants testified at the hearing that the probability of a merger between the SMH and TWH is less likely now than in the recent past, especially in light of the current economic downturn. The reduced likelihood of the merger puts the long-term financial viability of the inpatient cardiac services in question. Given the fact that the two hospitals have come forward as co-applicants, and given the facilities' space constraints and financial circumstances, it is not reasonable for OHCA to separate the hospitals and modify the proposal to only one location. OHCA appreciates the efforts of collaboration; however, it remains concerned with the redundancy that results from providing all of the advanced cardiac services at both hospitals. The agency will continue to monitor the ongoing financial benefit of this proposal in light of OHCA's view that the long term financial viability of these programs would be enhanced if this were one legal partnership in all aspects, not just the clinical teams and management of the programs (as in the case of the Harold Lever Cancer Center).

OHCA does not consider this one program, as it involves two hospital organizations that operate independently of and competitively with each other. Since OHCA views these as two independent inpatient cardiac programs, OHCA will remain consistent with the data reporting requirements stipulated in the "demonstration project" which was the precursor to this application. OHCA recognizes that the evidence to date indicates that SMH and TWH are operating quality programs. This conclusion is a factor in deciding whether to approve this proposal. OHCA remains concerned, however, that utilization will remain low at SMH and TWH and that strict monitoring of these low-volume providers must continue. Professional cardiac associations suggest that cardiac programs with low utilization be monitored closely.

In conclusion, the Applicants presented evidence that supports the benefits of continuing the inpatient cardiac services as it currently exists. The procedure volumes and operational issues for both TWH and SMH, will remain under OHCA's close monitoring.

## Order

**NOW, THEREFORE**, the Office of Health Care Access (“OHCA”) and The Waterbury Hospital (“TWH”) and Saint Mary’s Hospital (“SMH”) and John Dempsey Hospital (“JDH”) (together referred to as “Applicants”) hereby stipulate and agree to the terms of settlement with respect to the establishment of permanent primary and elective angioplasty and open-heart surgery programs at St. Mary’s Hospital and at The Waterbury Hospital, with no associated capital expenditure, as follows:

1. The Applicants’ request for a CON to establish permanent primary and elective angioplasty and open-heart surgery programs to be located at SMH and at TWH, with no associated capital expenditure, is hereby approved.
2. The scope of this CON authorization is being approved as was specifically presented in the Applicants’ proposal, which consists of two full-service inpatient cardiac programs, one at SMH and one at TWH, but both served by the same clinical team. The Applicants agree that this CON authorization will become invalid and therefore null and void, if either of the following occurs in the future:
  - (a) Any change to the structure of the single clinical team model serving both SMH and TWH (not including individual personnel changes), as highlighted in Finding of Facts numbers 17,29,30&31; or
  - (b) Any changes in the ownership or control of one or both of the legal entities, SMH and TWH.
3. There is no associated capital expenditure approved. In the event that the Applicants learn of potential significant capital costs associated with start of operations of this program, the Applicants shall notify OHCA in a timely manner.
4. The Applicants agree that SMH and TWH are each required to file with OHCA, an annual utilization report containing specific data and/or information related to their separate full-service cardiac programs in a format to be defined by OHCA subsequent to the execution of this agreement. OHCA will provide the Applicants with the specific format for the annual filing within ninety days of the authorization date of this agreement. OHCA will also set forth the filing schedule related to the annual utilization reporting at that time. It is acceptable to OHCA that the legal entity, Heart Center of Greater Waterbury, Inc. coordinate such annual filings and directly submit the filings to OHCA on behalf of SMH and TWH.
5. The Applicants agree that it is the intent of SMH and TWH to participate in the American College of Cardiology National Cardiovascular Database Registry (ACC-NCDR). SMH and TWH are required to comply with the ACC/AHA criteria and standards. If SMH or TWH determines not to participate in the ACC-NCDR, the Applicants shall notify OHCA in a timely manner regarding such

- decision not to participate and shall continue to comply with the ACC/AHA criteria and standards. Further, the Applicants agree that, if SMH and TWH do participate in ACC-NCDR, SMH and TWH are required to submit to OHCA any and all Executive Summary pages from the Institutional Outcomes Reports received by SMH or TWH from ACC-NCDR, such Executive Summary containing the PCI Quality Measures, PCI Utilization Measures, and Diagnostic Cath Quality Measures. All Executive Summaries received by SMH or TWH during the year, will be due to OHCA at the same time as the annual report specified and agreed upon in Stipulation #4 above. Further, SMH and TWH shall supply to OHCA the detail reports from ACC-NCDR to SMH and TWH only if OHCA specifically requests such detailed reporting. It is acceptable to OHCA that the legal entity, Heart Center of Greater Waterbury, Inc. coordinate such annual filings and directly submit the filings to OHCA on behalf of SMH and TWH.
6. The Applicants agree that it is the intent of SMH and TWH to participate in the Society of Thoracic Surgeons Database (STS-DB) database. If SMH or TWH determines not to participate in the STS-DB, the Applicants shall notify OHCA in a timely manner regarding such decision not to participate. Further, the Applicants agree that, if SMH and TWH do participate in STS-DB, SMH and TWH are required to submit to OHCA any and all Regional Outcomes Comparisons received by SMH or TWH from STS-DB, such Comparison Reports showing each Applicant hospital as compared to the Region. All Regional Outcomes Comparisons received by SMH or TWH during the year, will be due to OHCA at the same time as the annual report specified and agreed upon in Stipulation #4 above. Further, SMH and TWH shall supply to OHCA the detail reports from STS-DB to SMH and TWH, only if OHCA specifically requests such detailed reporting. It is acceptable to OHCA that the legal entity, Heart Center of Greater Waterbury, Inc. coordinate such annual filings and directly submit the filings to OHCA on behalf of SMH and TWH.
  7. The Applicants each agree to attend meetings with OHCA on a semi-annual basis for the purposes of discussion on quality monitoring, clinical team structure, and overall organization structure for the programs and for SMH and TWH. Such meetings must include at least one member of executive management of the three Applicant hospitals. The number of meetings to be held will be at the discretion of OHCA and OHCA may discontinue the meetings in the future after written notification to the Applicant hospitals, without modification to this Order.
  8. OHCA and SMH, TWH, and JDH agree that this Agreed Settlement represents a final agreement between OHCA and SMH and TWH, d/b/a Heart Center of Greater Waterbury and 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 08-31202-CON.

9. 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.

*Signed by John H. Tobin on January 16, 2009*

\_\_\_\_\_  
Date

\_\_\_\_\_  
Duly Authorized Agent for  
The Waterbury Hospital

*Signed by Chad W. Wable on January 16, 2009*

\_\_\_\_\_  
Date

\_\_\_\_\_  
Duly Authorized Agent for  
Saint Mary's Hospital

*Signed by Cato Laurencin M.D., PhD.*

\_\_\_\_\_  
Date

\_\_\_\_\_  
Duly Authorized Agent for  
John Dempsey Hospital

The above Agreed Settlement is hereby accepted and so ordered by the Office of Health Care Access on January 21, 2009.

***Signed by Commissioner Vogel on January 21, 2009***

\_\_\_\_\_  
Date

\_\_\_\_\_  
Cristine A. Vogel  
Commissioner