Office of Health Care Access
Certificate of Need Application

Agreed Settlement

Hospital:	**The Stamford Hospital and New York Presbyterian Healthcare System, Inc.**
Docket Number:	**04-30374-CON**
Project Title:	**Establish Elective Angioplasty and Open Heart Surgery Program at The Stamford Hospital**
Statutory Reference:	**Sections 19a-638 & 639, Connecticut General Statutes**
Filing Date:	**August 15, 2005**
Hearing Dates:	**Public Portion: September 22, 2005 Technical Portion: October 6, 2005 and October 27, 2005**
Commissioner & Presiding Officer:	**Cristine A. Vogel**
Agreed Settlement Date:	**January 4, 2006**
Default Date:	**Not Applicable**
OHCA Staff	**Steven W. Lazarus Michael Sabados**

Project Description: The Stamford Hospital ("TSH" and "Hospital") and New York Presbyterian Healthcare System, Inc. ("Applicants") propose the establishment of an elective angioplasty ("PCI") and open-heart surgery ("OHS") program, to be located at the Hospital, at a capital expenditure of $5,404,425.

Nature of Proceedings: On August 15, 2005, the Office of Health Care Access ("OHCA") received the Applicants' Certificate of Need ("CON") application seeking authorization to establish an elective angioplasty and open-heart surgery program, to be located at the Hospital, at a capital expenditure of $5,404,425. The Stamford Hospital is organized under the laws of Connecticut, and New York Presbyterian Healthcare System, Inc. is a corporation organized under the laws of the State of New York. The Hospital is a health care facility or institution as defined by Section 19a-630 of the Connecticut General Statutes ("C.G.S.").

Public hearings regarding the CON Application were held on September 22, 2005, October 6, 2005 and October 27, 2005. The Hospital was notified of the date, time, and place of the hearings and notices to the public were published prior to the hearings in *The Advocate* (Stamford) by OHCA. The hearings were conducted as a contested case in accordance with the provisions of the Uniform Administrative Procedure Act (Chapter 54 of the Connecticut General Statutes) and Sections 19a-638 and 19a-639, C.G.S.

Yale-New Haven Hospital, Bridgeport Hospital, and Greenwich Hospital collectively known as Yale-New Haven Heart Health Institute were granted Intervenor status with rights to cross-examine. St. Vincent's Medical Center was granted Intervenor status with the rights to cross-examine.

The Presiding Officer heard testimony from the general public, legislators, local officials and witnesses for the Hospital 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 these sections, as well as the principles and guidelines set forth in Section 19a-637, C.G.S., were considered by OHCA in its review.

Findings of Fact

Clear Public Need
Impact on The Hospital's Current Utilization Statistics
Proposal's Contribution to Accessibility and Quality of Health Care Delivery in the Region

1. The Stamford Hospital ("TSH" and "Hospital") is a not-for-profit, 305-bed acute care hospital located in Stamford, Connecticut. TSH, as an affiliate member of the New York Presbyterian Healthcare System ("System"). TSH provides a comprehensive array of services including: Medicine, Surgery, Obstetrics/Gynecology, Psychiatry as well as Medical and Surgical critical care units. *(Completeness Responses, Proposed Resolution, August 15, 2005, Exhibit 3 and Certificate of Need Application, August 15, 2005, page 1-3)*

2. The New York Presbyterian Healthcare System, Inc ("NYPHS") coordinates a system of hospitals and other healthcare institutions throughout the tri-state area, including The Stamford Hospital ("TSH") and New-York Presbyterian Hospital ("NYPH"). NYPH operates New York-Presbyterian Hospital/Columbia University Medical Center ("NYP/C") in affiliation with Columbia University College of Physicians and Surgeons ("CU"). *(Certificate of Need Application, August 15, 2005, pages 2-3)*

3. TSH and NYPHS ("Applicants") propose the establishment of an elective percutaneous coronary angioplasty[a] ("PCI") and open-heart surgery[b] ("OHS") program, to be located at the Hospital. *(Certificate of Need Application, August 15, 2005, page 2)*

4. TSH's proposal is for a full-service cardiovascular services program in the lower Fairfield County. TSH is located in the region's largest population center. *(Prefiled Testimony of Brian Grissler, September 19, 2005,)*

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[a] 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.

[b] 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.

5. On August 25, 2004, TSH received CON authorization from OHCA to perform primary[c] PCI services. *(Certificate of Need Application, August 15, 2005, page 2)*

6. The proposed program will augment existing cardiovascular services at the Hospital. The Hospital currently offers:

Primary Angioplasty	Electrocardiogram
Interventional electrophysiology (ablations)	Electrophysiology
Diagnostic cardiac catheterization	Holter monitoring
Coronary care unit	Intra-aortic balloon pump
Telemetry inpatient care	Nuclear stress testing
Cardiac imaging	Pulmonary function testing
Cardiac rehabilitation	Stress testing
Cardiac ultrasound	Tilt table testing
Cardiopulmonary testing	Vascular and thoracic surgical services

(Certificate of Need Application, August 15, 2005, pages 8-9)

7. TSH's cardiology primary and secondary service areas consist of the following Connecticut towns:

Table 1: Stamford Hospital's Proposed Service Area for this Proposal for FYs 2002 – 2005 (1st Two Quarters)

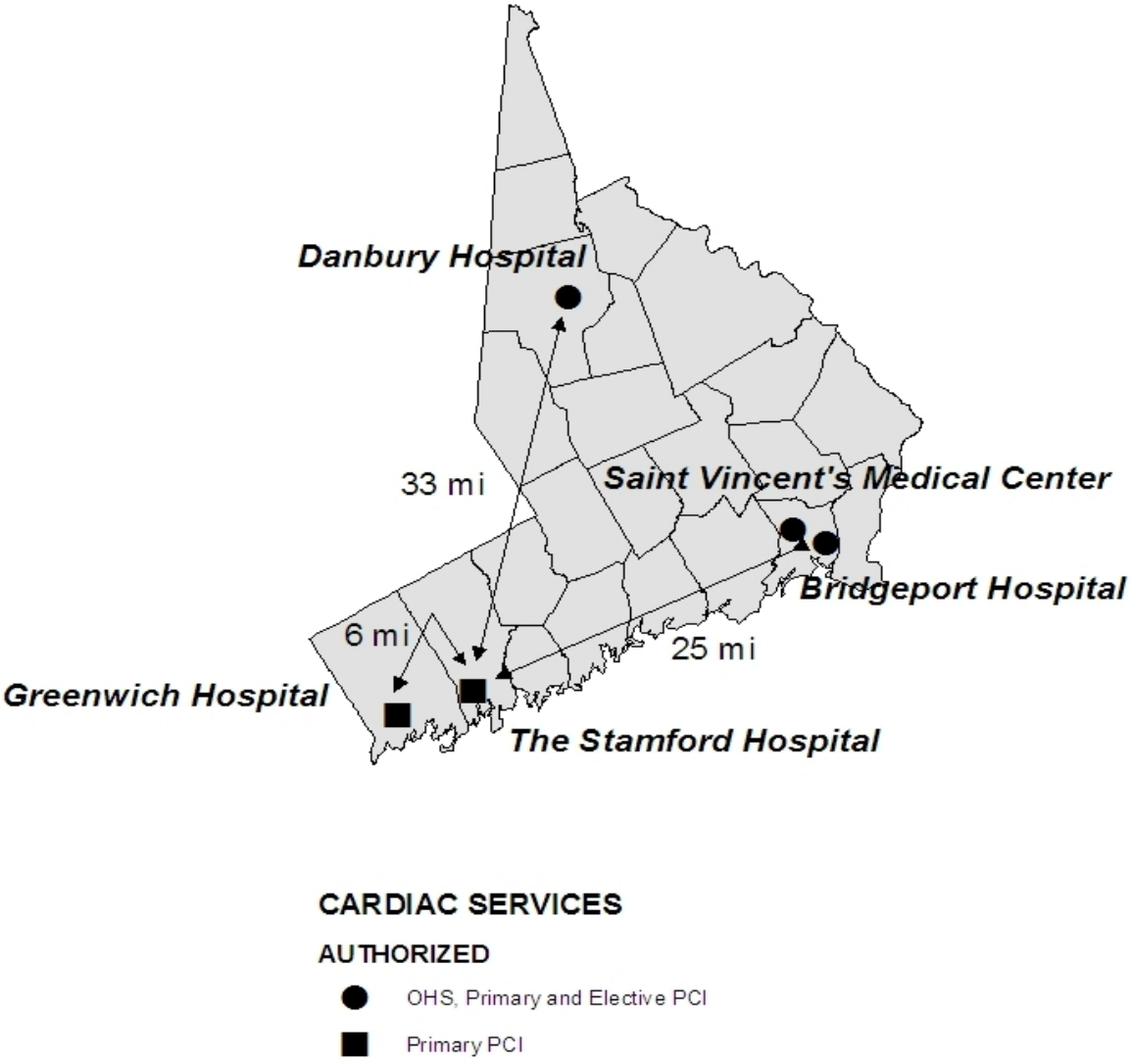
Towns	Primary	Secondary	Total Service Area
	Darien Stamford	Greenwich New Canaan Norwalk Weston Westport Wilton	Darien Greenwich New Canaan Norwalk Stamford Weston Westport Wilton
TSH's Share of Service Area's Inpatient Cardiac Catheterizations	57.4%	4.2%	26.1%
Service Area's share of TSH's Inpatient Cardiac Catheterizations	84.6%	8.7%	93.3%

(Source: Cardiac catheterization volume from *OHCA's Acute Care Hospital Inpatient Discharge Database. Service Area from Certificate of Need Application August 15, 2005, page 22)*

[c] Primary (Emergent) 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. 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.

8. Providers of interventional cardiac services in the Hospital's total service area ("TSA") are as follows

Map 1: Area Providers of Interventional Cardiac Services



Danbury Hospital began performing open heart surgery in January 2005.
Greenwich Hospital began performing Primary PCI in February 2005.
Stamford Hospital began performing Primary PCI in August 2005.

(Connecticut Acute Care Hospital Inpatient Discharge Database and Travel Distances from Yahoo Maps)

9. The Applicants based the need for the proposed Elective PCI and OHS program on the following:
   - Improved accessibility for patients;
   - Improved continuity of care;
   - Historical/Existing cardiac volume;
   - Adopting a standard of care that exists in the other large urban area; and
   - Improved quality of cardiac services.

   (Certificate of Need Application, August 15, 2005, pages 2-55)

10. TSH stated that the establishment of a full-service cardiac program in Stamford will provide timely access and local availability of these services in keeping with trends that have been already established nationally.
    (Prefiled Testimony of Kathleen Silard, Senior Vice President for Operations at TSH, September 19, 2005)

11. TSH's cardiac catheterization volume for FYs 2000 through 2005 are as follows:

Table 2: TSH's Historical Cardiac Catheterization Volume, FYs 2002 – 2005 1st Two Quarters

CT Service Area	2002	2003	2004	2005
Inpatient	354	352	296	147
Outpatient	321	283	332	-
Total	**675**	**635**	**628**	**147**

(Inpatient catheterization figures from OHCA's Acute Care Hospital Inpatient Discharge Database and outpatient volume from August 15, 2005, Responses to OHCA Completeness Letter, pages 1-2)

12. The following is a table of the average annual historical and projected Total PCI volumes (Primary & Elective) in TSH's service area:

Table 3: Average Annual Historical and Projected Total PCI Volumes in TSH's Service Area, FYs 2002 – 2005

	FYs 2002–2005 1st Two Quarters		Year One		Year Two		Year Three	
TSH Service Area	**Average PCIs**	**Adult Use Rate**	**Market Share (%)**	**Projected PCIs**	**Market Share (%)**	**Projected PCIs**	**Market Share (%)**	**Projected PCIs**
Primary	277	2.55	78%	216	83.5%	231	83.4%	231
Secondary	418	2.48	6.8%	28	11.0%	46	20.3%	85
Total Service Area	695	2.51	36.3%	244	40.6%	276	45.7%	316
Connecticut	**8,024**	**2.98**	-	-	-	-	-	-

Note: "Adult" refers to those 15 years and older. Adult use rate per 1,000 population.
Projected PCI volumes were calculated by applying the applicant's projected capture rate to the current PCI volume in the service area. For example, in Year One in the primary service area: 277 (average volume) * .78 (market share) = 216 PCIs.
(OHCA Acute Care Hospital Inpatient Discharge Database; MA, NY, and RI Hospital Discharge Databases; Census 2000 for population figures, and August 15, 2005 CON Application, p*ages 45& 23)*

13. The following table is the annual average historical and projected OHS for TSH in the proposed service area for FYs 2002-2005:

Table 4: Historical and Projected, Average Annual OHS Volumes in TSH's Service Area, FYs 2002–2005

	FYs 2000 – 2005 1st Two Quarters		Year One		Year Two		Year Three	
TSH Service Area	**Average OHS**	**Adult Use Rate**	**Market Share (%)**	**Projected OHS**	**Market Share (%)**	**Projected OHS**	**Market Share (%)**	**Projected OHS**
Primary	112	1.03	78.1%	88	83.5%	94	83.5%	94
Secondary	213	1.27	6.7%	14	10.9%	23	20.3%	43
Total Service Area	325	1.17	32.9%	102	38.8%	117	45.7%	137
Connecticut	**4,640**	**1.72**	-	-	-	-	-	-

Note: FY 2005 is First two quarters only.
"Adult" refers to those 15 years and older. Adult use rate per 1,000 population
Projected OHS volumes were calculated by applying the Applicant's projected capture rate to the current PCI volume in the service area. For example, in Year One in the primary service area: 112 (average volume) * .781 (market share) = 88 open-heart surgeries.

(OHCA Acute Care Hospital Inpatient Discharge Database; MA, NY, and RI Hospital Discharge Databases; Census 2000 for population figures; and August 15, 2005, CON Application, pages 46&23).

14. TSH projects the following number of elective PCIs procedures and OHS for its service area.

Table 5: Projected Cardiac Volume for TSH's Service Area

Service	FY 2007	FY 2008	FY 2009
Angioplasties (Elective only)	193	324	417
Open-heart surgeries	86	150	197

Note: TSH based the projected volumes on historical utilization and population data. The use-rates utilized are based on Claritas data. OHCA can not verify any of the above claimed data. *(Responses to the Interrogatories, September 28, 2005, Updated Financial Attachment and CON Application)*

15. The 2001 American College of Cardiology ("ACC") and the American Heart Association ("AHA") Guidelines for Percutaneous Coronary Intervention ("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, PCI is best done by high-volume operators in high-volume institutions. *(JACC, 2001, Vol. 37, No.8, page 2239)*

16. The ACC/AHA Guidelines for CABG Surgery (1999) state the following:
    - 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.
    - The ACC/AHA are supportive of a posture of close monitoring of institutions or individuals that perform <100 cases annually.

17. TSH states that it will utilize the existing guidelines published by the ACC and AHA as a basis for the development of standards for the proposed services, as specified in **Attachment I.** *(Certificate of Need Application, August 15, 2005, page 11)*

18. The Guidelines for Standards in Cardiac Surgery by the Advisory Council for Cardiothoracic Surgery ("ACCS") and the American College of Surgeons ("ACS") (1996) state the following:
    - 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.
    - 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.
    - 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.

19. Dr. Steven F. Horowitz testified to the following at the public hearing:
    - TSH can sustain a full-service cardiac program due to the increase in the size of the minority population.
    - Numerous studies have confirmed that the cardiovascular risk profile for both Hispanics and African Americans has been worsening in recent years as obesity and diabetes continue to rise exponentially within these populations.
    (Prefiled Testimony of Steven F. Horowitz, M.D. Chief of Cardiology at TSH, September 19, 2005)

20. Kathleen Silard testified to the following at the public hearing:
    - TSH has examined the significant disparity in utilization rates for PCI and OHS that exists for African Americans in TSH service area as well as other regions of the state when compared to the Caucasian population. TSH has seen how some of the major precursors of heart disease, such as diabetes and obesity, can disproportionately effect minority populations as well as the economically disadvantaged.
    - One of the primary goals of TSH's proposed program will be to address and hopefully eradicate some of those disparities by improving access to PCI and OHS to these high-risk groups.
    (Prefiled Testimony of Kathleen Silard, Senior Vice President for Operations at TSH, September 19, 2005)

21. The demographic characteristics by Race for TSH's TSA are as follows:

Table 6: TSH Demographics by Race

Service Area	Caucasian	African American	Native American	Asian	Other	Total
Primary	73.6%	13.2%	0.2%	4.6%	8.4%	100%
Secondary	85.7%	6.6%	0.1%	3.5%	4.1%	100%
Total Service Area	81.0%	9.2%	0.2%	3.9%	5.7	100%
Connecticut	81.6%	9.1%	0.3%	2.4%	6.6%	100%

Source: Census 2000.

22. The demographic characteristics by Hispanic ethnicity for the proposed TSA:

Table 7: Hispanic Ethnicity of TSH Service Areas

Service Area	Hispanic or Latino	Non-Hispanic	Total
Primary	14.7%	85.3%	**100%**
Secondary	8.4%	91.6%	**100%**
Total Service Area	10.8%	89.2%	**100%**
Connecticut	**9.4%**	**90.6%**	**100%**

Source: Census 2000.

23. The AMI discharges for the TSH TSA are as follows:

Table 8: Share of AMI by Race and Hispanic Ethnicity, FYs 2002 – 2005 (First 2 Quarters)

Service Area	Caucasian	African American	Hispanic	Asian	Native American	Other	Total
Primary	84.7%	7.0%	4.2%	0.1%	0.0%	4.0%	**100%**
Secondary	85.1%	7.1%	3.4%	1.0%	0.1%	3.3%	**100%**
Total Service Area	84.9%	7.0%	3.7%	0.6%	0.1%	3.6%	**100%**
Connecticut	**87.1%**	**4.7%**	**4.0%**	**0.3%**	**0.1%**	**3.8%**	**100%**

(Discharges from OHCA Acute Care Hospital Inpatient Discharge Database and MA, NY, and RI Hospital Discharge Databases. "White," "Black," "Asian," "Native American," and "Other" are non-Hispanic categories.)

24. NYPH has one of the largest cardiac surgery and cardiac catheterization[d] programs in New York State with its physicians performing over 3,000 PCIs and close to 2,000 OHS in calendar year 2004. *(Prefiled Testimony of Arthur A. Klein, M.D., September 19, 2005)*

[d] 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.

25. Dr. Steven Horowitz, testified on behalf of TSH to the following:
    - Diabetes is a leading cause of hospitalization among Connecticut's African American and Hispanic populations which are 3.8 and 2.2 times more likely to be hospitalized directly due to the disease as compared to the Caucasian Connecticut residents.
    - The percent difference for the African American utilization rates in the TSH's TSA versus those statewide is nearly 26% and 62% for PCI and cardiac surgery respectively. The same numbers skyrocket to 41% and 95% when the focus is placed solely on the City of Stamford.
    - TSH can target the African American and Hispanic population and relieve some of these barriers to access through the comprehensive preventive and medical outreach program.

    (Prefiled Testimony of Steven F. Horowitz, M.D., Chief of Cardiology Department at TSH, September 19, 2005)

26. Dr. Arthur Klein testified to the following at the public hearing:
    - NYPH and NYPHS have developed a number of strong and effective partnerships with affiliated hospitals to elevate the scope of and quality of cardiac care in the tri-state region.
    - NYPHS assists in the operation of nine (9) diagnostic cardiac catheterization programs through out the tri-state area, four elective angioplasty programs and one primary angioplasty program.
    - In this proposal, the cardiac surgery professional services will be provided exclusively by full-time faculty of the Division of Cardiothoracic Surgery, Department of Surgery of Columbia College of Physicians and Surgeons.
    - Oversight of elective angioplasty shall be through a joint committee co-chaired by Drs. Moses and Stone, senior faculty from Columbia University's Division of Cardiology and Stamford Hospital's cardiology leadership.

    (Prefiled Testimony of Arthur A. Klein, M.D., September 19, 2005)

27. Dr. Eric A. Rose testified at the public hearing that Columbia University Department of Surgery's professional expertise in cardiothoracic research, its strategic network of partnerships and its vast clinical experience will help support TSH in their cardiac health services. *(Prefiled Testimony of Eric A. Rose, M.D., Chairman for the Dept. of Surgery at NYP/C, September 19, 2005)*

28. TSH submitted a signed Draft Agreement with NYPHS. NYPHS' role is defined as follows:
    - Arrange consultative assistance to the Hospital in the following areas:
        - Preparation of the CON Application;
        - Clinical training of nursing and technical staff;
        - Development of the Hospital's standards of care, risk stratification criteria and operational policies;
        - Development of clinical guidelines and protocols;
        - Collection and analysis of quality data for clinical outcomes and performance monitoring;
        - Recruiting procedures; and

- Adoption by the Hospital of policies, procedures and protocols, including developing practice guidelines and requirements related to the proposed program.

- Recommend CPC standards and/or the standards of NYPHS-affiliated Connecticut institutions for physician, nursing and technical staff protocols to foster a high-quality credentialing program; and
- Advise the Hospital with respect to quality assurance and utilization management functions related to the proposed program.

(Completeness Responses, August 15, 2005, Draft Agreement between the Applicants, Exhibit 4, page 4)

29. TSH proposes to provide elective PCI utilizing five (5) interventional cardiologists, who are currently providing primary PCI services at TSH. *(Certificate of Need Application, August 15, 2005, page 11)*

30. The PCI volumes for the proposed interventionalists for FYs 2002-2005 1st two quarters are as follows:

Table 9: Volume of Proposed Program Interventionalists (FYs 2002 – FY 2005 1st Two Quarters)

Physician	Hospital Affiliation	Office/Home	Average Annual PTCA Volume
Alcan[1]	St. Vincent's & TSH	Norwalk	347
Jumper[2]	St. Vincent's & TSH	Valhalla, NY	119[3]
Charney	NY Presbyterian, Greenwich, & TSH	New Rochelle	X[4]
Messinger	NY Presbyterian, Greenwich, & TSH	New Rochelle	X[4]
Stone	NY Presbyterian, TSH (pending)	Greenwich	-

[1]Member of Cardiology Associates of Fairfield County
[2]In training
[3]Dr. Jumper performed 57 in FY 2004 and 122 in the first two quarters of FY 2005.
[4] TSH reported volume (FYs 2003 & 2004 – NYP physicians not specifically identified)
Physician C: 156 & 145 and Physician D: 108 & 126
(OHCA Acute Care Hospital Inpatient Discharge Database and CON Application, August 15, 2005, page 11&58 and Completeness Responses, August 15, 2005, page 8)

31. TSH stated that three additional cardiac interventionalists, Drs. Portnay, Lorenz and Corvaja will be added to the proposed program to perform PCIs at TSH. *(CON Application, August 15, 2005, pages 11&58 and Completeness Responses, August 15, 2005, page 8)*

32. TSH proposes to staff the proposed OHS program with two (2) board-certified cardiac surgeons, who will practice full-time at TSH and be credentialed at both TSH and at NYP/C. These two surgeons will be recruited through the formation of a three (3) person committee which will include as its members, Dr. Craig Smith, Dr. Mehmet Oz and Dr. Eric Rose, Chair of the Surgery Department at NYP/C. *(Certificate of Need Application, August 15, 2005, page 11)*

33. The average annual PCI and OHS volumes in TSH's TSA by hospital provider for FYs 2000-2005 (1st two quarters) are as follows:

Table 10: Average Annual PCI and Open-Heart Surgery Volumes by Provider in TSH's TSA by Provider, (FYs 2002 – 2005 1st Two Quarters)

	PCIs			Open-Heart Surgeries		
Hospital	**Procedures**	**Market Share**	**Area Volume as Share of Total Provider Volume (%)**	**Procedures**	**Market Share**	**Area Volume as Share of Total Provider Volume (%)**
Bridgeport	154	22.2%	12.3%	75	23.1%	24.3%
Danbury	0	0.0%	-	0	0.0%	-
Greenwich	1*	0.1%	100%	-	0.0%	-
Hartford	0	0.0%	-	0	0.0%	-
John Dempsey	1	0.1%	0.2%	0	0.0%	-
Saint Francis	0	0.0%	-	1	.3%	.1%
Saint Raphael's	4	0.5%	0.4%	3	.9%	.4%
Saint Vincent's	392	56.4%	34.9%	119	36.6%	39.7%
Yale	78	11.2%	4.8%	57	17.5%	6.4%
Out of State	65	9.3%	-	70	21.6%	-
Totals	**695**	**100%**	**-**	**325**	**100%**	-

*****Greenwich Hospital began providing primary PCI in February 2005.
(OHCA Acute Care Hospital Inpatient Discharge Database and MA, NY, and RI Hospital Discharge Databases)

34. Danbury Hospital, along with Waterbury Hospital and St. Mary's Hospital (one program, two sites in Waterbury) were authorized by OHCA to offer full-service cardiac programs in 2003. *(Certificate of Need Applications, Final Decision Docket Numbers 03-30167 & 03-30143, both dated July 23, 2005)*

35. St. Vincent's Medical Center ("SVMC") testified to the following:
    a. Angioplasty volume is flat nationally and has begun to decline in Connecticut.
    b. If TSH proposal is approved, St. Vincent's Medical Center would not be able to achieve both institutional and surgeon specific minimum volumes for OHS and would put the quality of St. Vincent's Medical Center at significant risk.
    c. SVMC performed 1,097 PCIs and 283 OHS in FY 2005.
    d. The overall risk adjusted mortality rate at SVMC is 1.3%.
    e. Other than volume, SVMC measures quality through independent third party companies (to whom they report data to).
    (Prefiled Testimony of Jose Missri, M.D. St. Vincent's Medical Center, September 28, 2005 and Public Hearing Testimony, October 6&27, 2005)

36. Bridgeport Hospital ("BH"), as part of Yale-New Haven Health Heart Institute, testified to the following:
    a. BH performed under 1,200 PCIs and under 250 OHS in FY 2005.
    b. BH could not specify their overall risk adjusted mortality rate, BH simply stated that it was under 2.0%.
    c. Other than volume, BH measures quality through independent third party companies (to whom they report data to).

d. If the proposed CON was to be approved, this would not impact the physician coverage at BH.
(Prefiled Testimony of Stuart .Zarich, M.D., Bridgeport Hospital, September 28, 2005 and Public Hearing Testimony, October 6&27, 2005)

37. Yale-New Haven Hospital ("YNHH"), as part of Yale-New Haven Health Heart Institute, testified to the following:
    a. There is a statewide decline in the number of OHS cases,
    b. There is a flattening of PCI volumes,
    c. Proliferation of full-service cardiac program will place additional stress on the state's staffing infrastructure,
    d. Additional cardiac programs will not improve mortality rates,
    e. The residents of Fairfield County have a wide range of options for their full-service cardiac care needs,
    f. There is a direct correlation between physician and institutional case volumes and quality outcomes, and
    g. In FY 2004, YNHH had 64 PCI discharges (4.3% of YNHH"s total PCI) and 52 OHS discharges (6.2% of YNHH's total OHS) from the Stamford service area.
    (Prefiled Testimony of Kyle Kramer, Executive Director of the Yale-New Haven Health Heart Institute, September 28, 2005 and Public Hearing Testimony, October 6&27, 2005)

38. In order to implement the proposed project, TSH will require a series of facility renovations. The renovations will include an expansion of surgical facilities on Level 2 of TSH's North building to allow for the creation of two new, state-of–the-art operating rooms that will be the primary operating suites for the proposed program as well as enlarged perioperative and other surgical support areas.
(Certificate of Need Application, August 15, 2005, page 13)

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

Consideration of Other Section 19a-637, C.G.S. Principles and Guidelines

39. The proposal has a total expenditure cost of $5,404,425 which consists of the following:

Table 11: Total Capital Expenditure

Description	Cost
Medical Equipment	3,109,345
Construction/Renovation	1,590,065
Project Contingency	704,925
Total Capital Expenditure	**$5,404,425**

(Certificate of Need, August 15, 2005, page 63)

40. The proposal will be financed from the TSH's equity through operations. *(Certificate of Need, August 15, 2005, page 64)*

41. TSH will pay NYPHS a fee for expenses related to training and oversight of TSH's proposed program. This arrangement will be finalized if the proposal is approved by OHCA. *(Arthur S. Klein, Chief Operating Officer of NYPHS, Public Hearing Testimony, October 6&27, 2005)*

42. TSH projects incremental to the project losses from operations for the first two years of operation for FYs 2007 and 2008 of ($1,940,000) and ($294,000), respectively. This is due to program start up. However, TSH is projecting incremental gains from operation of $1,082,000 for the third year of operation, FY 2009. *(Responses to the OHCA Completeness Letter, August 15, 2005,Updated Financial Attachment)*

43. TSH is projecting a gain from operations with the CON project of $10,137,000, $12,327,000 and $14,365,000, for FYs 2007, 2008 and 2009. *(Responses to the OHCA Completeness Letter, August 15, 2005,Updated Financial Attachment)*

44. TSH proposes to hire 26, 34 and 38 Full Time Equivalent employees for FYs 2007, 2008 and 2009, respectively. *(Responses to the OHCA Completeness Letter, August 15, 2005,Updated Financial Attachment)*

45. There is no State Health Plan in existence at this time. *(Certificate of Need Application, August 15, 2005, page 14)*

46. TSH has adduced evidence that this proposal is consistent with TSH's long-range plan. *(Certificate of Need Application, August 15, 2005, page 14)*

47. TSH has improved productivity and contained costs by participating in group purchasing, energy conservation, reengineering and through application of technology. *(Certificate of Need Application, August 15, 2005, page 59)*

48. TSH stated that this proposal will help enhance the existing academic affiliation with Columbia University College of Physicians and Surgeons. *(Certificate of Need Application, August 15, 2005, pages 59&60)*

49. TSH stated that the patient physician mix of TSH is unique as the cardiac patient care is fully integrated across all medical disciplines and is managed through a state-of-the-art multi-modality data management system. *(Certificate of Need Application, August 15, 2005, page 60)*

50. TSH's rates are sufficient to cover the proposed capital expenditure and operating costs associated with this proposal. *(Responses to Interrogatories, September 28, 2005, Updated Financial Attachment)*

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 TSH's current cardiac utilization, population served, quality of providers and physicians and geographic accessibility were significant factors in determining need.

The Stamford Hospital ("TSH") and New York Presbyterian Healthcare System, Inc. ("NYPHS") (collectively known as "Applicants"), propose to expand the cardiac services delivered at TSH to include elective angioplasty services and open heart surgery. The Applicants based the need for the elective PCI and open heart surgery programs on improved accessibility for patients, improved continuity of care, historical and existing cardiac volume, adopting a standard of care that exists in the other large urban areas and improved quality of care.

TSH's primary and secondary service area ("TSA") consists of eight (8) towns. There are no providers of elective PCI or OHS in TSH's TSA. The Hospital's service area is comprised of a higher proportion of African American and Hispanic population when compared to the rest of the state overall. The primary service area has experienced higher adult per capita rates of AMI discharges for African American and Hispanic as compared to the state as a whole. In addition, there appears to be a disparity in the utilization rates for PCI and OHS for Hispanics and African Americans in the service area when compared to the Caucasian population. This proposed cardiac program will enhance the access for the African American and Hispanic population in TSH's TSA. OHCA concludes that the Applicants proposal will provide the residents of lower Fairfield County with improved access to the full continuum of cardiac care.

TSH's historical cardiac catheterizations volumes for FYs 2002, 2003, 2004, and 2005 (1st 2 quarters) were 675, 635, 628 and 147, respectively. OHCA determined that TSH could potentially perform a minimum of 244 annual total PCIs (primary & elective) and 102 OHS cases on residents of TSH's TSA in the first full year of operation of the proposal based upon historical catheterization volume and its market share. This volume increases to 276 total PCI procedures and 117 OHS cases for the second year of operation, and 316 total PCI procedures and 137 OHS cases for the third of operation. Based on historical inpatient diagnostic cardiac catheterization volume and market share, the proposed full-service cardiac program at TSH 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 surgeries per year).

The proposal involves offering of elective Percutaneous Coronary Intervention ("PCI") through the use of five (5) interventional cardiologists, who are currently providing primary PCI services at TSH. TSH also proposes to provide OHS utilizing two (2) surgeons will be recruited from outside of Connecticut, through the formation of a three (3) person committee comprised of TSH and Columbia physicians. Therefore this program will not impact coverage at any of the existing cardiac programs in Connecticut. In addition, OHCA concludes that even though the PCI and OHS volumes may decline at the existing providers, the PCI and OHS volumes will not fall below the institutional minimum volumes recommended by ACC/AHA for PCI and American College of Surgeons-Advisory Council for Cardiothoracic Surgery for OHS.

TSH's proposal will increase the availability of quality PCI and OHS services for residents of TSH's TSA. The proposed elective PCI and OHS program will be developed in collaboration with NYPHS. NYPHS will provide or arrange for TSH consulting in the areas of clinical training for staff, development of TSH's standards of care, development of clinical guidelines, collection and analysis of data and recruiting procedures. NYPHS expects the initial training to continue over an eighteen month period. NYPHS will also advise TSH with respect to quality assurances and utilization management and provide assistance to TSH concerning the adoption of policies, procedures and protocols, including developing practice guidelines and program requirements. This proposal will improve the quality of care and continuity of TSH's cardiac services.

Finally, the CON proposal is financially feasible. The proposal has a total capital expenditure of $5,404,425, which consists $3,109,345 for medical equipment, $1,590,065 for construction/renovations and $704,925 for contingency costs. TSH proposes to fund the proposed total capital expenditure through TSH's equity, specifically through operations. TSH will pay NYPHS a fee for expenses related to training and oversight of TSH's proposed program; however, the details have not yet been finalized. TSH projects incremental losses from project operations for the first two years of operation of ($1,940,000), and ($294,000), respectively. However, TSH is projecting an incremental gain from operation of $1,082,000 by the third year of operation. Further, TSH is projecting gains from total Hospital operations with the CON project of $10,137,000, $12,327,000 and $14,365,000 for the first three years of operations. The projected utilization and financials of this proposal appear to be reasonable, financially feasible and cost-effective and will not adversely impact the interests of consumers and payers of such services.

TSH's proposed elective angioplasty and open heart surgery program is differentiated from other cardiac-related proposals in the following ways. TSH currently operates a high volume diagnostic cardiac catheterization program and recently initiated a primary angioplasty program. The Hospital's service area is comprised of a higher proportion of African American and Hispanic population than the rest of the state. The implementation of the proposed program should address some of the disparities in utilization of cardiac services by this population. Additionally, the proposed program is not expected to impact the physician coverage at any of the existing cardiac programs in Connecticut because the interventionalists are already on staff at TSH and the cardiac surgeons will be

recruited from out of state. TSH's strong collaborative relationship with the NYPHS will enhance the accessibility of high quality, community-based medical services offered by TSH. TSH will utilize the resources of NYPHS to further enhance provision of quality care including access to the expertise, information, and consultative support of a nationally recognized academic healthcare center renowned for the diagnosis and treatment of cardiac disease. Finally, implementation of TSH's proposal will bring appropriate access to high quality cardiac services to the residents of the proposal's TSA. In summary, the proposal will result in enhanced cardiac services in the Stamford region.

Order

NOW, THEREFORE, the Office of Health Care Access ("OHCA") and The Stamford Hospital ("TSH") and New York Presbyterian Healthcare System, Inc. ("NYPHS") (together referred to as "Applicants") hereby stipulate and agree to the terms of settlement with respect to the Applicants' request to establish elective angioplasty and open heart surgery program to be located at Stamford Hospital at a total capital expenditure of $5,404,425, as follows:

1. The Applicants' request for a CON to establish an elective angioplasty and open-heart surgery program to be located at TSH, a total capital expenditure of $5,404,425, is hereby approved.

2. TSH shall only commence operation of the OHS program at The Stamford Hospital initially. Once the number of OHS procedures exceeds 125, the Hospital may commence operation of the elective angioplasty program. Prior to commencement of the angioplasty services, TSH is required to provide OHCA evidence that it has performed the required 125 OHS.

3. TSH will have at least two cardiac surgeons as part of this proposal, who are in the process of being recruited and shall be identified prior to the beginning of the OHS program. The surgeons must be fully credentialed and have the following qualifications:
   - Board-Certified in cardiac surgery
   - Maintains a Connecticut license and admitting privileges at the Hospital
   - Has performed OHS procedures at a cardiac surgical center that meets or exceeds the annual ACCS/ACS minimum institutional volume standard for cardiac surgery for the past 2 years
   - TSH shall provide the Curriculum Vitae ("CV") of the cardiac surgeons prior to commencement of the OHS program. TSH shall demonstrate that the cardiac surgeons satisfy all requirements specified above. The OHS program shall not commence operation until OHCA acknowledges receipt of the CV and that it complies with this Order.

4. TSH shall provide the CVs of each of the cardiac operating room nurses, Board-certified cardiac anesthesiologists, intensivists and perfusionists for the authorized OHS program 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 they comply with this Order.

5. TSH shall not exceed the approved total capital expenditure of $5,404,425. In the event TSH learns of potential cost increases or expects final project costs will exceed those approved, the Hospital shall file with OHCA a request for approval of

the revised CON project budget. The source of funding for the project will be The Stamford Hospital's operations and owner equity.

6. TSH shall complete and submit to OHCA on a quarterly basis the data elements in the Connecticut Cardiac Data Registry (**Attachment II**). Data should be submitted to OHCA on a computer disk in either an excel workbook or comma-delimited text file in a format specified by OHCA. The most current version of the Connecticut Cardiac Data Registry includes, but may not be limited to, the elements listed in **Attachment II**. Data must be reported to OHCA thirty (30) calendar days following the end of the quarter. Fiscal Year quarters end December 31st, March 31st, June 30th, and September 30th. Upon receipt, OHCA will check the data's conformance to the required specifications and within ten (10) business days notify TSH in writing of its evaluation. If OHCA finds questionable material, TSH 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 TSH does not submit the data elements in the Connecticut Cardiac Data Registry on a quarterly basis, the programs may be terminated. In the event of such a termination, TSH shall file a CON for reinstitution of the programs.

7. TSH shall submit on an annual basis to OHCA the following reports which must be reported to OHCA thirty (30) calendar days following the end the year, for the first three (3) years of operation:
   a. A report of all elective PCIs and OHS performed each year by ethnicity and race, in a format to be specified.
   b. A report which illustrates that this CON proposal helped relieve the barriers to access through comprehensive preventive and medical out-reach programs for the African American and Hispanic population within TSH's TSA.

8. If TSH does not perform 125 OHS procedures within twelve months of the initiation of the OHS program, TSH shall submit monthly reports of OHS arrayed by physician to OHCA until such time as these volumes are met by TSH. If these volumes are not met for a period of two consecutive 12-month periods, TSH's OHS program shall be terminated. In the event of such a termination, TSH shall file a CON for reinstitution of the OHS program.

9. If TSH does not perform 200 elective PCIs within twelve months of the initiation of the PCI program, TSH shall submit monthly reports of elective PCIs arrayed by physician to OHCA until such time as these volumes are met by TSH.

10. TSH 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. TSH shall provide OHCA quarterly data reports from STS-DB and ACC-NCDR. Data must be

reported to OHCA thirty (30) calendar days subsequent to TSH receiving the reports from the STS and ACC. TSH is required to comply with the STS and ACC/AHA criteria and standards**.** If TSH determines not to participate in the STS-DB or ACC-NCDR, TSH shall notify OHCA immediately, and continue to comply with the STS and ACC/AHA criteria and standards set forth in Attachment III.

11. TSH shall provide OHCA with a copy of a dated and signed Consulting Services Agreement with NYPHS or its Affiliates prior to commencement of operation of the OHS program. This contract shall be renewed annually for a period of three years.

12. OHCA and TSH agree that this Agreed Settlement represents a final agreement between OHCA and TSH with respect to this request. The signing of this Agreed Settlement resolves all objections, claims and disputes, which may have been raised by the Hospital with regard to Docket Number 04-30374.

13. This authorization for the OHS program shall expire on December 31, 2008. Should the TSH's open-heart surgery program not commence operation by that date, TSH must seek further approval from OHCA to complete the project beyond that date.

14. 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 TSH's expense, if TSH fails to comply with its terms.

January 4, 2006

Brian G. Grissler
Duly Authorized Agent for
The Stamford Hospital

December 28, 2005

Arthur A. Klein, M.D.
Duly Authorized Agent for
New York Presbyterian Health System, Inc.

The above Agreed Settlement is hereby accepted and so ordered by the Office of Health Care Access on January 4, 2006.

January 4, 2006

Cristine A. Vogel
Commissioner & Presiding Officer

CAV:sl