



Office of Health Care Access Certificate of Need Application

Final Decision

Hospital: Norwalk Hospital and
University of Connecticut Health Center

Docket Number: 04-30286-CON

Project Title: Establish Primary and Elective Angioplasty and Open
Heart Surgery Program at Norwalk Hospital

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

Filing Date: November 26, 2004

Hearing Dates: January 19, 2005, January 25, 2005 and February 3, 2005

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

Decision Date: April 13, 2005

Default Date: Not Applicable

OHCA Staff Steven Lazarus
Michael Sabados

Project Description: Norwalk Hospital (“Hospital”) and University of Connecticut Health Center propose the establishment of primary and elective angioplasty (“PCI”) and open-heart surgery (“OHS”) program, to be located at the Hospital, at a capital expenditure of \$2,000,000.

Nature of Proceedings: On November 26, 2004, the Office of Health Care Access (“OHCA”) received the Hospital’s Certificate of Need (“CON”) application seeking authorization to establish primary and elective angioplasty and open-heart surgery program, to be located at Norwalk Hospital, at a capital expenditure of \$2,000,000. 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 January 19, 2005, January 25, 2005 and February 3, 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 Hour* (Norwalk) 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.

OHCA designated University of Connecticut Health Center as a Co-Applicant to this proposal at the Hearing on February 3, 2005.

Yale-New Haven Hospital, Bridgeport Hospital, and Greenwich Hospital collectively as Yale-New Haven Heart 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 Stamford Hospital was granted Intervenor status with no rights to cross-examination.

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. Norwalk Hospital ("Hospital") is a not-for-profit acute care hospital located at 34 Maple Street, Norwalk, Connecticut. (*May 3, 2004, Letter of Intent,*)
2. University of Connecticut Health Center ("UHC") is composed of the School of Medicine, School of Dental Medicine, John Dempsey Hospital ("JDH"), The UConn Medical Group, UConn Health Partners and University Dentists. JDH is an acute care hospital located at 263 Farmington Avenue, Farmington, Connecticut. (*January 18, 2005, Responses to the Interrogatories*)
3. The Hospital proposes the establishment of primary and elective angioplasty^a ("PCI") and open-heart surgery^b ("OHS") program, to be located at the Hospital. (*November 26, 2004 CON Application pages 5&7*)
4. The Hospital describes the proposal as a regionalized cardiovascular services care delivery model utilizing a "One Team Three Sites of Service." The three sites are Bridgeport Hospital, St. Vincent's Medical Center and the Hospital. The "team" would be made up of surgeons, anesthesiologists, physician assistants and perfusionists. (*May 3, 2004, Letter of Intent, November 26, 2004, CON Application pages 7& 74 and February 3, 2005, Public Hearing Testimony of Norwalk Hospital,*)

^a 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.

^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. The Hospital did not provide a schedule for the One-Team Three Sites of Service: *(November 26, 2004, Certificate of Need Application, pages 73&74)*
6. The Hospital submitted a signed "Letter of Intent" with UCHC in which the Hospital purchases certain clinical consulting and training services necessary for the development of the proposed program. UCHC's role is as follows:
 - Assist with development of the proposed program, including representation on the Executive Committee ("EC") for oversight of the proposed program;
 - As part of the EC, UCHC will:
 - Oversee the development of the annual plan of operation;
 - preparation of policies, procedures and protocols for services under this agreement;
 - Oversee continuous monitoring of quality, utilization and effectiveness of the proposed program; and
 - Oversee organize and provide ongoing medical education for the Hospital's cardiovascular staff;
 - Provide training for nursing staff of Critical Care, Operating Room and cardiac catheterization laboratory. *(January 18, 2005, Responses to the Interrogatories, Attachment 2, pages 27-31)*
7. The proposed program will augment existing cardiovascular services. The Hospital currently offers diagnostic cardiac catheterization, coronary care unit and telemetry inpatient care, cardiac imaging, cardiac rehabilitation, cardiac ultrasound, cardiopulmonary testing, electrocardiogram, electrophysiology, holter monitoring, intra-aortic balloon pumping, nuclear stress testing, pulmonary function testing, stress testing, tilt table testing and vascular and thoracic surgical services *(November 26, 2004, CON Application, pages 11-12)*

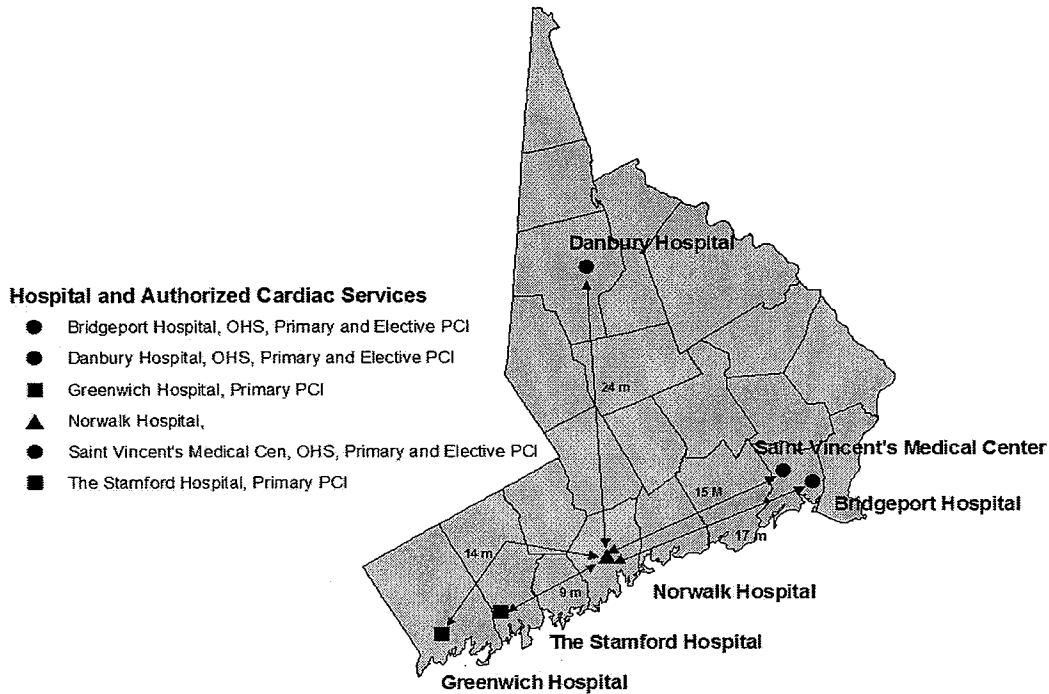
8. The Hospital's cardiology primary and secondary service areas consist of the following Connecticut towns:

Table 1: Norwalk Hospital's Proposed Open-Heart Surgery Program's Service Areas

Towns	Primary	Secondary	Total Service Area
	New Canaan	Darien	New Canaan
	Norwalk	Greenwich	Norwalk
	Weston	Stamford	Weston
	Westport		Westport
	Wilton		Wilton
			Darien
			Greenwich
			Stamford
Norwalk Hospital's Share of Area's Inpatient Diagnostic Cardiac Catheterizations	43%	1%	19%
Area's Share of Norwalk Hospital's Inpatient Diagnostic Cardiac Catheterizations	86%	4%	90%

(Source: Cardiac catheterization volume from OHCA Connecticut Inpatient Acute Care Hospital Discharge Database. Service area from September 30, 2004 CON Application 04-30286, page 17).

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



Note: Travel miles from Yahoo maps.
Danbury Hospital began performing open heart surgery in January 2005.
Greenwich Hospital began operation in February 2005.
The Stamford Hospital expected to begin operation in April 2005.
(Connecticut Inpatient Acute Care Hospital Discharge Database and February 3, 2004, Hearing Testimony)

10. The Hospital based the need for the proposed angioplasty and open-heart services on the following:
- Geographic/Transportation Barriers
 - Demographics of the Service Area Population
 - Delays in Care and Scheduling Backups
- (November 26, 2004, CON Application, pages 5-6)
11. The Hospital stated that the towns within the Hospitals proposed program service area are approximately 12-44 miles from the nearest provider of interventional cardiology and cardiac surgery services. I-95 is the main transportation artery utilized to access these providers in the city of Bridgeport and New Haven. According to the Hospital, travel on I-95, presents a challenge in that it is often congested and is frequently under construction. (November 26, 2004, Certificate of Need Application, page 49)

12. OHCA approved the following cardiac related CON proposals in 2004:
- Primary Angioplasty with acute myocardial infraction (“PAMI”) programs were approved at the following hospitals:
 - New Milford Hospital (DN: 03-30089);
 - Greenwich Hospital (DN:03-30148)
 - New Britain Hospital (DN:03-30207)
 - The Stamford Hospital (DN: 03-30176)
 - The following hospitals were approved to provide Primary and Elective Angioplasty and Cardiac Surgery services:
 - Waterbury Hospital and St. Mary’s Hospital (DN:03-30167);
 - Danbury Hospital (DN:03-30143)
13. The Hospital asserted that travel to geographic distant providers of interventional cardiology and cardiac surgery results in excessive travel time. According to the Hospital, the actual ambulance transport times to receiving hospitals in Bridgeport and New Haven range from 18-86 minutes. This was not documented by the Hospital. *(November 26, 2004, Certificate of Need Application, page 6)*
14. The Hospital’s cardiac catheterization volume for FYs 2000 through 2003 are as follows:

Table 2: Norwalk Hospital’s Historical Cardiac Catheterization Volume (FYs 2000 – 2003)

CT Service Area	2000	2001	2002	2003
Inpatient	227	262	247	204
Outpatient	201	186	194	190
Total	428	448	441	394

(OHCA Acute Care Hospital Inpatient Discharge Database and self-reported outpatient figures.)

15. The demographic characteristics of the Hospital’s CT service area is as follows:

Table 3: Demographic Characteristics of the Hospital’s Service Area

Service Area	Total	Population			
		Adults (15+)	15 – 44 (%)	45 – 64 (%)	65+ (%)
Primary	155,765	120,850	39.6	25.0	13.0
Secondary	197,791	156,334	41.6	23.1	14.3
Total Service Area	353,556	277,184	40.1	24.0	13.7
Connecticut	3,405,565	2,696,490	42.2	23.2	13.8

Source: Census 2000.

16. The Hospital cited a Solucient, Inc. population projection which forecasts a 5.1% increase in the total population of the Hospital’s proposed TSA by 2008. The model also projects a 16.2% growth in the number of those between 45 and 64, and 7.1% increase in the number of those 65 and older. Solucient’s Inc. projections could not be verified. Due to the claimed proprietary nature of the information, the Hospital did not

submit any documentation regarding these projections. (November 26, 2004, CON Application, page 24).

17. The Hospital stated that the ischemic heart disease^c for the over age 65 population in the service area is 12 percent higher compared to the rest of the State of Connecticut. (November 26, 2004, Certificate of Need Application, page 5)
18. The average annual ischemic heart disease and AMI discharges and deaths in the Hospital's CT service areas for FYs 2000-2003 are as follows:

Table 4: Average Annual Ischemic Heart Disease and AMI Discharges and Deaths in Norwalk Hospital's Proposed CT Service Areas, (FYs 2000 – 2003¹)

Service Area	Hospital Discharges				Mortality	
	Ischemic Heart Disease ²		AMI		Ischemic Heart Disease	
	Discharges	Adult Rate	Discharges	Adult Rate	Deaths	Adult Rate
Primary	851	7.0	279	2.3	206	1.7
Secondary	1,115	7.1	397	2.5	256	1.6
Total Service Area	1,966	7.1	676	2.4	462	1.7
Connecticut	-	8.2	-	3.2	-	2.1

Mortality figures are from CT Department of Public Health Vital Records.

Population figures are from Census 2000.

¹Deaths were from calendar years 2000 through 2003. AMI discharges were from Hospital Fiscal Years 2000 through 2004 (Hospital Fiscal Year from October 1st through September 30th).

²Includes discharges with a primary diagnosis of either coronary atherosclerosis or acute myocardial infarction (AMI).

ICD-9 codes: Ischemic Heart Disease 410 - 414; AMI 410.

ICD-10 codes: Ischemic Heart Disease Mortality I20 – I25.

(Discharges from OHCA Inpatient Acute Care Hospital Discharge Database and MA, NY, and RI Hospital Discharge Databases.)

Note: The adult rate was calculated by dividing the average annual total number of ischemic or AMI discharges or ischemic deaths originating in the service area by the adult population (age 15 and older) in that area and multiplying this by 1,000. Therefore, it is interpreted as the number of discharges or death per 1,000 adults in the service area (e.g. 7.1 ischemic heart disease discharges per 1,000 adults in Norwalk Hospital's total service area).

The proposed total service area has had lower adult per capita rates for ischemic heart disease and AMI discharges and ischemic mortality than the statewide rates.

^c Ischemic Heart Disease is defined as a coronary artery disease or coronary heart disease caused by narrowing of the coronary arteries and decreased blood flow to the heart

19. The average annual historical and projected PCI volumes for the Hospital's CT service areas for FYs 2000-2003 are as follows:

Table 5: Average Annual Historical and Projected PCI Volumes in CT Service Area for Norwalk Hospital's Proposed Program (FYs 2000 - 2003)

CT Service Area	FYs 2000 - 2003		Year One		Year Two		Year Three	
	Average PCIs	Adult Use Rate	Capture Rate (%)	Projected PCIs	Capture Rate (%)	Projected PCIs	Capture Rate (%)	Projected PCIs
Primary	307	2.5	55%	169	59%	181	61.5%	189
Secondary	385	2.5	16%	62	17%	66	21.5%	83
Total Service Area	692	2.5	-	231	-	247	-	272
CT	7,831	2.9	-	-	-	-	-	-

Source: *OHCA Inpatient Acute Care Hospital Discharge Database; MA, NY, and RI Hospital Discharge Databases; Census 2000 for population figures, and November 26, 2004 CON Application 04-30286, page 60 for capture rate. "Adult" refers to those 15 years and older. Adult use rate per 1,000 population.*

Note: The adult use rate was calculated by dividing the average annual total number of PCIs originating in the service area by the adult population (age 15 and older) in that area and multiplying this by 1,000. Therefore, it is interpreted as the number of PCIs per 1,000 adults in the service area (e.g. 2.5 PCIs per 1,000 adults in Norwalk Hospital's total service area).

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: 307 (average volume) * .55 (capture rate) = 169 PCIs.

20. The average annual historical and projected OHS volumes for the Hospital's CT service areas for FYs 2000-2003 are as follows:

Table 6: Average Annual Historical and Projected Open-Heart Surgery Volumes in CT Service Area for Norwalk Hospital's Proposed Program (FYs 2000 - 2003)

Service Area	FYs 2000 - 2003		Year One		Year Two		Year Three	
	Average Surgeries	Adult Use Rate	Capture Rate (%)	Projected Surgeries	Capture Rate (%)	Projected Surgeries	Capture Rate (%)	Projected Surgeries
Primary	154	1.3	55%	85	58.8%	91	61.6%	95
Secondary	188	1.2	16%	30	16.8%	32	21.5%	40
Total Service Area	342	1.2	-	115	-	123	-	135
CT	4,805	1.8	-	-	-	-	-	-

Source: *OHCA Inpatient Acute Care Hospital Discharge Database; MA, NY, and RI Hospital Discharge Databases; Census 2000 for population figures; and September 30, 2004 CON Application 04-30286, page 64 for capture rate. "Adult" refers to those 15 years and older. Adult use rate per 1,000 population*

Note: The adult use rate was calculated by dividing the average annual total number of open-heart surgeries originating in the service area by the adult population (age 15 and older) in that area and multiplying this by 1,000. Therefore, it is interpreted as the number of open-heart surgeries per 1,000 adults in the service area (e.g. 1.2 open heart surgeries per 1,000 adults in Norwalk Hospital's total service area).

Projected open-heart surgeries 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: 151 (average volume) * .55 (capture rate) = 83 open-heart surgeries.

21. 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*)
22. The ACC/AHA Guidelines for CABG Surgery (1999) state the following:
 - a) Studies suggest that survival after CABG is negatively affected when carried out in institutions that perform fewer than a threshold number of cases annually. Similar conclusions have been drawn regarding individual surgeon volumes.
 - b) The ACC/AHA are supportive of a posture of close monitoring of institutions or individuals that perform <100 cases annually.
23. The Hospital 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**. (*November 26, 2004, CON Application, page 38*)
24. 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:
 - a) An annual volume of at least 100 to 125 open-heart procedures per hospital is necessary from a quality standpoint and there is a greater variation in adjusted mortality rates for teams doing lower volumes of procedures as compared with those doing a high volume.
 - b) At least 200 procedures per year as previously recommended in the 1975 report of the Inter-Society Commission on Heart Disease Resources are necessary in order for a program to function efficiently.
 - c) A team approach with a minimum of two qualified cardiac surgeons is recommended to provide adequate and continuous perioperative care as well as assistance in the operating room.
25. The interventional cardiologists are members of Cardiology Associates, Inc., (“CA”) a private practice medical group, which has been providing cardiology services for 20 years to the Hospital without a contractual agreement. The Hospital and CA do not have a formal contractual agreement. (*January 18, 2005, Responses to the Interrogatories, page 2*)
26. The Hospital submitted an agreement between the Hospital and Cardiovascular & Thoracic Surgery Specialist, LLC, with the understanding that the Hospital will retain Dr. Robinson as their Chief of Cardiothoracic Surgery, upon approval of the proposed CON. (*January 18, 2005, Responses to the Interrogatories, pages 2 and 24-25*)

27. Although, Dr. Robinson is no longer Chief of Cardiology at BH, he continues to maintain privileges at BH (*February 3, 2005, Public Hearing Testimony of Dr. Clive Robinson*)
28. Dr. Robinson testified that there is a declining national trend in the number of CABG procedures between 1997 and 2002:

Table 7: Historical National CABG Surgery Volumes, Period Changes, 1997-2002

Growth in population requiring CABG	8%
CABG Utilization	-22%
Net Decline	-14%

(*January 18, 2005, Prefiled Testimony, page 89, Health Care Advisory Board, Future of Cardiac Surgery, Service line Innovation Brief-2004*)

29. In 2003, the Health Care Advisory Board Company, a national health care advisory board, published projections for CABG procedures between 2003 and 2008, which project a 7% decline. Further, Sg2, LLC, a national healthcare consulting firm, predicts a 37% decline in CABG procedures between 2001 and 2011. (*January 18, 2005, Prefiled Testimony R. Kyle Kramer, page 6*)
30. On a statewide basis, there was a 16.3% decline in the number of adult open-heart surgeries and a 4.5% increase in PCIs from 2000 to 2004, as seen in **Attachment II**.
31. Bridgeport Hospital testified to the following:
- BH experienced a 17.9% decline in OHS volume from 290 in FY 2003 to 244 in FY 2004;
 - The potential loss in volume to BH with approval of this proposal would be 55 OHS procedures and 144 PCI procedures, based on FY 2004 volumes; and
(*January 18, 2005, Prefiled Testimony Robert J. Trefy, pages 3 and 4 and Prefiled Testimony of Dr. Zarich.*)
32. YNHHHI testified that if this proposal was approved, based on FY 2004, YNH would loose 63 PCI procedures and 41 OHS procedures. (*January 18, 2005, Prefiled Testimony, R. Kyle Kramer, page 12*)
33. SVMC testified that if the proposed program is approved, it would draw 110 angioplasty cases and 33 cardiac surgery cases from SVMC. These procedures represent 10.1% of St. Vincent's fiscal year 2004 angioplasty volume and 11.3% of SVMC's FY 2004 OHS volume. (*January 18, 2005, St. Vincent's Medical Center, Prefiled Testimony, Jose Missri, M.D., page 16*)

34. The average annual PCI and OHS volumes in the Hospital's service area by area provider for FYs 2000-2003 are as follows:

Table 8: Average Annual PCI and Open-Heart Surgery Volumes by Provider in Norwalk Hospital's Proposed CT Service Area by Provider, (FYs 2000 – 2003)

Hospital	PCIs			Open-Heart Surgeries		
	Procedures	Market Share	Area Volume as Share of Total Provider Volume (%)	Procedures	Market Share	Area Volume as Share of Total Provider Volume (%)
Bridgeport	161	23.3%	13.1%	89	26.0%	25.9%
Hartford	1	0.2%	0.0%	1	0.3%	0.0%
John Dempsey	0	0.0%	0.0%	0	0.0%	0.0%
Saint Francis	0	0.0%	0.0%	0	0.0%	0.0%
Saint Raphael's	3	0.4%	0.3%	5	1.5%	0.6%
Saint Vincent's	379	54.7%	33.0%	110	32.2%	34.2%
Yale	82	11.9%	5.2%	67	19.8%	6.8%
Out of State	66	9.5%	-	70	20.5%	-
Totals	692	100.0%	-	342	100.0%	-

(CT OHCA Inpatient Acute Care Hospital Discharge Database and MA, NY, and RI Hospital Discharge Databases.)

35. The Hospital states that patients that require transport to providers of interventional cardiology services, experienced delays in care ranging between 1 day to 3.5 days. This delay was not documented by the Hospital. (November 26, 2004, Certificate of Need Application, page 6)
36. Patients transferred to other providers for interventional cardiac procedures between FYs 2002-2004, are as follows:

Table 9: Norwalk Hospital Patient transfer to Other Facilities for Interventional Cardiac Procedures, FYs 2002-2004

	FY 2002		FY 2003		FY 2004	
	PCI	OHS	PCI	OHS	PCI	OHS
SVMC	39	22	35	21	37	18
BH	24	26	8	15	6	11
HSR	0	0	1	0	0	0
YNHH	3	4	7	0	2	4
NYH	0	1	1	0	0	2
Totals	66	53	52	36	45	35

Note: BH: Bridgeport Hospital, SVMC: St. Vincent's Medical Center, HSR: Hospital of St. Raphael, YNHH: Yale-New Haven Hospital, NYH: New York Hospitals
ICD-9-CM Codes
PCI: 36.01, 36.02, 36.05, 36.06 & 36.07
OHS: 35.10-35.28 & 36.11-36.19

(February 17, 2005, Norwalk Hospital, Late File page 1)

37. The Hospital staffing plan for the proposed program includes four (4) cardiac surgeons and four (4) interventional cardiologists. (January 18, 2005, Responses to the Interrogatories, pages 1&2)

38. Dr. Sanchez, Chief of Cardiology at BH, testified that he is concerned with the dilution of cardiac services, “for example in FY 2004 there were 426 OHS from the Bridgeport and Norwalk area and if you were to take that 426 OHS and divide them between BH and SVMC and the proposed Norwalk Hospital site that would dilute the volume to 142 OHS per institution. This also does not take into account for the continued decline in the OHS.” *(January 25, 2005, Testimony of Dr. Juan Sanchez)*
39. Dr. Sanchez testified to the following regarding surgeons in the Bridgeport and Norwalk area:
- “An additional cardiac surgeon will need to be hired by the Hospital, as I will not participate in proposed program, for a total of five (5) cardiac surgeons;”
 - “BH may be required to hire an additional cardiac surgeon to fill coverage gap left by Dr. Robinson, for a possible total of six (6) cardiac surgeons;” and
 - “Introduction of new surgeons into the area is of concern, as it will dilute the individual surgeon experience.”
- (January 25, 2005, Testimony and Cross-Examination of Dr. Juan Sanchez)*
40. The volumes for the proposed cardiac surgeons could not be verified as the Hospital did not identify 3 out of the 4 cardiac surgeons associated with the proposed program. The Hospital stated that out of deference to the surgeons and their current work and personal situation, individual surgeon names, other than Dr. Robinson, can not be disclosed publicly at this time. *(January 18, 2005, Responses to the Interrogatories)*
41. CA is expected to hire a fifth interventionalist to its practice, who will be added to the proposed program. *(November 26, 2004, Responses to the Completeness Letter, page 15)*
42. The historical cardiac catheterization and PCI volume by CA physician for FYs 2000-2003 are as follows:

Table 10: Cardiac Catheterization by CA Physician, FYs 2000-2003

Physician	FY ‘00	FY ‘01	FY ‘02	FY ‘03
Dr. Augenbraun	90	93	94	77
Dr. Jumper	*	*	*	*
Dr. Alcan	351	363	321	319
Dr. Sheynberg	35	156	185	225
Physician E	**	**	**	**
Total Cases	476	612	600	621

* In training including Fellowship

** Potential newly recruited cardiologist

(November 26, 2004, Responses tot the Completeness Letter, page 16 and January 18, 2005, Responses to the Interrogatories, page 1)

Table 11: PCI Volume by CA Physician, FYs 2000 - 2003

Physician	2000	2001	2002	2003
Dr. Augenbruan	7	3	6	5
Dr. Jumper	*	*	*	*
Dr. Alcan	314	359	377	371
Dr. Sheynberg	0	64	77	92
Physician E	**	**	**	**
Total Cases	321	426	460	468

Source: OHCA Acute Care Hospital Inpatient Discharge Database.

*In training including Fellowship (*November 26, 2004 Responses to Completeness Letter, page 16*).

**Potential newly recruited cardiologist (*November 26, 2004 Responses to Completeness Letter, page 16*).

43. The Hospital projects the following number of primary and elective PCI's procedures and OHS procedures for its TSA. These projections can not be verified. (*November 26, 2004, pages 60-64 and February 10, 2005, Late File, Financial Attachment, page 4*)

Table 12: Projected CT Cardiac Volume

Service	FY 2005	FY 2006	FY 2007
Angioplasties	256	303	349
Open-heart surgeries	151	176	201

Note: The Hospital based the projected volumes on Chime Inpatient and Ambulatory Surgery Databases and includes HANYS volume from CT. Population estimates based on Claritas, Inc. (via Solucient, Inc.), PCI defined as Inpatient cases with ICD9 codes 36.0, 36.02, 36.05 and 36.06, and cardiac surgery is defined as Inpatient cases with ICD9 codes 35.1x-35.28 and 36.11-36.19.

**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**

44. The proposal has a total expenditure cost of \$2,000,000 which consists of the following:

Table 13: Total Capital Expenditure

Description	Cost
Medical Equipment	1,726,319
Installation & Contingency	273,681
Total Capital Expenditure	\$2,000,000

(November 26, 2004, CON Application, page101)

45. The proposal will be financed from the Hospital's equity through operations. *(November 26, 2004, CON Application, page 102)*
46. The Hospital will pay UCHC a fee of totaling \$400,000 per year for UCHC's expenses related to training and oversight of the Hospital's proposed program. *(February 10, 2005, Late File, Financial Attachment, page 4)*
47. UCHC reports no incremental gains as a result of this proposal. Even though UCHC receives \$400,000 per year from the Hospital for its part in this proposal, the operating expense (salaries and fringe benefits and other operating costs) per year cost \$400,000. *(February 10, 2005, Late File, UCHC Financial Attachment, page 5)*
48. The Hospital projects a gain from operations incrementally due to the project of \$949,000, \$2,134,000 and \$2,968,000 for FYs 2006 through 2008, respectively. *(February 10, 2005, Late File, Financial Attachment, page 4)*
49. The Hospital proposes to hire 43.3 Full Time Equivalent Employees for FY 2006 and none are proposed for FYs 2007 and 2008. *(February 10, 2005, Late File, Financial Attachment, page 4)*

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

The following findings are made pursuant to principles and guidelines set forth in Section 19a-637, C.G.S.:

50. There is no State Health Plan in existence at this time. *(November 26, 2004, CON Application, page 2)*
51. The Hospital has adduced evidence that this proposal is consistent with the Hospital's long-range plan. *(November 26, 2004, CON Application, page 2)*
52. The Hospital has improved productivity and contained costs by participating in group purchasing, energy conservation and reengineering. *(November 26, 2004, CON Application, page 99)*
53. The Hospital stated that this proposal will help enhance the independent cardiology fellowship program, which began in 1999. *(January 18, 2005, Prefiled Testimony of Eric M. Mazur, M.D. page 20)*
54. The patient physician mix for the Hospital is typical of an acute care hospital in Connecticut. *(November 26, 2004, CON Application)*
55. The Hospital's rates are sufficient to cover the proposed capital expenditure and operating costs. *(November 26, 2004, CON Application, pages 107-110 and February 10, 2005, Late File, Financial Attachment, page 4)*

Rationale

The Office of Health Care Access (“OHCA”) approaches community and regional need for proposed services on a case-by-case basis. Certificate of Need (“CON”) applications for cardiac services do not lend themselves to general applicability due to the variety and complexity of factors, which may affect any given proposal; e.g., the characteristics of the population to be served, the nature of the existing services, the specific services proposed to be offered, the current utilization of services, and the financial feasibility of the proposed service. In considering this application, OHCA determined that the demographics of the service area population, lower mortality due to ischemic heart disease, close proximity to existing providers and lack of geographic isolation factored in determining need for this proposal.

Norwalk Hospital (“Hospital”) proposes to establish a primary and elective angioplasty service and an open-heart surgery service at the Hospital. The Hospital will purchase clinical consulting and training services necessary for the development of the proposed cardiac program from University of Connecticut Health Center (“UCHC”). The Hospital describes the proposal as a regionalized cardiovascular services care delivery model utilizing a “One Team Three Sites of Service.” The three sites of service are Bridgeport Hospital (“BH”), St. Vincent’s Medical Center (“SVMC”) and the Hospital. The surgeons and interventional cardiologists associated with the proposed program currently perform procedures at Bridgeport Hospital and St. Vincent’s Medical Center, and Stamford Hospital.

The Hospital based the need for the proposed program on the demographics of the service area, delays in care, scheduling backups and geographic/transportation barriers. The Hospital asserts that there is an older population and higher mortality rate due to ischemic heart disease in the Hospital’s service area as compared to State of Connecticut. The data that supports these claims is alleged to be proprietary in nature or self-reported by the Hospital; in either case the data can not be verified. The Hospital’s analysis of the service area is not consistent with data from the U.S. Census, the Connecticut Department of Public Health Vital Records and OHCA’s Acute Care Discharge Data Base which demonstrates that compared with the State of Connecticut as a whole, the Hospital’s proposed primary service area (“PSA”) has a lower share of the 65 and older population and a lower adult per capita rate for ischemic heart disease and AMI discharges and ischemic mortality than the rest of the state.

With respect to the geographic/transportation barriers and delays in receiving care, the Hospital stated that the Hospital’s service area residents currently are required to travel 12-44 miles to the nearest provider of interventional cardiac services. The Hospital’s analysis was based on the residents of the Hospital’s TSA receiving interventional cardiac services from existing providers in New Haven and Bridgeport. Stamford Hospital and Greenwich Hospital were not included in the analysis. Stamford Hospital and Greenwich Hospital were recently approved for primary angioplasty (“PAMI”) services. These PAMI providers are located at a distance of 9 and 14 miles from the

Hospital. Since the TSA identified by the Hospital includes residents of Stamford and Greenwich, these two hospitals provide a closer alternative for PAMI services for these patients. It is estimated that 20% of MI patients are candidates for PAMI. Travel time and distance are critical for patients requiring PAMI services. Immediate intervention should occur within 90-120 minutes to prevent damage to the heart. Since BH, SVMC, Stamford Hospital and Greenwich Hospital are within 20 miles, OHCA finds that the Hospital's TSA residents have appropriate and timely access to primary angioplasty services. Travel time and distance are less critical for the elective angioplasty patient and for the open heart surgery patient. ACC/AHA guidelines recommend that transport to the receiving cardiac facility occur within 72 hours. According to the Hospital, current elective angioplasty patients are transported to the receiving cardiac facility within 1 to 3.5 days. This was also not documented by the Hospital. MI patients who require elective PCI or OHS (approximately 80% of all MI patients) are normally scheduled within 72 hours. Transferring these patients to existing providers for these cardiac services does not represent an access to care issue; rather it is an issue of convenience. Therefore, OHCA concludes that the Hospital failed to demonstrate the need for the proposed PCI and OHS services on any of the three bases relied by the Hospital, i.e. geographic/transportation barriers, demographic characteristics of the service area population, or delays in care and scheduling backlogs.

In addition to the above factors, OHCA considers an evaluation of volumes of cardiac procedures. Nationally, statewide and locally, there has been a decline in the volume of OHS procedures performed. Nationally, between 1997 and 2002, the number of OHS procedures experienced a net decline of 14%. Statewide there was a 16.3% decline in OHS procedures between 2000 and 2004. Health Care Advisory Board Company predicts a 37% decline in CABG procedures between 2001 and 2011. Regionally, in FY 2004, the total OHS procedures for the Bridgeport and Norwalk area was 426. It must be noted that the Hospital transferred only 53, 36 and 35 patients for OHS to facilities offering OHS services, for FYs 2002, 2003 and 2004, respectively. The Hospital projects 151, 176 and 201 OHS for FYs 2005 through 2007, which the Hospital based on Chime Inpatient and Ambulatory Surgery Databases and estimates based on Solucient, Inc. These projections could not be verified by OHCA. In light of the declining OHS volume nationally, statewide, and regionally, OHCA questions the validity of the Hospital's volume projections that demonstrate a significant increase in volume.

The Hospital has also experienced a decline in the number of diagnostic and cardiac catheterization procedures and referrals to other institutions for PCI procedures. The volume in the Hospital's cardiac catheterization laboratory has declined from 448 catheterizations in FY 2000 to 392 in FY 2003, including an 11% decline in cardiac catheterization volume from FY 2002 to FY 2003. The Hospital transferred 66, 52 and 45 patients for PCI procedures to facilities offering PCI services for FYs 2002, 2003 and 2004, respectively. While the Hospital is projecting 256, 303 and 349 PCIs for FYs 2005 through 2007, OHCA's data analysis indicates an average annual TSA volume of 272 PCIs procedures in the third year of operation of the proposed program at the Hospital. Due to the discrepancy in the projections and lack of verification of Hospital's

projections, OHCA questions the validity of the Hospital's estimated projections of PCI volumes.

The Guidelines for Standards in Cardiac Surgery by the Advisory Council for Cardiothoracic Surgery and the American College of Surgeons recommend at least 200 OHS procedures per year for a functionally efficient program. The American College of Cardiology ("ACC") and the American Heart Association ("AHA") recommend that angioplasty be performed by high volume (>75 PCIs) operators in high volume (>400 PCIs per year) institutions. Two of the four interventional cardiologists currently perform the recommended minimum number of annual PCIs. Another identified interventionalist is in training therefore his volumes were not reported. The other identified interventionalist does not meet the recommended annual minimum volume of PCIs. With respect to number of OHS procedures to be performed, in FY 2004, the total OHS procedures for the Bridgeport and Norwalk area were 426. Assuming the Hospital's program was operational in FY2004, there would have insufficient volume for the three facilities in the Norwalk and Bridgeport area to meet the recommended institutional guidelines. Furthermore, if the same 426 OHS procedures were divided among the possible five (5) cardiac surgeons, each surgeon would perform an average of 85 OHS procedures. OHCA considers the recommendations set forth in professional guidelines to be an important measure in evaluating the proposed program. OHCA is concerned that the proposed program will not meet minimum institutional volume requirements.

The proposal has a total expenditure for the Hospital consists of \$1,726,319 of medical equipment and \$273,681 of installation and contingency, for a total capital expenditure of \$2,000,000. The proposal will be financed from the Hospital's equity through operations of \$2,000,000. The Hospital has adequate funds to finance the capital expenditure; therefore OHCA concludes that the proposal is financially feasible. The Hospital projects an incremental gain from operations of \$949,000, \$2,134,000 and \$2,968,000 for FYs 2006, 2007 and 2008, respectively with the implementation of this CON proposal.. Since the Hospital's volume projections are questionable, the projected operating gains are also questionable. Therefore, OHCA can not draw any conclusions on the reasonableness of the financial projections.

After careful consideration, the Hospital's proposal is differentiated from other cardiac-related proposals in the following ways: First, Norwalk Hospital is not geographically isolated from providers of primary and elective angioplasty or open-heart surgery programs. Primary or emergent angioplasty is clinically indicated for STEMI and LBBB patients who need immediate intervention within 90-120 minutes. There are two existing providers of primary angioplasty services in Bridgeport who are 15 and 17 miles away from the Hospital and two recently approved primary angioplasty programs in Stamford and Greenwich who are 9 and 14 miles in distance from the Hospital. Therefore, residents of the Hospital's service area have appropriate access to primary angioplasty services both east and west of the Hospital. NSTEMI patients which consist of 80% of all myocardial infarctions or heart attacks are considered for angioplasty on an elective basis within 72 hours. There are two existing and three recently approved full-service interventional cardiac programs in Bridgeport, Danbury and Waterbury. Therefore, the

residents of the Hospital's service area are within an acceptable distance to full-service cardiac programs for elective or scheduled procedures. Secondly, OHCA understands that volume is not the only indicator of quality; however it remains an important measure in evaluating medical care. The volume of open-heart surgeries has been declining nationally, statewide and locally. OHCA was not able to verify nor confirm the Hospital's volume projections; therefore, OHCA is concerned that only minimum volume will be attainable for the institution and the physicians. In summary, the Hospital did not provide sufficient evidence of need and specifically failed to justify the proposed program based on the key factors identified by the Hospital. Therefore, the request for Certificate of Need is DENIED.

Order

The proposal of Norwalk Hospital and University of Connecticut Health Center to establish Primary and Elective Angioplasty and Open-Heart Surgery program at Norwalk Hospital, at a total capital expenditure of \$2,000,000 is hereby denied.

All of the foregoing constitutes the final order of the Office of Health Care Access in this matter.

Date Signed:
April 13, 2004

Signed by:
Cristine A. Vogel
Commissioner and Presiding Officer

CAV:sl

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

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

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

Attachment II

Adult Invasive Cardiac Therapeutic Procedure Volumes by Hospital, FYs 2000 - 2004

Hospital	Angioplasty					Open Heart Surgery				
	2000	2001	2002	2003	2004	2000	2001	2002	2003	2004
Bridgeport	1,228	1,193	1,217	1,268	1,298	338	391	345	314	272
Hartford	1,169	1,080	1,343	1,500	1,339	974	910	888	836	754
St. Raphael	1,094	696	728	993	933	928	758	764	690	621
Yale	1,361	1,477	1,677	1,767	1,514	1,018	1,045	959	893	852
Totals	7,703	7,376	7,764	8,354	8,050	5,048	4,852	4,625	4,467	4,226

Source: CT Office of Health Care Access Inpatient Acute Care Hospital Discharge Database.

Adult refers to those 15 years or older.

ICD-9-CM Codes: PCI 36.01, 36.02, 36.05, 36.06, & 36.07. Open Heart Surgery: 35.10 - 35.28 & 36.11 - 36.19.