



Office of Health Care Access Certificate of Need Application

Final Decision

Applicant: The Stamford Hospital

Docket Number: 03-30159-CON

Project Title: Expansion of Electrophysiology Program with the introduction of Cardiac Catheter Ablation Therapy

Statutory Reference: Section 19a-638 of the Connecticut General Statutes, as amended by Public Act 03-17

Filing Date: August 4, 2004

Decision Date: October 29, 2004

Default Date: November 2, 2004

Staff: Karen Roberts

Project Description: The Stamford Hospital (“Applicant” or “TSH”) proposes to expand the scope of its electrophysiology program with the introduction of cardiac catheter ablation therapy. The associated total capital expenditure is \$195,000.

Nature of Proceedings: On August 4, 2004, the Office of Health Care Access (“OHCA”) received the completed Certificate of Need (“CON”) application of The Stamford Hospital seeking authorization to expand the scope of its electrophysiology program with the introduction of cardiac catheter ablation therapy. The associated total capital expenditure is \$195,000. The Applicant is a health care facility or institution as defined by Section 19a-630 of the Connecticut General Statutes (“C.G.S.”).

On September 1, 2004, the Applicant was informed that a notice to the public regarding OHCA’s receipt of the Applicant’s completed CON application would be published in *The Advocate*. OHCA has received no comments from the public concerning the Applicant’s completed CON application.

OHCA's authority to review and approve, modify or deny the CON application is established by Section 19a-638, C.G.S., as amended by Section 1 of Public Act 03-17. 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 Applicant's Current Utilization Statistics Contribution of the Proposal to the Accessibility and Quality of Health Care Delivery in the Region

- 1) The Stamford Hospital ("Applicant" or "TSH") is an acute care general hospital located at Shelburne Road at West Broad Street in Stamford, Connecticut. (*February 9, 2004 Certificate of Need ("CON") Application, page 5*)
- 2) The Applicant is proposing to expand its electrophysiology services¹ ("EPS") with the introduction of cardiac catheter ablation therapy². (*February 9, 2004 CON Application, Page 7*)
- 3) On September 10, 2003, OHCA issued a CON determination under Report Number 03-30159-DTR that stated, "*OHCA has determined that some of the proposed procedures to be performed in the existing cardiac catheterization laboratory are therapeutic or interventional in nature and therefore represent a new service. This determination is consistent with previous OHCA decisions regarding catheterization services. OHCA considers cardiac laboratories to be either diagnostic or therapeutic/interventional. Separate CON authorization is required for laboratories to perform therapeutic/interventional procedures. Therapeutic or interventional EP studies (i.e. ablations) are currently not performed in diagnostic cardiac catheterization laboratories in the state.*" (*CON Determination under Docket Number 03-30159-DTR*)
- 4) The proposed cardiac catheter ablation services will be provided in the Applicant's existing cardiac catheterization laboratory. The Applicant's diagnostic cardiac catheterization laboratory has been in operation for over 20 years. (*February 9, 2004 CON Application, Page 6 and CON Determination filing received on August 12, 2003*)
- 5) The Applicant currently provides the following cardiac related services:

¹ Electrophysiology is a subspecialty of cardiology related to the diagnosis and treatment of conduction disease. Conduction disease causes electrical disturbances in the heart that disrupt its ability to maintain a normal heart rate and rhythm. These disturbances are known as cardiac arrhythmias (irregular heart beats). Electrophysiology studies can help evaluate both bradycardias (slow heart arrhythmias) and tachycardias (rapid heart arrhythmias). Bradycardia is most often treated by insertion of a permanent pacemaker; ablation therapy can be an appropriate treatment method for selected patients suffering from either ventricular or atrial tachycardia.

² Radiofrequency catheter ablative procedures are currently accepted as a primary therapy for most patients with supraventricular tachycardia and for several forms of ventricular tachycardia ("VT"). Catheter Ablation refers to the intentional destruction of arrhythmogenic myocardial tissue, atrioventricular connections or parts of the specialized conduction system in order to cure or control cardiac arrhythmias.

- Cardiac Catheterization including right and left heart catheterizations and coronary angiography procedures (Docket Number 03-30176-CON)
- AICD (automatic internal cardioverter/defibrillator) evaluation and follow-up
- Cardioversions, bedside cardioversions
- Pacemaker Installations and Pacemaker evaluation and follow-up
- CT and MRI scanning
- Tilt Table Studies for assessment of syncope or dizziness
- Special Care in a 20 bed Special Care Unit, which is designed to handle patients who have more severe coronary syndromes. This unit and the CCU are used for post cardiac catheterization patients needing special observation and services.
- Cardiac Rehabilitation Program in the Tully Health Center
- Critical Care in a 14-bed Critical Care Unit (“CCU”)
- Echocardiography (trans thoracic and trans esophageal)
- 24-hour Holter monitoring
- 24 hour EKG monitoring
- Health and Fitness Center for patients at risk in the Tully Health Center
- Stress Testing
- Nuclear Cardiac Imaging (stress and at rest)
- Resting and Exercise Echocardiography
- Monitoring in a 32 bed monitored unit focusing on cardiac care through special protocols for patients with congestive heart failure, coronary artery disease and arrhythmias. In addition, the unit admits patients who also need EKG monitoring.

(February 9, 2004 CON Application, Page 6)

- 6) The Applicant will not be performing interventional electrophysiology procedures on pediatric patients, ages 0-14. *(August 4, 2004 Completeness Responses, page 1)*
- 7) The proposed hours of operation for regular scheduling of cardiac ablations will be Monday through Friday, 7:00 A.M. to 4:00 P.M., with evening and weekend hours available as needed. Physician coverage for cardiac ablation will be available 24 hours a day, seven days a week. *(February 9, 2004 Certificate of Need Application, Pages 6 and 16-17)*
- 8) The Applicant projects that 90% of the ablations will be outpatient procedures and 10% will be inpatient procedures. *(February 9, 2004 Certificate of Need Application, Pages 16-17)*
- 9) The Applicant has had an active pacemaker program for over two decades. The Applicant performed 160 pacemaker insertions in 2003 in addition to the insertion of implantable arrhythmia recording devices (loop recorders) as well as ambulatory event recorders. *(February 9, 2004 CON Application, Page 6)*
- 10) The Applicant based the need for the proposed cardiac catheterization ablation service on the following:
 - Existing cardiac volume
 - Reduction in mortality and morbidity in the service area
 - Improved accessibility for patients
 - Improved continuity of care*(February 9, 2004 CON application, pages 10-17)*

11) TSH's proposed service areas ("PSA") for the proposed program consist of the following towns:

Table 1: Stamford Hospital's PSA

Towns	Primary	Secondary
	Stamford	Darien Greenwich New Canaan Norwalk Westport Wilton
Hospital's Market Share for All Inpatient Cardiac Catheterizations	63.4%	8.3%
Area's Share of Hospital's CT Inpatient Cardiac Catheterizations	79.0%	16.0%

Source: February 6, 2004 CON Application, page 16 & CT Office of Health Care Access Acute Care Hospital Acute Care Hospital Inpatient Discharge Database

12) The demographic characteristics of TSH's PSA are as follows:

Table 2: Demographic Characteristics of Applicant's PSA

Population					
Service Area		Adults (15+)	15 – 44 (%)	45 – 64 (%)	65+ (%)
Primary	117,083	94,819	45.5	21.7	13.8
Secondary	226,436	175,220	38.5	24.9	13.9
Total PSA	343,519	270,039	40.1	23.8	13.8
Connecticut	3,405,565	2,696,490	42.2	23.2	13.8

Source: Census 2000.

13) The Applicant used Environmental Systems Research Institute ("ESRI") data to project that in the primary and secondary service areas the 45-64 age cohort would grow by 14.2% and 65 years and older would grow by 1.9% from 2003 to 2008. These projections could not be verified due to the claimed proprietary nature of the information. (February 9, 2004 Certificate of Need Application, Pages 10-11)

14) The volume of inpatient cardiac catheter ablations in TSH's Connecticut service area for FYs 2000-2003 are as follows:

Table 3: Inpatient Cardiac Catheter Ablations within TSH's PSA, FYs 2000 - 2003

Service Area	2000	2001	2002	2003	Total	Seniors' Share (%)
Primary	5	17	9	15	44	39
Secondary	33	58	37	46	170	22
CT Service Area	38	75	46	61	214	60

Source: OHCA Acute Care Hospital Inpatient Discharge Database.

15) The average annual congestive heart failure discharges and deaths in TSH's PSA are as follows:

Table 4: Average Annual Congestive Heart Failure Discharges and Deaths in Stamford Hospital's Proposed Service Area, (FYs 1999 – 2003¹)

Service Area	Discharged from CT Hospitals		Mortality	
	Discharges	Adult Rate	Deaths	Adult Rate
Primary	420	4.4	88	0.93
Secondary	563	3.2	220	1.26
CT Service Area	983	3.6	308	1.14
Connecticut	10,289	3.8	3,134	1.16

Source: OHCA Acute Care Hospital Inpatient Discharge Database, CT Department of Public Health Vital Records, and Census 2000 for population figures.

¹Discharges were from FYs 2000 through FY 2003; Deaths were from calendar years 1999 through 2001.

ICD-9 code: Congestive Heart Failure 428.0

ICD-10 code: Congestive Heart Failure Mortality I50.0.

16) The Applicant has an average of 317 discharges of patients suffering from heart failure and shock annually, making this the Applicant's single largest DRG (DRG 127: Heart Failure and Shock) for Medicare patients. (OHCA Acute Care Hospital Inpatient Discharge Database)

17) The number of residents from the Applicant's service area discharged from all Connecticut hospitals for treatment under DRG 127 (Heart Failure and Shock) totaled 917 for CY 2002 according to CHIME data. (OHCA Acute Care Hospital Inpatient Discharge Database)

18) The Applicant also has an average of 239 cases annually involving diagnosis of cardiac arrhythmia and conduction disorder and 183 cases involving syncope and collapse from its proposed service area. (OHCA Acute Care Hospital Inpatient Discharge Database)

19) Ablation procedures will be performed on patients with the following types of cardiac electrical disorders:

- Selected patients with ventricular tachycardia (fast heartbeat)
- Selected patients with atrial fibrillation (chaotic or irregular heartbeat)
- All patients with pre-excitation accessory pathways (for example, Wolff-Parkinson-White and Lown-Ganong-Levine syndromes and Supraventricular tachycardias.

(August 4, 2004 completeness responses, pages 2-3)

20) The North America Society of Pacing and Electrophysiology (“NAPSE”) Policy Statement of Catheter Ablation states the following:

- Full cardiac surgical support is desirable but that at minimum, facilities performing ablation should have thoracic surgical backup.
- The overall risk of developing a thromboembolic complication after catheter ablation recently has been estimated to be only 0.6%. The risk of a thromboembolic complication is higher when ablation is performed in the left heart and/or for ventricular tachycardia
- The percent of successful ablations and the percent of complications were compared for medical centers which did more than 100 cases annually versus those that did less than 100 cases annually. NASPE found no significant difference in the incidence of successful ablation or complications between the two groups. In addition, comparison of data for large volume centers (i.e., those performing greater than 100 cases) versus lower volume centers (less than 100 cases) showed no significant difference between the groups.

(February 9, 2004 CON Application, pages 7-8, pages 52-53, and page 56 {the NASPE Policy Statement on Catheter Ablation})

21) The Applicant will be compliant with the latest NAPSE Policy Statement on Catheter Ablation in that it will have a fully equipped EPS laboratory and on-site thoracic surgical back up. The Applicant has five thoracic surgeons on staff. *(February 9, 2004 CON Application, pages 7-8)*

22) Cardiac catheter ablation therapy is not currently provided within the Applicant’s primary or secondary service area towns. *(February 9, 2004 CON application, page 15)*

23) Currently, patients presenting to TSH needing ablation must travel between 24 – 80 miles to receive this service at one of the seven Connecticut hospitals offering the procedure. *(February 9, 2004 Certificate of Need Application, Page 13)*

24) The Stamford Hospital accounts for 95% of the discharges to any Connecticut hospital for DRG 127 (Heart Failure and Shock) for Stamford residents. *(OHCA Acute Care Hospital Inpatient Discharge Database and August 4, 2004 completeness responses, Attachment 2)*

25) The Applicant projects ablation volume as follows:

Year One FY 2004	Year Two FY 2005	Year Three FY 2006	Year Four FY 2007
32	41	51	56

(February 9, 2004 Certificate of Need Application, Pages 16-17)

26) The Applicant used the following methodology to develop its projected volumes: based its projected volumes on the following calculation demonstrates the application of the 6.5% factor to projected cardiac catheterization volumes to arrive at an unadjusted projected cardiac ablation volume figure:

Fiscal Year	Projected cardiac catheterization volumes	X 6.5%*	Unadjusted Projected Ablation Volume	Program Development**	Revised Projected Volumes
2004	705 cardiac catheterizations	X 6.5%	46	70%	32
2005	780 cardiac catheterizations	X 6.5%	51	80%	41
2006	864 cardiac catheterizations	X 6.5%	56	90%	51
2007	956 cardiac catheterizations	X 6.5%	62	90%	56

(August 4, 2004 completeness responses, page 8)

*The Applicant's consultant John Goodman & Associates assumed that ablations represent 6.5% of cardiac catheterization and PCI volume. The validity of this assumption could not be determined due to the proprietary nature of the information.

**John Goodman & Associates define program development as the time required for the proposed program to become fully operation. The validity of this factor could not be determined due to the proprietary nature of the information.

27) Over the four year period, FYs 2000 through 2003, statewide ablation volumes increased by almost 50% from 563 to 821. (OHCA Acute Care Hospital Inpatient Discharge Database)

28) All EPS services offered at TSH will meet or exceed the guidelines set forth in the ACC/AHA Clinical Competence Statement on Invasive Electrophysiology Studies, Catheter Ablation and Cardioversion. These guidelines include the following:

- All of the physicians performing EPS procedures will be board certified in electrophysiology. (February 9, 2004 CON Application, Page 19)
- All physicians performing EPS procedures will meet the following volume standards: 38 Radiofrequency ablation procedures per year; 130 Complete EP studies per year; 4 DC Cardioversion elective procedures per year; and 20 Tilt Table testing procedures per year. These same physicians will also attend a minimum of 30 hours of continuing medical education every 2 years. (February 9, 2004 CON Application, Pages 20 - 21)
- All physicians performing EPS procedures will have completed one year of specialized training in an accredited CCEP after the completion of an accredited cardiovascular disease residency program. (February 9, 2004 CON, Pages 20 - 21)
- All physicians performing EPS procedures will demonstrate (i) the ability to safely and efficiently perform the catheterization procedures for intracardiac recording and simulation; and (ii) an understanding of the electrophysiological mechanisms and clinical manifestations of arrhythmias, the applications and limitations of the available recording and stimulation technologies, the pharmacological effects of medications used during the studies and the risks, benefits and applications of nonpharmacological therapy. (February 9, 2004 CON, Pages 20 - 21)

- 29) The Applicant will model its EPS policies and procedures after protocols established by New York Presbyterian Hospital /Columbia Presbyterian Medical Center (“NYPH/CPMC”). In addition TSH support staff are in the process of undergoing EPS training at NYPH/CPMC. *(February 9, 2004 Certificate of Need Application, Page 22)*
- 30) The Applicant stated that five interventional cardiologists who will perform ablation therapy. The physicians are Dr. David A. Rubin, Dr. Jose Dizon, Dr. Michael Pittaro, Dr. Jeffrey Banker, and Dr. Anthony Magnano. The volumes provided below by physician can not be verified through OHCA’s Acute Care Hospital Inpatient Discharge Database:

Table 8: Proposed Program Interventionalists

Physician	Hospital Affiliation	Average Annual Procedures
Rubin	TSH, SVMC, CPMC	100
Dizon	TSH, SVMC, CPMC	40
Magnano	TSH, Norwalk Hospital	40
Pittaro	SVMC, CPMC, TSH*	40**
Banker	TSH, BH, Yale-New Haven	

*Currently applying for admitting privileges

**Annualized using 6 months actual from 10/03-3/04

(February 9, 2004 CON Application, Pages 20 – 21 and August 4, 2004 completeness response, page 5)

- 31) The Applicant stated that patients who require cardiac surgery will be transferred on an urgent basis to Connecticut Hospitals that offer full-service cardiac programs. The Applicant has executed transfer agreements with Bridgeport Hospital, St. Vincent’s Medical Center, and Hospital of St. Raphael. *(February 9, 2004 Certificate of Need Application, Page 23 and Attachment 11)*
- 32) The average number of inpatient ablation patients from TSH’s Connecticut service area, discharged from New York hospitals from FYs 2000 through FY 2002, was seven. While the average number of congestive heart patients from the same service area discharged from New York hospitals was an annual average of 32. Potentially this accounts for an additional 39 patients who could receive inpatient ablation therapy at TSH. *(New York Inpatient Acute Care Discharge Data)*
- 33) Currently Yale-New Haven Hospital (“YNHH”) provides almost 80% of the inpatient catheter ablations in the Applicant’s proposed primary service area and about 63% of the procedure in the proposed Connecticut Service Area. However this is only 13% of YNHH’s total volume. Other significant providers in the area are Bridgeport Hospital (10%), Hospital of St. Raphael’s (7%) and St. Vincent’s Medical Center (5%) accounting for 10%, 3% and 15% of their volume respectively . In all the inpatient volume from the proposed service area is 7% of the state total. *(OHCA Acute Care Hospital Inpatient Discharge Database)*

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

- 34) The capital expenditure related to this CON proposal is \$195,000 for the purchase of medical equipment. It is being funded through TSH operating funds. *(February 9, 2004 Certificate of Need Application, Pages 24-26)*
- 35) Equipment purchases total \$195,000 for EP Stimulator (\$25,000), Monitoring Device (\$128,000), EP Ablation Generator (\$30,000) and Biventricular Defibrillator (\$12,000). *(February 9, 2004 Certificate of Need Application, Pages 27-28)*
- 36) The revenue, expense and volume projections that have been provided include the revenues and expenses for ablation procedures as well as similar data for EPS diagnostic studies, AICD implants and AICD generator changes. TSH intends to expand its EPS program to include these other services at the same time as it begins ablation procedures and include a June 1, 2004 start date. *(February 9, 2004 Certificate of Need Application, pages 27-28 and Attachment 12)*
- 37) The Project Related Gains from Operations for FY 2004, FY 2005, FY 2006 and FY 2007 are expected to be \$35,000, \$98,000, \$148,000 and \$166,000, respectively. *(August 4, 2004 Completeness Responses, Exhibit H)*
- 38) Project related payer mix is estimated to be 50% Medicare/50% non-Medicare/Commercial. *(February 9, 2004 Certificate of Need Application, Pages 27-28)*

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

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

- 39) There is no State Health Plan in existence at this time. *(February 9, 2004 CON Application, Page 9)*
- 40) The Applicant has adduced evidence that the proposal is consistent with the Applicant's long-range plan. *(February 9, 2004 CON Application, Page 9)*
- 41) The Applicant has improved productivity and contained costs by undertaking energy conservation and group purchasing activities. *(February 9, 2004 CON Application, Page 22)*
- 42) The proposal will not result in any change to the Applicant's teaching and research responsibilities. *(February 9, 2004 CON Application, Page 23)*

43) There are no distinguishing or unique characteristics of the Applicant's patient/physician mix related to the proposal. (*February 9, 2004 CON Application, Page 23*)

44) The Applicant has sufficient technical, financial and managerial competence and expertise to provide efficient and adequate service to the public. (*February 9, 2004 CON Application, Pages 63-129*)

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, and the financial feasibility of the proposed service. In considering this application, OHCA determined that the existing electrophysiology services ("EPS"), the older demographic make-up of the service area, as well as the high rate of congestive heart failure and patients diagnosed with cardiac arrhythmia are significant factors in determining need.

The Stamford Hospital ("Applicant or TSH") is proposing to expand its electrophysiology services ("EPS") with the introduction of cardiac catheter ablation therapy. The proposed cardiac ablation therapy services will be provided in the Applicant's existing cardiac catheterization laboratory. The Applicant has extensive programs for the prevention, diagnosis and treatment of various cardiac conditions, including most recently the approval of a Primary Angioplasty (PAMI) program. The Applicant has an existing electrophysiology program including pacemaker insertions and implantable arrhythmia recording devices (loop recorders) as well as ambulatory event recorders.

The rate of hospitalization for congestive heart failure (CHF) in the hospital's CT service area is slightly below the statewide rate (3.6 versus 3.8 per 1000 adults). However, the primary service area rate is above statewide average (4.4 versus 3.8 per 1000 adults). The crude death rate for the same disease in the Applicant's total service area is also slightly below the state's rate (1.14 versus 1.16 per 1000 adults). The rate in the secondary service area however exceeds the statewide rate (1.26 versus 1.16 per 1000 adults). The Applicant has an average of 317 discharges of patients suffering from heart failure and shock annually. The Applicant also has on average 239 cases annually involving diagnosis of cardiac arrhythmia and conduction disorder and 183 cases involving syncope and collapse from its proposed service area.

The Applicant's service area (PSA) for this project consists of Stamford, Darien, Greenwich, New Canaan, Norwalk, Westport and Wilton. TSH has the largest market share (95%) of hospitalizations of congestive heart diseases in its proposed primary PSA. Cardiac catheter ablation therapy is not currently provided within the Applicant's service area towns. The number of residents from the Applicant's service area discharged from all Connecticut hospitals for treatment under DRG 127 (Heart Failure and Shock) totaled 917 for CY 2002 according to CHIME data. The Stamford Hospital accounts for 95% of the discharges to any Connecticut hospital for DRG 127 for Stamford residents. Currently, patients presenting

to the Applicant needing ablation must travel between 24 – 80 miles to receive this service at one of the seven Connecticut hospitals currently offering the procedure. The 65 and older population account for 60% of inpatient ablation discharges from the Applicant's proposed service area, with almost two-thirds (39%) from the primary service area. The Applicant projects ablation volume for the first four years of the program as 32 ablations in FY 2004, 41 in FY 2005, 51 in FY 2006 and 56 in FY 2007. Ablation volumes have increased in Connecticut on an annual basis of 9.8% per year from FY 2000 to FY 2003.

The proposed program will be operated in compliance with the guidelines of both the North America Society of Pacing and Electrophysiology ("NAPSE") which state that full cardiac surgical support is desirable, but that at a minimum a facility providing ablation should have thoracic surgical backup. The Applicant currently operates a fully equipped EPS laboratory and on-site thoracic surgical back up program. The overall risk of developing a thromboembolic complication after catheter ablation recently has been estimated to be only 0.6%. The NASPE has concluded that ablation of the AV junction, slow AV nodal pathway for patients with AVNRT, and accessory pathway ablation, *"have matured to the point where these procedures can be performed effectively and safely in either academic or in experienced community hospitals."*

Additionally, all EPS services offered at TSH will meet or exceed the guidelines set forth in the ACC/AHA Clinical Competence Statement on Invasive Electrophysiology Studies, Catheter Ablation and Cardioversion. The Applicant has assembled a team of five board-certified electrophysiologists to provide ablation therapy and other EPS services to selected low risk patients in its existing catheterization laboratory. The physicians who will be providing ablation therapy services at The Stamford Hospital will meet the ACC/AHA recommended number of ablation procedures a year. The Stamford Hospital will model its EPS policies and procedures after protocols established by NYPH/CPMC. In addition TSH support staff are in the process of undergoing EPS training at NYPH/CPMC. Patients who require cardiac surgery will be transferred on an urgent basis to Bridgeport Hospital, SVMC, and Hospital of St. Raphael, which TSH has transfer agreements with.

Based on the foregoing reasons, OHCA finds that there is a clear public need for expansion of The Stamford Hospital's electrophysiology program by the addition of cardiac catheter ablation therapy, and that the proposal will improve the quality and accessibility of cardiac catheter ablation therapy services available to residents of The Stamford Hospital's primary and secondary service areas.

Finally, the CON proposal is financially feasible. The proposal has a total capital expenditure of \$195,000 and will be financed from the Applicant's operating funds. The Applicant projects a gain from operations in all years of the program. If volume projections are achieved, the Applicant's rates are sufficient to cover the minimal proposed capital expenditure and operating costs associated with the project. The Applicant's financial projections appear to be reasonable and should not have any negative impact on the Applicant's future financial results.

Based upon the foregoing Findings and Rationale, the Certificate of Need application of The Stamford Hospital to expand the scope of its electrophysiology program with the introduction of cardiac ablation therapy at a total capital expenditure of \$195,000 is hereby **GRANTED**.

Order

The Stamford Hospital located at Shelburne Road at West Broad Street in Stamford, Connecticut, is hereby authorized to expand its electrophysiology program to include cardiac catheter ablation therapy, at a total capital expenditure of \$195,000, subject to the following conditions:

1. This authorization shall expire October 29, 2005. Should the Applicant's cardiac catheter ablation therapy program not be fully implemented by that date, the Applicant must seek further approval from OHCA to complete the project beyond that date.
2. The Applicant shall not exceed the approved capital expenditure of \$195,000. In the event that the Applicant learns of potential cost increases or expects that the final project costs will exceed those approved, the Applicant shall file with OHCA a request for approval of the revised project budget.
3. The Applicant shall submit a copy of the protocols to be used for the cardiac catheter ablation therapy program.
4. The Applicant will provide OHCA with utilization reports on a quarterly basis for a period of one (1) year from the inception of the program. The Applicant will notify OHCA of the start of commencement within one month of such commencement date. The quarterly reports shall be filed within thirty days subsequent to the end of each quarter. The quarterly reports shall include the following information:
 - a) The number of total catheter ablations by inpatient versus outpatient
 - b) Catheter ablations by patient town of origin
 - c) The number of catheter ablation patients requiring a related emergency procedure at The Stamford Hospital
 - d) The number of catheter ablation patients requiring transfer for emergency treatment at a tertiary facility and the reason for such transfer.

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

By Order of the
Office of Health Care Access

October 29, 2004

Signed by Cristine A. Vogel
Commissioner