



Office of Health Care Access Certificate of Need Application

Final Decision

Applicant: Norwalk Hospital

Docket Number: 03-30188-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

Filing Date: October 17, 2005

Decision Date: January 12, 2006

Default Date: January 15, 2006

Staff: Karen Roberts

Project Description: Norwalk Hospital (“Applicant”) proposes to expand the scope of its electrophysiology program with the introduction of cardiac catheter ablation therapy. The associated total capital expenditure is \$14,085.

Nature of Proceedings: On October 17, 2005, the Office of Health Care Access (“OHCA”) received the completed Certificate of Need (“CON”) application of Norwalk 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 \$14,085. The Applicant is a health care facility or institution as defined by Section 19a-630 of the Connecticut General Statutes (“C.G.S.”).

Pursuant to Section 19a-638, C.G.S., a notice to the public concerning OHCA’s initial receipt of the Applicant’s CON application was published in *The Hour* on March 17, 2004. OHCA received no comments from the public concerning the Applicant’s CON application. Pursuant to Public Act 05-75, three individuals or an individual representing an entity with five or more people had until November 7, 2005, the twenty-first calendar day following the filing of the

Applicant's completed CON Application, to request that OHCA hold a public hearing on the Applicants' proposal. OHCA received no hearing requests from the public by November 7, 2005.

OHCA's authority to review and approve, modify or deny the CON application is established by Section 19a-638, C.G.S. The provisions of this section, as well as the principles and guidelines set forth in Section 19a-637, C.G.S., were fully considered by OHCA in its review.

Findings of Fact

Clear Public Need

Impact on the Applicant's Current Utilization Statistics

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

1. Norwalk Hospital ("Applicant") is an acute care general hospital located at 34 Maple Street in Norwalk, Connecticut. (*March 8, 2004 Certificate of Need ("CON") Application, page 1*)
2. The Applicant is proposing to expand its electrophysiology services¹ ("EPS") with the introduction of cardiac catheter ablation therapy². The proposed cardiac catheter ablation services will be provided in the Applicant's existing cardiac catheterization laboratory. (*March 8, 2004 CON application, page 2*)
3. The Applicant has been providing electrophysiology services since 1968, in conjunction with the cardiology group, Cardiology Associates, P.C. These services included pacemaker insertion, pacemaker lead and battery changes, pacemaker follow-up and monitoring. In October of 2003, the Applicant expanded its services to include diagnostic electrophysiology testing, automatic implantable cardio-defibrillator implantation and follow-up and bi-ventricular pacemaker insertion. (*October 17, 2005 completeness responses, cover letter and pages 2-3*)
4. The Applicant will only perform adult interventional electrophysiology procedures. (*October 17, 2005 completeness responses, page 1*)

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.

5. The Applicant’s primary and secondary service areas for the proposed program consist of the following towns:

Table 1: Norwalk Hospital’s PSA

	Primary Service Area Towns	Secondary Service Area Towns
	Norwalk	Bethel
	Westport	Brookfield
	Weston	Danbury
	New Canaan	Darien
	Wilton	Greenwich
		New Fairfield
		Newtown
		Redding
		Ridgefield
		Sherman
		Stamford
Area’s Share of Applicant’s CT Inpatient Cardiac Catheterizations	83.9%	4.3%

(March 8, 2004 CON application, Pages 18 – 19)

CT Office of Health Care Access Acute Care Hospital Inpatient Discharge Database 2003 – 2004

Cardiac Catheterization: ICD-9-CM Codes 37.21 - 37.23.

6. The Applicant currently provides the following cardiac related services:

Diagnostic Cardiac Catheterization

Coronary Care Unit and Telemetry Inpatient Care

Cardiac Imaging

Cardiac Rehabilitation

Cardiac Ultrasound

Cardiopulmonary Testing

Electrocardiograms

Electrophysiology, including

- Pacemaker Insertion
- Pacemaker Lead and Battery Changes
- Pacemaker Follow-up and monitoring
- Diagnostic Electrophysiology Testing
- Automatic Implantable Cardioverter-Defibrillator Implantation & Follow-up
- Biventricular Pacemaker Insertion

Holter Monitoring

Intra-Aortic Balloon Pumping

Nuclear Stress Testing

Pulmonary Function Testing

Stress Testing

Tilt Table Testing

Vascular and Thoracic Surgical Services

(March 8, 2004 CON Application, page 6)

7. The hours of operation of the proposed catheter ablation program will be the same hours of operation of the current electrophysiology program, Monday through Friday, 7:00 A.M. to 4:00 P.M., evening and weekend hours as required. *(March 8, 2004 CON application, page 35)*
8. The cardiac catheterization laboratory has open access to available time slots. The coordination of the appointment schedule for EPS studies and cardiac catheterization procedures is readily accomplished as nearly all of the EPS studies and the cardiac catheterization procedures are scheduled and performed on an elective basis. In the rare event that an emergency cardiac catheterization is required, and an elective procedure is already booked at that time, the elective procedure would be rescheduled to accommodate the emergency cardiac catheterization. *(October 17, 2005 completeness responses, pages 3-4)*
9. A catheter ablation typically takes two to six hours and is routinely performed under mild sedation with local anesthesia. *(March 8, 2004 CON application, page 13)*
10. The Applicant projects that 90% of the ablations will be outpatient procedures and 10% will be inpatient procedures. *(March 8, 2004 CON application, page 12)*
11. The Applicant indicates that the primary service area towns will account for 90% of the cardiac ablation procedures and the secondary service area towns will account for 10%. *(March 8, 2004 CON application, page 52)*
12. The Applicant has based the need for the proposed cardiac catheterization ablation service on the following:
 - The aging of the population in the Applicant's service area;
 - Cardiovascular disease prevalence in the Applicant's service area;
 - Statewide growth in ablation procedure volume;
 - Arrhythmia standards of care;
 - Ablation success rates in community hospitals;
 - Improvement in quality of life scores and reduction in disease-specific symptoms;
 - Cost savings to the patient over drug therapy options.*(March 8, 2004 CON application, pages 4-5)*
13. The Applicant indicates that new treatment modalities such as bi-ventricular pacing for congestive heart failure and ablation for atrial fibrillation will lead to an exponential rise in electrophysiology procedures. *(March 8, 2004 CON application, page 21)*

14. The following table demonstrates demographic characteristics of Norwalk Hospital's Service Area, using Census 2000 statistics:

Table 2: Demographic Characteristics of Norwalk Hospital Service Area, 2000

Service Area	Population		Age Cohort Share of total		
	Total	Adults *	15-44	45 – 64	65+
Primary	155,765	120,850	39.6%	25.0%	13.0%
Secondary	381,094	310,260	36.6%	31.1%	13.7%
Total Service Area	536,859	431,110	37.5%	29.4%	13.5%
Connecticut	3,405,565	2,696,490	42.2%	23.2%	13.8%

Source: Census 2000

* "Adults" refers to those 15 years of age or older

15. The Applicant provided the following information to demonstrate that the aging of the population in the primary and secondary service area is growing at a faster rate than the State of Connecticut. The source of the Applicants' information is Solucient using 2002 as a base to project forward to 2007. The information provided is not verifiable by OHCA:

Table 3: CY 2002 Demographic Characteristics of Applicant's PSA

Service Area	Total 2002	Ages	Ages 65+	Total 2007	Ages	Ages 65+
	Population	45 – 64		Population	45 – 64	
Primary	158,001	41,529	20,341	163,301	47,379	21,227
Secondary	354,425	88,564	43,972	367,767	101,400	46,256
Total Service Area	512,426	130,093	64,313	531,068	148,779	67,483
Connecticut	3,436,532	836,511	470,443	3,509,453	943,113	485,497

(Source of Applicant's information is Solucient, Inc. March 8, 2004 CON application, pages 19- 21)

16. The Applicant provided the following volume statistics for its existing electrophysiology program, for the period October 2003 through June 2005 (a period of approximately 20 months combined). This date is not verifiable by OHCA and the Applicant did not provide this separately for each fiscal year, so OHCA is unable to determine whether the volumes have been increasing over time.

Table 4: Patient Origin Data for Norwalk Hospital Electrophysiology Studies for October 2003 through June 2005

<i>Electrophysiology Volume</i>						
	Diagnostic Electrophysiology		Implantable Electrophysiology			
	Loop Recorders	EP Studies	AICD ³	BIV ⁴	Pacemaker	Total EP*
Norwalk	0	12	88	60	88	248
Westport	2	1	22	6	22	53
New Canaan	0	4	10	12	10	36
Wilton	0	2	19	4	19	44
Weston	0	0	7	3	7	17
PSA	2	19	146	85	146	398
Stamford	0	2	6	27	6	41
Darien	0	0	7	6	7	20
Ridgefield	0	1	3	1	3	8
Redding	0	0	5	0	5	10
Greenwich	0	0	0	2	0	2
Newtown	0	0	0	2	0	2
Danbury	0	0	1	0	1	2
SSA	0	3	22	38	22	85
All other towns	0	4	8	8	9	29
Total EP Procedures	2	26	176	131	177	512

(October 17, 2005 completeness responses, page 9)

(* Corrected totals from the figures provided by the Applicant on page 9 of the completeness responses)

17. The Applicant indicates that there are currently no providers of cardiac catheter ablation within the Applicant's primary service area towns. (March 8, 2004 CON application, page 32)

18. Stamford Hospital commenced operation of its cardiac catheter ablation therapy program October 18, 2005. (Stamford Hospital Cardiac Ablation CON file under Docket Number 03-30159-CON)

³ AICD is Automatic Implantable Cardioverter Devices

⁴ BIV is Biventricular Lead Revision/Replacement

19. The Applicant indicates that, at the time of the CON application in March 2004, there were seven ablation providers in the State, with the four facilities closest to Norwalk as follows (all located to the service area population primarily via the I-95 corridor):

- Bridgeport Hospital in Bridgeport
- St. Vincent’s Medical Center in Bridgeport
- Yale-New Haven Hospital in New Haven
- Hospital of Saint Raphael in New Haven

(March 8, 2004 CON application, page 33)

20. The Applicant indicates that the proposed service will have minimal impact on ablation program volumes of the existing providers of the service and any impact would be offset by the annual growth rates in ablation volume. OHCA is unable to verify the Applicant’s assumptions. *(March 8, 2004 CON application, page 32)*

21. The Applicant projects cardiac catheter ablation volume as follows:

FY 2005	42
FY 2006	50
FY 2007	57

These volume projections can not be verified by OHCA. *(October 17, 2005 completeness responses, page 51)*

22. The Applicant submitted the following methodology to demonstrate how the Applicant had arrived at its volume projections for the first three years of operation. However, OHCA is unable to verify the population projections and use rates per 1,000 population upon which the utilization projections are based. *(October 17, 2005 completeness responses, pages 15 – 17 and 51)*

Table 5: Applicant’s calculation to arrive at projected volumes for the proposal:

	2002	Projected 2005	Projected 2006	Projected 2007
Population Age 44+ *				
Primary S.A.	61,870	65,912	67,259	68,606
Secondary S.A.	132,536	141,608	144,632	147,656
Use Rates per 1,000 pop.				
Primary S.A.	0.113	0.539	0.629	0.706
Secondary S.A.	0.189	0.678	0.792	0.889
PSA Market Share		90%	90%	90%
SSA Market Share		10%	10%	10%
Projected Volume from PSA		32**	38	44
Projected Volume from SSA		10	11	13
Total projected volume from SA		42	50	57

* Source of Applicant’s assumptions and calculation is Solucient, Inc.

** Example of Calculation: Population projected for 2005 for the PSA is 65,912 / 1,000 = 65.9 X 0.539 use rate per 1,000 pop for 2004 PSA = 35.5 X 90% market share penetration in the PSA = 31.9 or 32 projected procedures for PSA in 2005.

23. Ablation procedures will be performed on selected patients suffering from supra ventricular tachycardia, which is a rapid heartbeat originating from the atria, including selected patients with the following types of supra ventricular tachycardia:

- Atrial fibrillation (chaotic or irregular heartbeat)
 - Atrial Flutter
 - AV Node Te entrant Tachycardia
 - AV reentrant tachycardia
 - Atrial Tachycardia
- (October 17, 2005 completeness responses, page 21)

24. According to the Applicant, most ablation procedures are performed at the same time as the diagnostic electrophysiology study. If the electrophysiology study were for supra-ventricular arrhythmia, for example, over 90% of patients would have an ablation performed at the same time as the electrophysiology study. (October 17, 2005 completeness responses, page 28)

25. According to the report issued in 2003 by the American College of Cardiology/American Heart Association Task Force and the European Society of Cardiology Committee for Practice Guidelines entitled *ACC/AHA/ESC Guidelines for the Management of Patients with Supraventricular Arrhythmias*, the incidence rate of supraventricular arrhythmias amount patients with Congestive Heart Failure⁵ is 11.1%. (ACC/AHA/ESC report provided in March 8, 2004 CON application pages 261 – 325)

26. Heart Failure and Shock is a common arrhythmia precursor. Heart Failure and Shock Inpatient Discharges for FY 2003 – FY 2004 are as follows:

Table 6: Heart Failure and Shock Discharges, FYs 2003 – 2004

	2003	2004
Norwalk Hospital Heart Failure Shock and Discharges	360	349
Heart Failure and Shock Discharges from Norwalk Hospital's Primary Service Area to all CT hospitals	342	338
Heart Failure and Shock Discharges from Norwalk Hospital's Secondary Service Area to all CT hospitals	906	908
Heart Failure and Shock Discharges from Norwalk Hospital's Total Service Area to all CT hospitals	1,248	1,246

Source: CT Office of Health Care Access Inpatient Acute Care Hospital Discharge Database. Reporting discharges from Connecticut Hospitals only. Heart Failure and Shock: DRG 127.

⁵ According to the February 2002 report on Cardiovascular Disease issued by the Connecticut Department of Public Health, Congestive heart failure is a heart disease condition that involves loss of pumping ability by the heart, generally accompanied by fluid accumulation in organs like the lungs. It occurs when the heart becomes progressively weaker due to conditions such as high blood pressure or heart attack. (March 8, 2004 CON application, page 195)

27. Cardiac Arrhythmia & Conduction and Syncope & Collapse are also common arrhythmia precursors. The Service Area Residents Discharged from Norwalk Hospital for Cardiac Arrhythmia and Conduction Disorders or Syncope and Collapse for FY 2003 – FY 2004, are as follows:

Table 7: Service Area Residents Discharged from Norwalk Hospital for Cardiac Arrhythmia and Conduction Disorders or Syncope and Collapse, FYs 2003 – 2004

Service Area	2003		2004	
	CA&CD* discharges	S&C ** Discharges	CA&CD* discharges	S&C ** Discharges
Primary Service Area	161	107	172	130
Secondary Service Area	7	6	12	7
Total Service Area	168	113	184	137
Total Norwalk Hospital Discharges	181	127	210	156

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

*CA&CD = Cardiac Arrhythmia and Conduction Disorders: DRG 138 & 139

** S&C = Syncope and Collapse: DRG 141 & 142.

28. The average number of inpatient cardiac catheter ablations by existing service provider for service area residents for FY 2003- FY 2004 is as follows:

Table 8: Average Annual Service Area Residents receiving inpatient Cardiac Catheter Ablations by Provider, FYs 2003 – 2004 combined

Provider	Primary	Secondary	Total	Market Share	Area's share of each provider's total inpatient ablation volume
Yale-New Haven Hospital	6.5	16	22.5	35.7%	15.2%
Bridgeport Hospital	9.5	4.5	14	22.2%	17.4%
Hospital of St. Raphael	0	12.5	12.5	19.9%	12.9%
St. Vincent's Medical Center	4.5	2.5	7	11.1%	18.2%
Others	2	5	7	11.1%	-
Total	22.5	40.5	63	100.0%	-

Source: CT Office of Health Care Access Inpatient Acute Care Hospital Discharge Database and New York Statewide Planning and Research Cooperative (SPARCS) Inpatient Acute Care Hospital Database (average volume for FYs 2001 – 2002). Cardiac Catheter Ablation ICD-9-CM Code: 37.34

29. The Applicant indicates that the current cardiac ablation therapy wait times range from one to two weeks and that with the anticipated volume increases consistent with recent trends, it is further expected that wait times will become excessive in length. This information is not verifiable by OHCA. (March 8, 2004 CON application, page 32)

30. Norwalk Hospital's Interventional Cardiac Procedures for FY 2003 – FY 2004 are as follows:

Table 9: Norwalk Hospital Interventional Cardiac Procedures, FYs 2003 – 2004

Procedure	2003	2004
Inpatient Cardiac Catheterizations ¹	204	195
Pacemaker Insertions	45	59
Biventricular Pacemaker Insertions	2	2
Automatic Implantable Cardioverter Defibrillator Implantations	2	21

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

ICD-9-CM Codes:

Catheterizations: 37.21 – 37.23

Pacemaker Insertion: 37.80 – 37.89.

Biventricular Pacemaker Insertion: 37.87.

Automatic Implantable Cardioverter Defibrillator Implantations: 37.94 – 37.99

¹OHCA does not currently collect outpatient data and therefore cannot present outpatient cardiac catheterization figures.

31. 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. (*October 17, 2005 completeness responses, pages 53-54*)

32. The Applicant indicates that The North American Society of Pacing and Electrophysiology (“NASPE”) Policy Statement on Catheter Ablation (2002) will be utilized for patient selection criteria. The NASPE Policy Statement 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.
(*March 8, 2004 CON application, page 45 and Attachment 6, the NASPE Policy Statement on Catheter Ablation, pages 254 – 257*)

33. According to the Applicant, major complications occur in less than 2% of patients, including thromboembolism in less than 1% and death in less than 0.3%. Rare complications, including heart attack, stroke or sudden death, occur in less than 1%. (*March 8, 2004 CON application, page 14*)

34. The Applicant filed its Cardiology Continuous Quality Improvement Plan which includes the Department of Electrophysiology. This plan includes Quality Assurance Indicators for Ablation. (*March 8, 2004 CON Application, pages 447 and 451*)

35. 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 patient transfer agreements with Bridgeport Hospital and Yale-New Haven Hospital. *(March 8, 2004 CON application, pages 552 - 560)*
36. According to the Applicant, cardiac catheter ablation has an overall success rate exceeding 90%. The common form of supraventricular tachycardia is curable with a single ablation procedure with a success rate of at least 90 to 95%. Cure rates for unifocal atrial tachycardia and common right atrial flutter are somewhat lower but still approach 90%. *(March 8, 2004 CON application, page 14)*
37. According to the Applicant, all physicians performing cardiac ablation procedures will meet the educational guidelines set forth in the American College of Cardiology / American Heart Association ("ACC/AHA") Clinical Competence Statement on Invasive Electrophysiology Studies, Catheter Ablation and Cardioversion (2000) and will be board certified in electrophysiology. *(March 8, 2004 CON application, page 42)*
38. According to the ACC/AHA Clinical Competence Statement on Invasive Electrophysiology, Catheter Ablation and Cardioversion (2000), the benefit gained through arrhythmia treatment with catheter ablation is superior to that achieved through medical therapy and catheter ablation provides a safe and highly effective treatment for symptomatic patients with supraventricular tachycardia. *(March 8, 2004 CON application, page 245)*
39. The NASPE AdHoc Committee on Catheter Ablation has recommended that a physician who performs catheter ablation should have been the primary operator on ≥ 30 ablations *(March 8, 2004 CON application, page 246)*
40. The ACC/AHA guideline for Clinical Competency volume standard is 20 to 50 ablations per year with a mean of 38. *(March 8, 2004 CON application, Page 246)*
41. Michael Pittaro, M.D. will be the primary physician performing ablation procedures at Norwalk Hospital. Dr. Pittaro is a member of Cardiology Associates and is the Program Director for the Applicant's Diagnostic Electrophysiology Program. It is estimated that Dr. Pittaro will perform 40 of the estimated 42 procedures in Year One. Dr. Pittaro also has privileges at St. Vincent's Medical Center. The Applicant indicates that for FY 2004, Dr. Pittaro performed 40 ablations at St. Vincent's Medical Center which meets the ACC/AHA competency standards. The amount of ablations performed by Dr. Pittaro at St. Vincent's Medical Center has not been verified. *(March 8, 2004 CON application, page 15 and October 17, 2005 completeness responses, pages 25-26)*
42. Dr. Pittaro has admitting privileges at Norwalk Hospital, Stamford Hospital and St. Vincent's Medical Center. *(March 8, 2004 CON application, page 43)*
43. The Applicant is currently in discussion with a second physician who will meet or exceed the ACC/AHA Guidelines for Clinical Competency to also perform cardiac ablation procedures at Norwalk Hospital. *(October 17, 2005 completeness responses, Page 26)*

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
Consideration of Other Section 19a-647, C.G.S. Principles and Guidelines

44. The Applicant's cardiac catheterization laboratory is currently equipped with various electrophysiology equipment. The sole additional equipment requirement necessary to perform cardiac ablation procedures is an ablation generator. The capital expenditure related to this CON proposal is \$14,085 for the purchase of a Stockert 70 Generator from Biosense Webster, Inc. It is being funded through the Applicant's operating funds. *(March 8, 2004 CON application, pages 42, 49 and 561)*
45. The Project Related Gains from Operations for Year One, Year Two and Year Three are estimated to be \$13,000, \$16,000, and \$19,000, respectively. *(October 17, 2005 completeness responses, Attachment #6, page 56)*
46. Project related payer mix is estimated to be 50% Medicare/50% non-Medicare/Commercial. *(October 17, 2005 completeness responses, page 28)*
47. There is no State Health Plan in existence at this time. *(March 8, 2004 CON application, Page 2)*
48. The Applicant has adduced evidence that the proposal is consistent with the Applicant's long-range plan. *(March 8, 2004 CON application, page 2)*
49. The Applicant has improved productivity and contained costs by undertaking energy conservation, group purchasing and reengineering activities, as well as the application of technology. *(March 8, 2004 CON application, page 46)*
50. The proposal will not result in any change to the Applicant's teaching and research responsibilities. *(March 8, 2004 CON application, page 46)*
51. The Applicant has not provided evidence of distinguishing or unique characteristics of the Applicant's patient/physician mix related to the proposal. *(March 8, 2004 CON application, page 46 -47)*
52. The Applicant has sufficient technical, financial and managerial competence and expertise to provide efficient and adequate service to the public. *(March 8, 2004 CON application, pages 43 and 397 - 442)*

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.

Norwalk Hospital (“Applicant”) is proposing to expand its electrophysiology services (“EPS”) with the introduction of adult 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 existing programs for the prevention, diagnosis and treatment of various cardiac conditions. The Applicant has an existing electrophysiology program including pacemaker insertion, pacemaker lead and battery changes, pacemaker follow-up and monitoring as well as diagnostic electrophysiology testing, automatic implantable cardio-defibrillator implantation and follow-up and bi-ventricular pacemaker insertion.

The Applicant based the need for the proposed expansion of electrophysiology services to include cardiac ablation treatment on the following: The aging of the population in the Applicant’s service area; cardiovascular disease prevalence in the Applicant’s service area; statewide growth in ablation procedure volume; arrhythmia standards of care; ablation success rates in community hospitals; improvement in quality of life scores and reduction in disease-specific symptoms; and cost savings to the patient over drug therapy options.

The Applicant’s service area has a population age 65 and older which account for 13.5% of the Census 2000 population in the Applicant’s total service area which is comparable to the State of Connecticut age 65 and older population which is 13.8% of the total population. The population age 45 – 64 in the Applicant’s total service area is 29.4% which is above the statewide percentage of 23.2%.

Diseases which are arrhythmia precursors include heart failure and shock, cardiac arrhythmia and conduction disorder and syncope and collapse. The Applicant has an average of 354.5 annual inpatient discharges of patients suffering from heart failure and shock annually. There are on average 1,247 annual inpatient discharges of patients from the Hospital’s total primary and secondary service area for patients suffering from heart failure and shock from all Connecticut hospitals. The Applicant has on average 195.5 cases annually involving diagnosis of cardiac arrhythmia and conduction disorder, with an average of 166.5 from the Applicant’s primary service area. In addition, the Applicant has on average 141.5 cases involving syncope and collapse with an average of 118.5 from the Applicant’s primary service area.

Cardiac catheter ablation therapy is not currently provided within the Applicant’s primary service area towns. Currently, patients presenting to the Applicant needing cardiac catheter ablation must travel to a Bridgeport area hospital, a New Haven area hospital or to Stamford Hospital.

The Applicant projects ablation volume for the first three years of the program as 42 ablations in year one, 50 in year two and 57 in year three. Ablation volumes have increased in Connecticut on an annual basis of 12% from FY 2003 to FY 2004. The Applicant's inpatient pacemaker insertions increased from 45 to 59 from FY 2003 to FY 2004 and the Applicant performed 21 inpatient automatic implantable cardioverter defibrillator implantations in FY 2004 (its first full year performing the procedure).

The proposed program will be operated in compliance with the guidelines of both the North America Society of Pacing and Electrophysiology ("NASPE") 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 Norwalk Hospital will meet or exceed the guidelines set forth in the ACC/AHA Clinical Competence Statement on Invasive Electrophysiology Studies, Catheter Ablation and Cardioversion. Dr. Michael Pittaro will be the primary physician performing the procedure at Norwalk Hospital. Dr. Pittaro has privileges at Norwalk Hospital, Stamford Hospital and St. Vincent's Medical Center. A second physician is currently being sought. The physicians who will be providing ablation therapy services at Norwalk Hospital will meet the ACC/AHA recommended number of ablation procedures a year. Patients who require cardiac surgery will be transferred on an urgent basis to Bridgeport Hospital or Yale-New Haven Hospital, which the Applicant has transfer agreements with.

Based on the foregoing reasons, OHCA finds that this proposal will complement the existing cardiac related services at Norwalk Hospital. The expansion of the Applicant's existing electrophysiology services to include cardiac ablation therapy services will improve the quality and accessibility of cardiac services available to residents of Norwalk Hospital's primary service area.

The proposal has a total capital expenditure of \$14,085 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 this project. Although OHCA can draw no specific conclusion, the Applicant's financial projections appear to be reasonable and achievable and should not have any negative impact on the Applicant's future financial results. Therefore, the CON proposal appears to be financially feasible and cost effective and in the best interest of consumers and payors.

Based upon the foregoing Findings and Rationale, the Certificate of Need application of Norwalk Hospital to expand the scope of its electrophysiology program with the introduction of cardiac ablation therapy at a total capital expenditure of \$14,085 is hereby **GRANTED**.

Order

Norwalk Hospital located at 34 Maple Street in Norwalk, Connecticut, is hereby authorized to expand its electrophysiology program to include adult cardiac catheter ablation therapy, at a total capital expenditure of \$14,085, subject to the following conditions:

1. This authorization shall expire on January 12, 2007. 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 \$14,085. 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 Norwalk Hospital; and
 - 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

January 12, 2006

Signed by Cristine A. Vogel