



Office of Health Care Access Certificate of Need Application

Final Decision

Applicant: Saint Francis Hospital and Medical Center

Docket Number: 06-30684-CON

Project Title: Replacement Equipment in the Existing
Electrophysiology Laboratory and Acquisition of an
Additional (Second) Electrophysiology Laboratory
and Associated Renovations

Statutory Reference: Section 19a-639 of the Connecticut General Statutes

Filing Date: August 25, 2006

Decision Date: November 7, 2006

Default Date: November 23, 2006

Staff Assigned: Steven W. Lazarus

Project Description: Saint Francis Hospital and Medical (“Hospital”) proposes the replacement of its equipment in the Electrophysiology (“EP”) laboratory and acquisition of an additional (second) EP laboratory and associated renovations, at a total capital expenditure of \$6,838,212.

Nature of Proceedings: On August 25, 2006, the Office of Health Care Access (“OHCA”) received a Certificate of Need (“CON”) application from the Hospital seeking authorization for the replacement of its equipment in its existing EP laboratory and acquisition of an additional EP laboratory and associated renovations, at a total capital expenditure of \$6,838,212. The Hospital is a health care facility or institution as defined by Section 19a-630 of the Connecticut General Statutes (“C.G.S.”).

A notice to the public regarding OHCA’s receipt of the Hospital’s Letter of Intent (“LOI”) to file its CON Application was published on February 10, 2006 in the *Hartford Courant*. OHCA received no responses from the public concerning the Hospital’s proposal.

OHCA’s authority to review and approve, modify or deny this proposal is established by Section 19a-639, 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 of the Proposal on the Hospital’s Current Utilization Statistics Proposal’s Contribution to the Quality of Health Care Delivery in the Region Proposal’s Contribution to the Accessibility of Health Care Delivery in the Region

1. Saint Francis Hospital and Medical Center (“Hospital”) is an acute care general hospital located at 114 Woodland Street, Hartford, Connecticut. (*May 26, 2006, Initial CON Application Filing, page 2*)
2. The Hospital is proposing the acquisition of replacement equipment in its existing Electrophysiology¹ (“EP”) laboratory and acquisition of an additional (second) EP laboratory and associated renovations. (*May 26, 2006, Initial CON Application Filing, page 2*)
3. Currently, the Hospital operates one (1) EP laboratory on the third floor of the Patient Care Tower. (*May 26, 2006, Initial CON Application Filing, page 4*)
4. The Hospital currently performs Catheter Ablation, Pacemaker Implants, Defibrillator Implants and EP Diagnostic Studies in the existing EP laboratory. (*May 26, 2006, Initial CON Application Filing, page 3*)

¹ Electrophysiology (cardiac) is the science of the mechanisms, functions, and performance of the electrical activities of specific regions of the heart.

5. The Hospital's total service area ("TSA") for the proposal consists of the following towns:

Table 1: The Hospital's TSA

Primary Towns	Secondary Towns
West Harford	Rocky Hill
Harford	Wethersfield
East Hartford	Newington
Bloomfield	New Britain
Windsor	Plainville
Windsor Locks	Cromwell
East Granby	Berlin
Granby	Southington
Suffield	Glastonbury
South Windsor	Marlborough
Simsbury	Hebron
Canton	Bristol
Avon	Burlington
Farmington	Harwinton
East Windsor	Thomaston
Ellington	Plymouth
Somers	Wolcott
Stafford/Union	Middletown
Enfield	Meriden
Manchester/Bolton	Middlefield
Andover	Meriden
Vernon	Portland
Tolland	East Hampton
	Colebrook
	Hartland
	New Hartford
	Norfolk
	Barkhamsted
	Torrington
	Winchester/Winsted

(May 26, 2006, Initial CON Application Filing, pages 10 & 181).

6. The Hospital has a major cardiovascular program known as the Hoffman Heart Institute of Connecticut. It provides a wide range of cardiovascular services including open heart surgery, cardiac catheterizations, percutaneous transluminal angioplasty procedures, stress tests, cardiac rehabilitation, echocardiography tests, electrophysiology, and electrocardiogram services. *(May 26, 2006, Initial CON Application Filing, page 3)*

7. The following table indicates the total number of open heart surgeries performed at all Connecticut hospitals between FYs 2003-2005, as illustrated below:

Table 2: Open Heart Surgeries by Provider, FYs 2003-2005

Provider	FY 2003	FY 2004	FY 2005	Total
Bridgeport Hospital	313	268	263	844
Danbury Hospital	0	0	114	114
John Dempsey Hospital	134	121	174	429
Hartford Hospital	844	756	726	2,326
St. Francis Hospital & Medical Center	1,299	1,311	1,188	3,798
St. Mary's Hospital	0	0	19	19
Hospital of St. Raphael	687	617	510	1,814
St. Vincent's Medical Center	296	293	291	880
Waterbury Hospital	0	0	20	20
Yale-New Haven Hospital	905	860	861	2,626

Note: ICD-9-CM Codes: 35.10-35.28 and 36.11-36.19

(Connecticut Office of Health Care Access, Acute Care Hospital Inpatient Discharge Database)

8. The annual number of EP laboratory procedures performed in the existing EP laboratory by primary procedures for FYs 2003-2005 is as follows:

Table 3: Hospital's Primary Inpatient EP Procedures for FYs 2003-2005¹

Procedure	2005	2004	2003
Electrophysiology study	46	82	100
Ablation	54	45	28
Advanced ablation	15	7	4
ICD implantation	110	96	97
Bi-ventricular pacemaker insertion	90	56	26
Permanent pacemaker insertion	14	66	57
Internal loop recorder	2	6	6
Generator change	12	6	8
Lead revision	13	6	4
Internal cardiac defibrillator check ²	15		
Tilt table testing ³	48	47	54
Other procedures	11	10	11
Totals	430	427	395

¹ CT Office of Health Care Access Acute Care Hospital Inpatient Discharge Database, which does not include Outpatient Data.

²New code (8849) in FY 2005. FY 2004 & 2003 obtained from Hospital's CON Application

³No code available, obtained from the Hospital's CON Application

(Connecticut Office of Health Care Access, Acute Care Inpatient Database and August 28, 2006, Response to OHCA Completeness Letter)

9. The Hospital reported its inpatient, outpatient and emergent EP laboratory procedures as 863, 838, 855 for FYs 2003-2005. *(August 28, 2006, Response to OHCA Completeness Letter)*
10. The Hospital based the need for the proposed replacement equipment for the existing EP laboratory on the age of the existing EP laboratory, according to the Hospital the existing EP laboratory has been in operation for ten (10) years and is obsolete. *(May 26, 2006, Initial CON Application Filing, page 4)*
11. The Hospital's existing EP laboratory is experiencing increasing down time due to malfunctioning of the older equipment. To meet the Hospital's existing demand, the Hospital presently does 20% of its EP cases in the Hospital's operating rooms. *(May 26, 2006, Initial CON Application Filing, page 7)*
12. The Hospital's existing EP laboratory equipment will be replaced with a Siemens EP Laboratory. *(May 26, 2006, Initial CON Application Filing, page 7)*
13. The Hospital based the need for the proposed equipment acquisition for the second EP laboratory on the following:
 - Advanced EP technology;
 - Improved quality;
 - Increased EP and cardiac utilization.*(May 26, 2006, Initial CON Application Filing, pages 3-12)*
14. The proposed additional EP laboratory will be a new Siemens Laboratory with stereotaxis² capability. *(May 26, 2006, Initial CON Application Filing, page 7)*
15. The Hospital stated that the advantages of stereotaxis technology include:
 - Streamlining complex cases, therefore, more cases may be scheduled per day;
 - Improved access to challenging lesions that otherwise are not accessible;
 - Improved ability to develop new procedures;
 - Reduced radiation exposure for physician and staff;
 - Improved patient safety due to reduction in contrast, shortened procedure time and precise wire tip control; and
 - Decreased disposable costs of guide wires due to in-vivo tip reshaping and other EP equipment.*(May 26, 2006, Initial CON Application Filing, pages 7-8)*
16. The proposed EP equipment with its advanced technology will enable the Hospital's Comprehensive Arrhythmia Center not only to treat increased volumes of patients, but also to conduct clinical research on emerging treatments for arrhythmias. *(May 26, 2006, Initial CON Application Filing, pages 4-10)*

² The Stereotaxis is a magnetic navigational system using magnetic fields. The Stereotaxis system is integrated with cardiac CT or MRI images in order to create an accurate and detailed 3-D map of the heart.

17. The proposed stereotaxis EP laboratory will be one of two laboratories with stereotaxis capability in the state of Connecticut. *(May 26, 2006, Initial CON Application Filing, page 10)*

18. According to the Hospital, the proposed EP laboratories will remedy the following:

- Current space limitations at the Hospital’s existing EP laboratory;
- The additional EP laboratory will decrease the amount of time from diagnosis to treatment;
- Increase throughput;
- Increase access to care; and
- Decrease hospital length of stay for inpatients requiring EP services.

(May 26, 2006, Initial CON Application Filing, page 12)

19. According to the Hospital, total number of EP procedures for FYs 2003-2005 in its existing EP laboratory is as follows:

Table 4: Hospital’s Historical EP Procedures

FYs	2003	2004	2005
Total EP Volume	1,214	1,163	1,268

Note: OHCA is not able to verify these numbers as OHCA only collects Inpatient data in its CT Office of Health Care Access Acute Care Hospital Inpatient Discharge Database.
(May 26, 2006, Initial CON Application Filing, page 11)

20. The Hospital is projecting the following total EP volume for both proposed EP laboratories for FYs 2006-2008:

Table 6: Hospital’s Projected EP Volume

FYs	2006	2007	2008
Total EP Volume	1,344	1,425	1,510

Note: The Hospital is basing the projected utilization for its EP laboratories on a 6% annual increase between FY 2006 & 2008.
The Hospital based the 6% projected increase in aging of the population, increased equipment capabilities and faster throughput of new equipment.
OHCA can not verify these projected EP laboratories utilizations.
(May 26, 2006, Initial CON Application Filing, pages 11-12)

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

21. The total capital expenditure for this proposal is \$6,838,912 which includes:

Table 7: Total Capital Expenditure

Components	Cost
Medical Equipment (Purchase)	\$3,274,424
Non-Medical Equipment (Purchase)	59,488.75
Construction/Renovation	2,039,628
Total Capital Expenditure	\$6,838,912

(May 26, 2006, Initial CON Application Filing, page 20)

22. The Hospital's proposed total capital expenditure of \$6,838,912 will be financed through Hospital equity, specifically through cash and short term investments. *(May 26, 2006, Initial CON Application Filing, page 23)*
23. The Hospital projects Gains from Operations for FY 2007 and FY 2008 of \$26,693 and \$188,847, respectively. The Hospital did not project any incremental revenues from this proposal in FY 2006 as it does not anticipate beginning operation of the proposed EP laboratories until March of 2007. *(May 26, 2006, Initial CON Application Filing, page 309)*
24. The Hospital projects an increase of 3.3 and 6.5 full time equivalents ("FTE") incremental to the project for FY 2007 and FY 2008, respectively. These positions include an RN Coordinator (1.5 FTE), Staff RN (3.25 FTE), EP Technician (3.0 FTE) and a Transport Aide (1.5 FTE). *(May 26, 2006, Initial CON Application Filing, pages 309 and 313)*
25. The proposed renovations will consist of approximately 4,300 square feet and will include two (2) new EP laboratories. The renovations are required to the clinical support spaces such as (2) equipment control rooms, soiled utility room, clean supply room, staff locker, toiled room, housekeeping, storage, and stretcher storage. Minor renovations will also occur in the Department of Anesthesiology. *(May 26, 2006, Initial CON Application Filing, pages 20-21)*
26. Construction of these EP laboratories will require temporary access to the imaging department, located directly below the proposed project area on level 2 of Building 1A, to allow for modification of the steel structure and installation of the radiation and magnetic shielding and plumbing below the EP units. *(May 26, 2006, Initial CON Application Filing, pages 20-21)*

27. The two proposed EP laboratories will be located on the third floor of the newly renovated space. *(May 26, 2006, Initial CON Application Filing, page 7)*
28. There is no State Health Plan in existence at this time. *(May 26, 2006, Initial CON Application Filing, page 3)*
29. The Hospital has adduced evidence that the proposal is consistent with the Hospital's long-range plan. *(May 26, 2006, Initial CON Application Filing, page 3)*
30. The Hospital has stated that its teaching or research responsibilities would not be affected as a result of the proposal. *(May 26, 2006, Initial CON Application Filing, page 18)*
31. There are no distinguishing or unique characteristics of the Hospital's patient/physician mix related to the proposal. *(May 26, 2006, Initial CON Application Filing, page 18)*
32. The Hospital has implemented various activities to improve productivity and contain costs including group purchasing, reengineering and applications of new technology. *(May 26, 2006, Initial CON Application Filing, pages 15-18)*
33. The Hospital has sufficient technical, financial and managerial competence to provide efficient and adequate service to the public. *(May 26, 2006, Initial CON Application Filing, pages 243-295)*
34. The Hospital's rates are sufficient to cover the proposed capital expenditure and operating costs associated with the proposal. *(May 26, 2006, Initial CON Application Filing, pages 308-3018)*

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.

Saint Francis Hospital and Medical Center (“Hospital”) is proposing the acquisition of replacement equipment for its existing electrophysiology (“EP”) laboratory and the acquisition of an additional EP laboratory. Both proposed EP laboratories will be located on the third floor of the newly renovated space.

The Hospital has a major cardiovascular program, which is a center of excellence of the Hospital, known as the Hoffman Heart Institute of Connecticut. It provides extensive programs for the prevention, diagnosis and treatment of various cardiac conditions, including a full range of cardiac diagnostic services, diagnostic catheterizations, angioplasty and other interventional cardiology procedures, as well as open heart surgery. The Hospital had the highest volume of open heart surgeries in Connecticut between FYs 2003-2005.

The Hospital based the need for the proposed replacement equipment of the existing EP laboratory on age of the existing EP laboratory, which is ten years old and is experiencing excessive down time. According to the Hospital, in order to meet demand, the Hospital presently performs 20% of its EP procedures in the Hospital’s operating rooms. The Hospital is proposing to replace its existing EP laboratory equipment with a Siemens EP laboratory. The Hospital based the need for the proposed additional EP laboratory on advanced EP technology, improved quality and increased EP and cardiac utilization. The additional EP laboratory will be a Siemens laboratory with Stereotaxis capability. The proposed second EP laboratory with Stereotaxis capability will enable the Hospital to handle complex cases, treat challenging lesions and schedule more cases per day. The replacement of the existing EP laboratory and the acquisition of the proposed additional EP laboratory will improve quality of EP service for Hospital’s existing patients in its service area.

In summary, the proposed EP laboratory equipment will allow the Hospital’s Hoffman Heart Institute to offer the latest technology to ensure its patients high quality EP services. Further, this proposal will improve access to EP services for the Hospital’s patients by addressing current space limitations at the Hospital’s existing EP laboratory due to increasing EP volume and decreasing the time from diagnosis to treatment, as well as the Hospital’s length of stay for inpatient EP services.

The proposal has a total capital expenditure of \$6,838,912 and will be financed from the Hospital's equity, specifically through cash and short term investments. The Hospital also projects an increase of 3.3 and 6.5 full time equivalents in FYs 2007 and 2008, as a result of this proposal. The Hospital projects gains from operations of \$26,693 and \$188,847 for FY 2007 and FY 2008, respectively. Although, OHCA cannot draw any conclusions, the Hospital's volume and financial projections upon which they are based appear to be reasonable and achievable. Therefore, OHCA finds that the CON proposal is both financially feasible and cost effective.

Based upon the foregoing Findings and Rationale, the Certificate of Need application of Saint Francis Hospital and Medical Center's proposal for the replacement equipment the existing EP laboratory and the acquisition of an additional (second) EP laboratory at a total capital expenditure of \$6,838,912, is hereby **GRANTED**.

Order

Saint Francis Hospital and Medical Center is hereby authorized to replace equipment in its existing Electrophysiology (“EP”) laboratory and to acquire an additional (second) EP laboratory and associated renovations, at a total capital expenditure of \$6,838,912, subject to the following conditions:

1. This authorization shall expire December 31, 2007. Should the Hospital’s replacement of its existing EP laboratory equipment and the acquisition of its additional (second) EP laboratory not be fully implemented by that date, the Hospital must seek further approval from OHCA to complete the project beyond that date.
2. The Hospital shall not exceed the approved capital expenditure of \$6,838,912. In the event that the Applicant learns of potential cost increases or expects that the final project costs will exceed those approved, the Hospital shall file with OHCA a request for approval of the revised project budget.
3. The Hospital is required to dispose of the current equipment in its existing EP laboratory and provide evidence of disposal of the current EP equipment no later than 30 days after the replacement equipment becomes operational.

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

November 7, 2006

Signed by Cristine A. Vogel
Commissioner

CAV:swl