



Office of Health Care Access Certificate of Need Application

Final Decision

Applicant: Yale-New Haven Hospital

Docket Number: 08-31144-CON

Project Title: Proposal to Acquire and Operate Electrophysiology (“EP”) Equipment, Replacing Existing EP Equipment, and to Modernize the Existing EP Laboratory

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

Filing Date: October 3, 2008

Decision Date: December 24, 2008

Default Date: January 1, 2009

Staff: Jack A. Huber

Project Description: Yale-New Haven Hospital proposes to acquire and operate electrophysiology laboratory equipment, replacing existing electrophysiology equipment, at a total capital expenditure of \$3,857,448.

Nature of Proceedings: On October 3, 2008, the Office of Health Care Access (“OHCA”) received a Certificate of Need (“CON”) application from Yale-New Haven Hospital seeking authorization to acquire and operate electrophysiology laboratory equipment, replacing existing electrophysiology equipment, at a total capital expenditure of \$3,857,448. The Hospital is a health care facility or institution as defined in Section 19a-630 of the Connecticut General Statutes (“C.G.S.”).

Pursuant to Section 19a-639, C.G.S., a notice to the public concerning OHCA’s receipt of the Hospital’s Letter of Intent was published by the New Haven Register on May 12, 2008. OHCA received no responses from the public concerning the Hospital’s proposal.

Pursuant to Section 19a-639, C.G.S., three individuals or an individual representing an entity with five or more people had until October 24, 2008, the twenty-first calendar day following the filing of the Hospital's CON application, to request that OHCA hold a public hearing on the Hospital's proposal. OHCA received no hearing requests from the public.

OHCA's authority to review and approve, modify or deny this proposal is established by Section 19a-639 of the 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

1. Yale-New Haven Hospital ("Hospital") is an acute care, teaching hospital located at 20 York Street in New Haven. *(August 4, 2008, Initial CON application, page 12 and Appendix X, page 175)*
2. The Hospital's Electrophysiology ("EP") Department provides electrodiagnostic electrophysiology testing, intracardiac electrical conduction system mapping, radiofrequency ablation, pacemaker implantation; defibrillator implantation; post-implant defibrillator testing and other related electrophysiologic tests/procedures. *(April 22, 2008, Letter of Intent, page 7)*
3. The Hospital operates two electrophysiology laboratories as follows:
 - EP Lab #1 – originally utilized a Fisher XR System, which was purchased under the CON capital threshold and installed in 1994. The system was acquired to expand and enhance the growing EP need and services for the community. The 14 year old system was determined by the Hospital to have reached the end of its useful life and was deinstalled in October 2007; and
 - EP Lab #2 – utilizes a Siemens Bi-Cor System, which was approved by OHCA under Docket Number: 05-30531-WVR on June 27, 2005. The system replaced outdated equipment approved under Docket Number: 78-531 and has been operational for two years.
(October 3, 2008, Completeness Responses, page 229)
4. The Hospital is requesting the acquisition and operation of EP laboratory equipment, replacing EP Laboratory #1 with a modern laboratory, which will provide the same services as noted above. The proposal also includes the following:
 - A new robotic navigation system for use in complex ablation procedures such as atrial fibrillation ablations; and
 - Renovations necessary to accommodate the new EP equipment.
(April 22, 2008, Letter of Intent, page 7 & 8 and August 4, 2008, Initial CON application, page 10)
5. The Hospital anticipates the acquisition of the following equipment for the proposal:
 - a. General Electric, Inova 2100 IQ System for EP Imaging Equipment; and
 - b. Hansen Medical, Sensei Robotic Catheter System for complex ablation procedures.
(April 22, 2008, Letter of Intent, page 4 and August 4, 2008, Initial CON application, Appendix XIII, page 185)

6. The Hospital indicates the EP laboratory replacement is needed for the following reasons:
 - The Fisher XR System was 14 years old and was beyond it useful life;
 - The system was no longer being serviced by the vendor;
 - The system could not provide the quality of imaging necessary for safe care delivery or for critical testing for implants and ablations; and
 - The system did not have the capability to minimize patient and staff radiation exposure to the lower levels as is found in newer equipment.
 (October 3, 2008, Completeness Responses, page 228)

7. The Hospital indicates the proposed replacement EP laboratory with robotic navigation system will provide current imaging technology, mapping and precise remote instrumentation control, which will enable greater efficiency in terms of site identification, catheter localization and stabilization. Clinical advantage resides in the ability to utilize technology to efficiently move catheters in the heart that would be difficult to execute manually in high complex procedures. In addition, the equipment will reduce the length of patient procedures and subsequently the patient's radiation exposure, contributing to patient safety and comfort. (April 22, 2008, Letter of Intent, page 8 and October 3, 2008, Completeness Responses, page 231)

8. The Hospital indicates that the current population served and the target population to be served include residents of Ansonia, Bethany, Branford, Cheshire, Clinton, Deep River, Derby, East Haven, Essex, Guilford, Hamden, Killingworth, Madison, Meriden, Milford, New Haven, North Haven, Old Saybrook, Orange, Oxford, Seymour, Wallingford, West Haven, Westbrook and Woodbridge. (April 22, 2008, Letter of Intent, page 7 and August 4, 2008, Initial CON application, page 7 & Appendix I, page 19)

9. The Hospital indicates the Hospital of Saint Raphael provides EP services in the proposed geographic area. The Hospital believes that the proposed level of navigation system technology is not currently available in the immediate service area. (April 22, 2008, Letter of Intent, page 8 and May 2, 2008, Initial CON application, page 9)

10. The Hospital's actual and projected EP service volumes is presented as follows:

Table 1: Actual and Projected EP Service Volume by Hospital Site

Description	FY 2005	FY 2006	FY 2007	CFY 2008*	FY 2009	FY 2010	FY 2011
Lab #1- Fisher	532	491	0	0	0	0	0
Lab #2- Siemens Bi-Cor			689	661			
Proposed GE Lab					1,101	1,381	1,570
Hosp. Operating Suite**	1,101	854	726	765	383	191	96
	1,633	1,345	1,415	1,426	1,484	1,572	1,666

Chronology: Siemens Bi-Cor was brought on-line in latter FY 2005. Internal systems did not allow for tracking of procedures by room in FY 2006. Fisher system deinstalled in 2007 with no volume recorded.

Notes: *Fiscal Year 2008 volume is annualized.

**As temporary stop-gap measure until the needed ED labs are all on-line, EP procedures not requiring anesthesia coverage are being performed in the operating suite and will be redirected to the new EP lab once it is modernized.

*** With stable infrastructure EP annual volume growth projected to be 4%, 6% and 6% over the next three fiscal years based on anticipated demand.

(October 3, 2008, Completeness Responses, page 230)

11. The electrophysiology service currently operates Monday through Friday, 7:30 a.m. to 8:00 p.m. The laboratory is available on an as needed basis and covered by on-call staff Monday through Friday from 8:00 p.m. through 7:30 a.m. When Lab #1 is equipped with the replacement equipment, the service will maintain the same hours of operation. *(August 4, 2008, Initial CON application, page 8)*

**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 of Health Care
Services and Payers for Such Services
Consideration of Other Section 19a-637, C.G.S. Principles and Guidelines**

12. The proposal totals \$3,857,448 in capital expenditures and is itemized as follows:

Table 4: Total Capital Expenditure

Description	Component Cost
Navigation Medical Equipment	\$660,000
EP Imaging Equipment	\$1,668,058
Renovation Work for EP Lab	1,529,390
Total Capital Expenditure	\$3,857,448

(August 4, 2008, Initial CON application, page 13 and October 3, 2008, Completeness Responses, page 232)

15. The Hospital will fund the proposal through operating funds of \$2,357,448 and a Connecticut Health and Educational Facilities Authority bond issuance of \$1,500,000. *(August 4, 2008, Initial CON application, page 15)*
16. Renovations to the laboratory totaling 800 square feet will commence immediately following the receipt of a CON authorization. *(August 4, 2008, Initial CON application, page 19)*
17. The project has been designed in a manner that will allow the Hospital to provide services in an uninterrupted fashion. *(August 4, 2008, Initial CON application, page 14)*
18. The Hospital projects incremental operating losses of \$271,000, \$542,000 and \$542,000 due to non-cash depreciation expense in FYs 2009 through 2011, respectively. *(August 4, 2008, Initial CON application, page 17 and Attachment XVI, pages 218 and 219)*
19. The Hospital projects overall operating gains of \$46.5 million, \$24.6 million and \$26.4 million with the proposal in FYs 2009 through 2011, respectively. *(August 4, 2008, Initial CON application, page 17 and Attachment XVI, pages 218 and 219)*

20. The current and projected payer mix for the first three years of operation with the proposed equipment is illustrated in the following table:

Table 5: Current and Three-Year Projected Payer Mix

Payer Mix	Current	Year 1	Year 2	Year 3
Medicare	29.6%	29.3%	28.5%	27.4%
Medical Assistance	11.4%	12.3%	12.3%	12.3%
TriCare or Champus	0.7%	0.6%	0.6%	0.6%
Total Government	41.7%	42.2%	41.4%	40.3%
Commercial Insurers	51.5%	50.8%	51.6%	52.7%
Uninsured	5.5%	5.8%	6.0%	6.0%
Workers Compensation	1.3%	1.2%	1.0%	1.0%
Total Non-Government	58.3%	57.8%	58.6%	59.7%
Total Payer Mix	100.0%	100.0%	100.0%	100.0%

(August 4, 2008, Initial CON application, pages 16 and 17)

21. There is no State Health Plan in existence at this time. *(August 4, 2008, Initial CON application, page 6)*
22. The Hospital has adduced evidence that this proposal is consistent with its long-range plan. *(August 4, 2008, Initial CON application, page 6)*
23. The Hospital has improved productivity and contained costs by undertaking energy conservation measures regarding its facilities; by participating in activities involving the application of new technology and reengineering; and by employing group purchasing practices in its procurement of supplies and equipment. *(August 4, 2008, Initial CON application, page 11)*
24. The proposal will not result in any change to the Hospital's teaching and research responsibilities. *(August 4, 2008, Initial CON application, page 12)*
25. The Hospital's current patient/physician mix is similar to that of other quaternary care hospitals. The proposal will not result in any change to this mix. *(August 4, 2008, Initial CON application, page 12)*
26. The Hospital has sufficient technical and managerial competence to provide efficient and adequate services to the public. *(August 4, 2008, Initial CON application, page 10 and Attachment VII, pages 139 through 169)*
27. The Hospital's rates are sufficient to cover the proposed capital expenditure and operating costs. *(May 2, 2008, Initial CON application, page 17 and Attachment XVI, page 219)*

Rationale

The Office of Health Care Access (“OHCA”) approaches community and regional need for Certificate of Need (“CON”) proposals on a case by case basis. CON applications do not lend themselves to general applicability due to a variety 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 types of services proposed to be offered, the current utilization of services and the financial feasibility of the proposal.

The Hospital proposes to acquire and operate electrophysiology (“EP”) laboratory equipment including robotic navigation system that will replace its deinstalled EP equipment and modernize EP Lab # 1. EP Lab #2, the second of the Hospital’s two EP laboratories, was updated with new equipment that became operational two years ago. The Hospital plans to acquire and operate a General Electric, Innova 2100 IQ electrophysiology system. The former Lab #1 Fisher XR System was acquired in 1994 and was deinstalled from service in October 2007.

The Hospital states the equipment in EP Lab #1 needed to be replaced as the system was 14 years old and beyond its useful life. The system could not provide the quality of imaging necessary for safe care delivery or for critical testing for implants and ablations. Additionally, the system did not have the capability to minimize patient and staff radiation exposure to lower levels found in newer equipment. The proposed replacement EP equipment with robotic navigation system will provide current imaging technology, mapping and precise remote instrumentation control, which will enable greater efficiency in terms of site identification, catheter localization and stabilization. Clinical advantage resides in the ability to utilize technology to efficiently move catheters in the heart that would be difficult to execute manually in high complex procedures. The equipment will reduce the length of patient procedures and subsequently the patient’s radiation exposure, contributing to patient safety and comfort. OHCA finds that the replacement of the EP Lab #1 equipment will serve the Hospital’s patients residing in its service area via important quality and safety enhancements provided by the new EP equipment.

The CON proposal’s total capital expenditure is \$3,857,448 and consists of costs attributable to the replacement laboratory equipment and renovation work to accommodate the EP lab equipment. The project’s capital expenditure will be financed through a combination of Hospital operating funds and a Connecticut Health and Educational Facilities Authority bond issuance. While the Hospital projects overall operating gains in the initial years of operating the new electrophysiological laboratory, the Hospital projects incremental operating losses from EP service activity in each of the fiscal years due to non-cash funded depreciation. 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 financially feasible.

Order

Based on the foregoing Findings and Rationale, the Certificate of Need application of Yale-New Haven Hospital (“Hospital”) to acquire and operate electrophysiology laboratory equipment, replacing existing equipment, at a total capital expenditure of \$3,857,448 is hereby **granted**, subject to the following conditions.

1. This authorization shall expire on January 1, 2010. Should the Hospital’s replacement project not be completed 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 \$3,857,448. In the event that the Hospital learns of potential cost increases or expects that final project costs will exceed those approved, the Hospital shall immediately notify OHCA.
3. With respect to the acquisition of the electrophysiology laboratory equipment, the Hospital shall notify OHCA regarding the following information in writing by no later than one month after the equipment becomes operational:
 - a) The name of the imaging equipment manufacturer;
 - b) The model name and description of the equipment; and
 - c) The initial date of the operation of the equipment.
4. Should the Hospital propose any change in the electrophysiology service, the Hospital shall file with OHCA a Certificate of Need Determination Request or Certificate of Need letter of Intent regarding the proposed service change.

Should the Hospital fail to comply with any of the aforementioned conditions, OHCA reserves the right to take additional action as authorized by law. 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

Signed by Commissioner Vogel on December 24, 2008

Date

Cristine A. Vogel
Commissioner

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