



Office of Health Care Access Certificate of Need Application

Final Decision

Hospital: Hospital of Saint Raphael

Docket Number: 03-30097-CON

Project Title: Cardiac Catheterization Laboratory Renovation,
Equipment Replacement, and Acquisition of
Magnetic Navigation System

Statutory Reference: Section 19a-639, C.G.S.

Filing Date: August 13, 2003

Hearing Date: Waived

Decision Date: September 16, 2003

Default Date: November 11, 2003

Staff Assigned: Laurie Greci

Project Description: Hospital of Saint Raphael (“Hospital”) proposes to renovate the cardiac catheterization laboratory, replace and upgrade aging equipment and acquire a magnetic navigation system for the cardiac catheterization laboratory, at a total capital expenditure of \$4,402,308.

Nature of Proceedings: On August 13, 2003, the Office of Health Care Access (“OHCA”) received Hospital of Saint Raphael’s (“Hospital”) completed Certificate of Need (“CON”) application seeking authorization to renovate the cardiac catheterization laboratory, replace and upgrade aging equipment and acquire a magnetic navigation system for the cardiac catheterization laboratory, at a total capital expenditure of \$4,402,308. The Hospital is a health care facility or institution as defined by Section 19a-630 of the Connecticut General Statutes (“C.G.S.”).

The Hospital requested a waiver of public hearing for the CON application pursuant to Section 19a-643-45 of OHCA's Regulations and claimed that the proposal was non-substantive as defined in Section 19a-643-95(3) of OHCA's Regulations. On August 27, 2003, the Hospital was informed that the CON application was eligible for consideration of waiver of hearing, and a notice to the public was published in *The New Haven Register*. OHCA received no comments from the public concerning the Hospital's request for waiver of hearing during the public comment period, and therefore on September 15, 2003, OHCA granted the Hospital's request for waiver of hearing.

OHCA's authority to review and approve, modify or deny this application is established by Section 19a-639, C.G.S. The provisions of these sections, as well as the principles and guidelines set forth in Section 19a-637, C.G.S., were fully considered by OHCA in its review.

Findings of Fact

Clear Public Need

Current Utilization Statistics

Contribution to Accessibility and Quality of Health Care Delivery in the Region Impact of the Proposal on the Interests of Consumers of Health Care Services and Payers for Such Services

1. Hospital of Saint Raphael ("Hospital") is an acute care hospital located at 1450 Chapel Street, New Haven, Connecticut. (*August 13, 2003, CON Application, page 230*)
2. The Hospital's service area consists of 22 towns in the Greater New Haven area:

Ansonia	East Haven	New Haven	Seymour
Bethany	Guilford	North Branford	Shelton
Branford	Hamden	North Haven	Wallingford
Cheshire	Madison	Orange	West Haven
Clinton	Meriden	Oxford	Woodbridge
Derby	Milford		

(*August 13, 2003, CON Application, page 2*)

3. The Hospital's proposal has the following components:
 - Replacement of the Toshiba CAS-10A single plane angiographic digital unit with a Siemens AXION Artis dFC imaging system.
 - Acquisition of a magnetic navigation system.
 - Renovation of the cardiac catheterization laboratory ("cath lab"), including expansion of the patient holding area.

(*August 13, 2003, CON Application, page 4*)

4. The need for this proposed is based on the following:
 - Aging equipment.
 - Technological advances.
 - Increasing population and aging of the population.
 - Patient care and outcomes.
 - Compliance with State of Connecticut Department of Public Health (“DPH”) Voluntary Consent Agreement.
(August 13, 2003, CON Application, page 2)
5. The Toshiba unit currently being used in the cath lab was installed in 1993. The equipment is fully depreciated. Advances in technology have since rendered this equipment inadequate and continued regular maintenance cannot be guaranteed.
(August 13, 2003, CON Application, pages 5 and 7)
6. The Toshiba unit will be removed and disposed of by a third party contractor associated with Siemens Medical Systems, Inc. *(August 13, 2003, CON Application, page 15)*
7. The Toshiba unit will be replaced with a Siemens AXION Artis dFC, an all-digital cardiovascular imaging system. The AXION Artis dFC has a digital flat plane detector and uses the C-arm design. *(June 11, 2003, Letter of Intent, page 30)*
8. The proposed magnetic navigation system is the Niobe Magnetic Interventional Instrument Control System manufactured by Stereotaxis, Inc. The Niobe uses computer-controlled magnets, positioned outside the patient’s body, to programmatically steer magnetically enabled catheters and guidewires through the patient’s cardiovascular system. The system automatically navigates the catheters or guidewires to a selected site within the patient’s body. *(August 13, 2003, CON Application, page 318)*
9. The Niobe system has been designed to integrate with the AXION Artis system.
(August 13, 2003, CON Application, pages 318)
10. The new technology in the integrated system has been designed to reduce the amount of radiation that physicians, clinical staff and patients are exposed to during procedures. *(August 13, 2003, CON Application, page 18)*
11. The renovations to the cath lab include the following:
 - Renovation and reconfiguration of two procedure rooms.
 - Expansion of the patient holding area to accommodate six (6) patient holding stations plus a tilt room.
 - Installation of scrub rooms adjacent to the procedure rooms.
 - Relocation of the reading room.
 - Redesign of central nurse’s station.
 - Installation of a pneumatic tube station.
 - Expansion of equipment storage space.

- Addition of patient toilet, janitor’s closet, soiled workroom, and female shower facility.
- Reconfiguration of office area and employee locker rooms and lounge.
(August 13, 2003, CON Application, page 17)

12. The major issues related to the deficiency of the physical plant are as follows:

- Space and configuration requirements for the new equipment
- Need to expand the number of patient holding areas
- Inefficient use of space in relation to current patient volume.
(August 13, 2003, CON Application, page 5)

13. On October 29, 2002, the Hospital and the DPH signed a Voluntary Consent Agreement. This agreement, in part, requires that the Hospital establish an area within the cath lab that shall at a minimum have dedicated staff, sufficient space and the necessary equipment to monitor patients before their transfer to an appropriate clinical setting. *(October 29, 2002, Voluntary Consent Agreement, page 5)*

14. DPH standards require that hospitals maintain an 8’ by 9’ space per patient in holding and recovery areas. The current configuration of the holding area in the cath lab limits the Hospital to only three (3) patients. *(August 13, 2003, CON Application, page 5)*

15. The consent agreement with DPH also required that the Hospital consider modifications to the cath labs that would improve delivery and enhance the quality of care. Renovations to the two existing procedure rooms have been included in the proposal. *(August 13, 2003, CON Application, page 5)*

16. The following table presents historical and projected volumes for the cardiac cath lab at the Hospital:

Table 1: Actual and Projected Cardiac Catheterization Laboratory Cases

FY	Actual			Projected					
	2000	2001	2002	2003	2004	2005	2006	2007	
Cath Lab:									
Interventions	1,187	1,100	954	1,040	1,063	1,077	1,090	1,095	
Diagnostics	2,414	2,318	2,288	2,216	2,280	2,313	2,346	2,348	
Electrophysiology:									
Interventions	250	201	225	203	228	239	251	264	
Diagnostics	500	543	535	535	551	579	607	638	
Total Cases	4,351	4,162	4,002	3,994	4,122	4,208	4,295	4,345	

(August 13, 2003, CON Application, page 6)

17. The volume projections for the cardiac cath lab are based on the Hospital’s existing patient population and on a conservative increase of 3% per year. The projections also reflect the expected impact of drug-eluting stents on the cardiovascular program at the Hospital. The Hospital anticipates an initial volume shift to the cath lab as more patients choose this less invasive technology, follow by a decrease in the

number of repeat angioplasties for this same patient population. *(August 13, 2003, CON Application, page 6)*

18. The volume projections for electrophysiology cases reflect an overall growth rate of 5% per year. The fastest growing area within the Hospital's Department of Cardiology is the electrophysiology program. *(August 13, 2003, CON Application, page 6)*

Financial Feasibility of the Proposal and its Impact on the Hospitals' Rates and Financial Condition
Impact of the Proposal on the Interests of Consumers of Health Care Services and Payers for Such Services

19. The total capital expenditure for this proposal is \$4,402,308 which includes:

Table 2: Total Capital Expenditure

Components	Cost
Construction and Renovation	\$1,520,000
Medical Equipment (Purchase)	1,354,830
Imaging Equipment (Purchase)	1,524,228
Non-Medical Equipment (Purchase)	3,250
Total Capital Expenditure	\$4,402,308

(August 13, 2003, CON Application, page 16)

20. The fixed and moveable equipment and the related costs are given in the following table:

Table 3: List of Equipment and Associated Cost

Type	Item	Cost
Fixed	Siemens AXION Artis dFC	\$1,524,228
	NIOBE Magnetic Navigation System	820,000
Movable	Witt System	252,705
	Biphasic Difibrillator	17,264
	EKG Machine	8,760
	2 Prucka Systems	180,000
	2 Propac Transport Monitors	19,500
	Bloom Stimulator	25,000
	Ablator	30,000
	4 Carts	1,200
	2 IV Poles	400
	13 Chairs	3,250
TOTAL	(Fixed and Movable)	\$2,882,308

(August 13, 2003, CON Application, page 296)

21. The Hospital proposes to fund the total capital expenditure through operating funds of \$1,520,000 and lease financing of \$2,882,308. *(August 13, 2003, CON Application, page 19)*
22. For the nine months ended on June 30, 2003, the Hospital has a net income gain of \$2.2 million. The Hospital reports an operating fund cash balance of \$47.8 million, as of June 30, 2003. *(August 13, 2003, CON Application, page 7)*

23. The project incremental gain from operations is expected to be \$116,300, \$434,700, and \$563,200 for FY 2005, 2006, and 2007, respectively. FY 2005 through 2007 will be the first three years of the renovated cath lab's operations. *(August 13, 2003, CON Application, page 7)*
24. The project is not expected to affect the delivery of patient care. No more than two rooms will be out of service at any time. To accommodate the patient volume, the Hospital will temporarily utilize a mobile cardiac catheterization unit. Electrophysiology cases will be accommodated in the Hospital's operating room. *(August 13, 2003, CON Application, page 18)*

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

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

25. There is no State Health Plan in existence at this time. *(August 13, 2003, CON Application, page 1)*
26. The Hospital has adduced evidence that this proposal is consistent with its long-range plan. *(August 13, 2003, CON Application, page 1)*
27. The Hospital has improved productivity and contained costs through energy conservation, group purchasing, reengineering and applications of technology. *(August 13, 2003, CON Application, page 10)*
28. The proposal will result in changes to the Hospital's current teaching and research responsibilities. The Hospital sponsors a 3-year, freestanding Cardiovascular Fellowship program for the advanced training of six clinical Fellows. In addition, 75 medical residents and interns enroll in the Hospital's Medicine Residency Programs. The Hospital will incorporate the use of the new technology in the training program. *(August 13, 2003, CON Application, pages 4 and 14)*
29. There are no distinguishing characteristics of the patient/physician mix of the Hospital. *(August 13, 2003, CON Application, page 14)*
30. The Hospital has sufficient technical, financial and managerial competence to provide efficient and adequate service to the public. *(August 13, 2003, CON Application, Attachment 9)*

Rationale

Hospital of Saint Raphael (“Hospital”) is proposing to renovate the cardiac catheterization laboratory (“cath lab”), replace aged equipment, and acquire a new magnetic navigation system at a total capital expenditure of \$4,402,308.

The need for the cath lab renovations and equipment upgrade is based on patient safety, fully depreciated equipment, and compliance with industry guidelines and State of Connecticut Department of Public Health guidelines and standards. Due to the delicate and precise nature of cardiovascular procedures, properly maintained equipment is a necessity of the highest priority. The existing Toshiba imaging system, purchased in 1993, has been fully depreciated and is technologically out of date. Toshiba Corporation cannot guarantee to the Hospital that the system can be maintained at optimum working order. Replacement equipment is necessary to provide services to the Hospital’s existing patient population. The proposed replacement equipment is the digital AXION Artis dFC system.

To complement the AXION Artis dFC system, the Hospital proposes to acquire a Niobe Magnetic Navigation system, a magnetic navigation system designed to ensure patient safety in regards to the manipulation of the catheters or guidewires through the body’s cardiovascular system. In addition, it will limit the patients and physicians exposure to radioactive material. The AXION system and the Niobe system have been designed to integrate together to provide high definition imaging and safety to patients and staff.

The proposed renovations will provide the needed space for patients and staff. Industry guidelines and the Voluntary Consent Agreement with the State of Connecticut’s Department of Public Health dictate that these renovations be made so that the Hospital can improve delivery and enhance the quality of the care that its patients receive in the cardiac cath lab.

The Hospital’s volume projections are 4,122, 4,208, and 4,295 cases for FY 2004, FY 2005 and FY 2006, respectively, The Hospital projects incremental increases in operating revenues relating to this project for the first three years of operation. The Hospital reports an operating fund cash balance of \$47.8 million on June 30, 2003, which includes cash from the Hospital’s wholly owned subsidiaries. If volume projections are achieved and the Hospital’s cash balance is maintained, the Hospital’s rates and net revenue will be sufficient to cover the proposed capital expenditure and operating costs associated with the project. The number of cases and the financial projections relating to the operational aspects of this project appear reasonable and achievable. Based on the above, the proposal is in the best interest of the Hospital’s patients and the payers of the service.

Based on the foregoing Findings and Rationale, the Certification of Need application of The Hospital of Saint Raphael to renovate the cardiac catheterization laboratory, replace aged equipment, and acquire a new stereotaxis system at 1450 Chapel Street, New Haven, is hereby **GRANTED**.

Order

Hospital of Saint Raphael is hereby authorized to replacement existing equipment in the cardiac catheterization laboratory, renovate the cardiac catheterization laboratory, including patient holding and recovery areas, and acquire a Stereotaxis Niobe Magnetic Interventional Instrument Control System, at a total capital expenditure of \$4,402,308, subject to the following conditions:

1. The authorization shall expire on September 16, 2005. Should the renovations of the cardiac catheterization laboratory not be completed by that date, Hospital of Saint Raphael must seek further approval from OHCA to complete the project beyond that date.
2. Hospital of Saint Raphael shall not exceed the approved capital expenditure of \$4,402,308, which will be funded through operating funds and lease financing. In the event that the Hospital learns of potential cost increases or expects that the final project costs will exceed those approved, Hospital of Saint Raphael shall file with OHCA a request for approval of the revised budget.
3. This authorization requires the removal of the Hospital of Saint Raphael's existing cardiac catheterization equipment to be replaced for certain disposition, such as sale or salvage, outside of and unrelated to the Hospital's service provider location. Furthermore, the Hospital will provide evidence to OHCA of the disposition of the equipment by no later than six months after the new replacement equipment has become 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

Date Signed:
September 16, 2003

Signed by:
Mary M. Heffernan
Commissioner

MMH:lkg

Table 1

Table 1 reports the actual number of cardiac catheterization laboratory cases for Fiscal Years 2000 through 2003. The numbers of cases are broken down into the following categories: cath lab interventions; cath lab diagnostics; electrophysiology interventions; electrophysiology diagnostics; and the total number of cases. In Fiscal Year 2003, the annualized total number of cases was reported as 3,994.

Table 2

Table 2 lists the following components of the proposal along with the component's associated cost: construction and renovation; purchased medical equipment; purchased imaging equipment; and purchased non-medical equipment.

Table 3

Table 3 lists each piece of fixed or movable medical equipment being purchased for the cath lab and its proposed associated cost. The cost associated with the Siemens AXION Artis dFC is \$1,524,228; the cost associated with the NIOBE Magnetic Navigation System is \$820,000; and the total cost for movable equipment is \$538,079. The total associated cost for all fixed and movable equipment is \$2,882,308.