Office of Health Care Access
Certificate of Need Application

Final Decision

Applicant:	**The Hospital of Saint Raphael**
Docket Number:	**08-31224-CON**
Project Title:	**Acquisition and Operation of a New Fixed-Based C-Arm Angiography System**
Statutory Reference:	**Section 19a-639 of the Connecticut General Statutes**
Filing Date:	**December 19, 2008**
Decision Date:	**February 17, 2009**
Default Date:	**March 19, 2009**
Staff Assigned:	**Jack A. Huber**

Project Description: The Hospital of Saint Raphael proposes to acquire and operate a new fixed-based C-Arm angiography system at a total capital expenditure of $2,848,433.

Nature of Proceedings: On December 19, 2008, the Office of Health Care Access ("OHCA") received a Certificate of Need ("CON") application from The Hospital of Saint Raphael ("Hospital") to acquire and operate a new fixed-based C-Arm angiography system at a total capital expenditure of $2,848,433. 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 concerning OHCA's receipt of the Hospital's Letter of Intent was published on August 31, 2008, in *The New Haven Register*. OHCA received no response from the public concerning the Hospital's proposal.

Pursuant to Section 19a-639 of the Connecticut General Statutes ("C.G.S.") three individuals or an individual representing an entity with five or more people had until January 9, 2009, 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, 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. The Hospital of Saint Raphael ("Hospital") is a community teaching hospital located at 1450 Chapel Street in New Haven, Connecticut. *(December 19, 2008, Initial CON Submission, page 10 and Attachment IV, page 157)*

2. The Hospital proposes to acquire and operate a new fixed-based C-Arm angiography system. The equipment will augment surgical services that are currently offered by the Hospital. The proposal also includes construction within existing space necessary to accommodate the new system. *(December 19, 2008, Initial CON Submission, pages 10 and 11)*

3. The Hospital intends to purchase a Siemens Zeego angiography system and install the equipment in a dedicated operating room ("OR") suite to be used for the following procedures:
   a. Patients with vascular disease that require some type of catheter based vascular or endovascular procedure: examples include endovascular grafting for abdominal aortic aneurysms, angioplasty and stenting for arterial occlusive disease in peripheral vessels, renal or carotid arteries; and
   b. Patients with cardiac rhythm disturbances that require implantation of automated implantable cardioverter-defibrillators.
   (December 19, 2008, Initial CON Submission, pages 10, 12 and 15)

4. The Hospital reports the following advantages of vascular surgery over traditional open surgery are as follows:
   a. Vascular surgery presents significantly less risk to patients when reduced operative and post-operative mortality rates are observed;
   b. Patients experiencing vascular surgery require a few days hospital stay as oppose to a ten day stay for patients experiencing traditional surgery; and
   c. Fewer patients require skilled nursing care when having vascular surgery.
   (December 19, 2008, Initial CON Submission, page 13)

5. The Hospital indicates that as surgical procedures using intra-operative imaging have increased in sophistication, the need for high quality imaging in the operating room has greatly increased. In particular vascular surgeons, cardiothoracic and invasive cardiologists rely on C-arm angiography imaging to perform many complex operating room procedures. *(December 19, 2008, Initial CON Submission, page 10)*

6. The Hospital states that to date its intra-operative fluoroscopy needs have been met with the use of portable C-arm equipment. However, as certain surgeries have become more complex, the need for higher quality images now warrants the Hospital's acquisition of a fixed-based C-arm angiography system. *(December 19, 2008, Initial CON Submission, page 10)*

7. The proposal is intended to serve patients residing in the Hospital's existing primary ("PSA") and secondary ("SSA") service areas. *(December 19, 2008, Initial CON Submission, page 15)*

8. The Hospital indicates it's PSA and SSA consists of the following Connecticut towns:

Table 1: Service Area Towns

PSA:				
New Haven	East Haven	North Haven	West Haven	Hamden

SSA:				
Ansonia	Bethany	Branford	Cheshire	Clinton
Derby	Guilford	Madison	Meriden	Milford
North Branford	Orange	Oxford	Seymour	Shelton
Wallington	Woodbridge			

(December 19, 2008, Initial CON Submission, pages 14 and 15)

9. The Hospital operates five full size portable C-arm units. Two units were acquired in 1991, one in 1997 and two in 2001. The three older units are considered by the Hospital to be in fair condition, although none are picture archiving communication system compatible. Additionally the three older units have developed repair part replacement issues and need service more frequently. *(December 19, 2008, Initial CON Submission, page 14)*

10. The Hospital states that due to recent increases in fluoroscopy procedures in the operating rooms ("ORs"), the portable C-arm equipment is in high demand and there are frequent scheduling conflicts. *(December 19, 2008, Initial CON Submission, page 11)*

11. The Hospital indicates the proposed imaging equipment is required due to the complexity and high resolution needed in many of the vascular cases performed. The proposed equipment will improve the quality of patient care, patient safety and accuracy of diagnostic and interventional procedures. The proposed equipment will also allow the existing complement of mobile C-arm equipment to meet the demand of other surgical specialties that do not require the same level of imaging resolution that is required for vascular cases. *(December 19, 2008, Initial CON Submission, page 11)*

12. The Hospital reports the following utilization trends:
    a. The total number of OR fluoroscopy encounters has increased from 2,774 in fiscal year ("FY") 2006 to 3,023 in FY 2008;
    b. There has also been an increase in vascular fluoroscopy cases which grew from 246 in FY 2006, to 283 in FY 2007 and to 307 in FY 2008; and
    c. Vascular surgeons performed a total of 891 cases in FY 2006, 864 cases in FY 2007 and 951 cases in FY 2008.

    (December 19, 2008, Initial CON Submission, pages 11, 17 and 18)

13. The Hospital expects continued growth in vascular procedures due to the following factors:
    a. The growth and aging of the population:
    b. The higher prevalence of vascular disease in older individuals;
    c. The recent addition of a vascular surgeon to the Hospital's Connecticut Vascular Center with the prospect of recruiting another vascular surgeon within the next two years; and
    d. The continued evolution of catheter based procedures for diagnostic and treatment of vascular conditions.

    (December 19, 2008, Initial CON Submission, page 12)

14. The Hospital's actual procedure volume as measured by the number of OR patients receiving fluoroscopy for FYs 2006 through 2008 is presented in the following table:

Table 2: Actual OR Fluoroscopy Procedure Volume

Procedures	FY 2006	FY 2007	FY 2008
Total with Portable Systems	**2,774**	**2,676**	**3,023**

Source: Fluoroscopy encounters identified through the Hospital's Information Systems Department.
(December 19, 2008, Initial CON Submission, page 17)

15. The Hospital's projected procedure volume as measured by the anticipated number of OR patients requiring fluoroscopy by system type for FYs 2009 through 2012 is presented in the following table:

Table 3: Projected OR Fluoroscopy Procedure Volume

Procedures	CFY 2009*	FY 2010	FY 2011	FY 2012
Existing Portable Systems	3,104	2,932	3,027	3,118
Proposed Fixed –Vascular**	89	453	535	555
Proposed Fixed- Cardiac**	24	96	96	96
Total Procedures	**3,217**	**3,481**	**3,658**	**3,769**

Note: *Current fiscal year ("CFY") 2009 volume is based on two months actual data annualized. The growth in projected volume for FYs 2010 through 2012 represents an increase of approximately 2 percent each fiscal year.
** Assumes fixed-based equipment is operational for 3 months in CFY 2009.
(December 19, 2008, Initial CON Submission, page 17)

16. The other area providers offering intra-operative imaging are Yale-New Haven Hospital, Milford Hospital; Griffin Hospital and Temple Surgical Center. *(December 19, 2008, Initial CON Submission, page 20)*

17. As the proposal is intended for the use of existing and future patients of the Hospital, the Hospital indicates that the proposal will not affect other area providers of intra-operative imaging. *(December 19, 2008, Initial CON Submission, page 20)*

18. The hours of operation of the existing portable C-arm systems coincides with the scheduled operating room cases that require their use. Routine OR hours of operation are generally between 7:00 a.m. and 3:30 p.m., although urgent and emergent cases can be performed when required. Late day activity is generally due to add-on cases that are of an urgent or emergency nature. *(December 19, 2008, Initial CON Submission, page 16)*

19. The Hospital follows the current standards of practice outlined in the guidelines of The Society for Vascular Surgery. (*December 19, 2008, Initial CON Submission, page 21)*

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

20. The proposal's capital expenditure totals $2,848,433 and is itemized as follows:

Table 4: Total Capital Expenditure

Description	Expenditure
Medical Equipment Purchase	$220.390
Imaging Equipment Purchase	$1,489,770
Non-medical Equipment Purchase	$148,626
Building Work	$799,647
Contingency	$190,000
Total Capital Expenditure	**$2,848,433**

(December 19, 2008, Initial CON Submission, pages 24 and 25)

21. The imaging system will be installed in operating room suite # 27, which currently consists of 820 square feet of shelled space within the Hospital's surgical services department. *(December 19, 2008, Initial CON Submission, page 25)*

22. The costs associated with preparing the operating suite are as follows:

Table 5: Building Costs

Description	Cost
Building Work	$608,332
Architectural and Engineering	$106,900
Insurance, Fees & Permits	$84,415
Total Building Costs	**$799,647**

(December 19, 2008, Initial CON Submission, page 26)

23. The Hospital states that the construction associated with the proposal will not affect the delivery of patient care services. *(December 19, 2008, Initial CON Submission, page 26)*

24. The work schedule required to accommodate the system is as follows: *(December 19, 2008, Initial CON Submission, page s 26 and 27)*

Table 6: Project Schedule

Stage	Target
Construction Commencement	March, 2009
Construction Completion	June, 2009
Commencement of Operations	July 2009

25. The proposal will be funded through Hospital operating funds, generated from the provision of services to patients. *(December 19, 2008, Initial CON Submission, page 27)*

26. The Hospital projects incremental gains from operations for the first three full years of operating the fixed-based C-arm system as follows:

Table 7: Projected Incremental Gains with the Proposal

Fiscal Year	FY 2010	FY 2011	FY 2012
Incremental Gain	$240,420	$510,620	$710,837

(December 19, 2008, Initial CON Submission, pages 29 and 30 and Attachment XI, page 250)

27. The current and projected payer mix for the first three fiscal years of operating the C-arm system is provided in the following table:

Table 8: Current and Projected Payer Mix

Payer	Current	Year 1	Year 2	Year 3
Medicare	55.8%	55.8%	55.8%	55.9%
Medicaid*	11.5%	11.5%	11.5%	11.4%
CHAMPUS & TriCare	0.1%	0.1%	0.1%	0.1%
Total Government Payers	**67.4%**	**67.4%**	**67.4%**	**67.5%**
Commercial*	28.8%	28.8%	28.8%	28.8%
Uninsured	2.2%	2.2%	2.2%	2.2%
Workers Compensation	1.6%	1.6%	1.6%	1.5%
Total Non-Gov't Payers	**32.6%**	**32.6%**	**32.6%**	**32.6%**
Total	**100.0%**	**100.0%**	**100.0%**	**100.0%**

(December 19, 2008, Initial CON Submission, pages 29)

28. There is no State Health Plan in existence at this time. *(December 19, 2008, Initial CON Submission, page 12)*

29. The proposal is consistent with Hospital's long-range plan. *(December 19, 2008, Initial CON Submission, page 12)*

30. The proposal will not change the Hospital's teaching or research responsibilities. *(December 19, 2008, Initial CON Submission, page 23)*

31. The Hospital will not experience a significant change to its patient/physician mix with project implementation. *(December 19, 2008, Initial CON Submission, page 29)*

32. The Hospital has improved productivity and contained costs through energy conservation, group purchasing, reengineering, and applications of new technologies. *(December 19, 2008, Initial CON Submission, page 22)*

33. The Hospital has sufficient technical and managerial competence to provide efficient and adequate service to the public. *(December 19, 2008, Initial CON Submission, pages 21 & 22 and Attachment III, pages 83 through 155)*

34. The Hospital's rates are sufficient to cover the proposed capital expenditure and operating costs. *(December 19, 2008, Initial CON Submission, pages 29 and 30 and Attachment XI, page 250)*

Rationale

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

The Hospital of Saint Raphael ("Hospital") is a community teaching hospital located in New Haven, Connecticut. The Hospital proposes to acquire and operate a new fixed-based C-arm angiography system. The equipment will augment surgical services that are currently offered by the Hospital. The Hospital intends to purchase a Siemens Zeego angiography system and install the equipment in a dedicated operating room ("OR") suite. The system will be used for patients with vascular disease that require catheter based vascular or endovascular procedures and for patients with cardiac rhythm disturbances that require implantation of automated implantable cardioverter-defibrillators. The Hospital anticipates the fixed C-arm system will become operational in July 2009.

The Hospital indicates the proposed imaging equipment is required due to the complexity and high resolution needed in many of the vascular cases offered at the Hospital. Due to recent increases in fluoroscopy procedures performed in the operating room ("OR") suites, the Hospital's five portable C-arm units are in high demand with frequent scheduling conflicts for their use. Two units were acquired in 1991, one in 1997 and two in 2001. While the three older units are considered by the Hospital to be in fair working condition, the units have developed part replacement issues, need more frequent servicing and are not compatible with picture archiving communications systems.

The proposed equipment will improve the quality of patient care, patient safety and accuracy of diagnostic and interventional procedures. The proposed equipment will also allow the existing complement of portable C-arm equipment to meet demand generated by routine services as well as other surgical specialties that do not require the same level of imaging resolution that is required for vascular cases. The total number of OR fluoroscopy encounters has increased from 2,774 in fiscal year ("FY") 2006 to 3,023 in FY 2008. There has also been an increase in vascular fluoroscopy cases which grew from 246 in FY 2006 to 307 in FY 2008. Lastly, vascular surgeons, who performed 891 cases in FY 2006, performed 951 cases in FY 2008. OHCA finds that the Hospital has provided evidence to support the need for the proposed acquisition. The CON proposal will enhance access to and the quality of intra-operative imaging provided by the Hospital.

The total capital expenditure of the proposal is $2,848,433. The proposal will be financed through Hospital operating funds generated from the provision of patient revenue. The Hospital projects an incremental gain from operations related to the proposal of $240,420, $510,620 and $710,837 for FYs 2010 through 2012, respectively. The Hospital's volume and financial projections upon which they are based appear to be reasonable and achievable.

Order

Based upon the foregoing Findings and Rationale, the Certificate of Need application of The Hospital of Saint Raphael ("Hospital") to acquire and operate a new fixed-based C-arm angiography system, at a total capital expenditure of $2,848,433, is hereby GRANTED, subject to conditions.

1. This authorization shall expire on July 1, 2010. Should the Hospital's imaging system not be operational by that date, the Hospital must seek further approval from OHCA to complete the project beyond that date.

2. The authorized capital expenditure shall not exceed $2,848,433. In the event that the Hospital learns of potential cost increases or expects that final project costs will exceed those approved, the Hospital shall notify OHCA immediately.

3. With respect to the acquisition of the new fixed-based C-arm angiography system, 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 C-arm system manufacturer;
    b) The model name and description of the C-arm system; and
    c) The initial date of the operation of the C-arm system.

4. Should the Hospital propose any change in its imaging services, 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 February 17, 2009

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Date Cristine A. Vogel
Commissioner

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