



Office Of Health Care Access Certificate of Need Application

Final Decision

Applicant: Saint Raphael Magnetic Resonance Center

Docket Number: 02-562

Project Title: Acquisition of 3T MRI Unit

Statutory Reference: Section 19a-639, Connecticut General Statutes

Filing Date: February 20, 2003

Hearing: March 25, 2003

Presiding Officer: Mary M. Heffernan

Decision Date: March 31, 2003

Default Date: May 21, 2003

Staff Assigned: Kim Martone
Laurie Greci

Project Description: Saint Raphael Magnetic Resonance Center (“Applicant”) proposes to acquire a 3T MRI Unit at 330 Orchard Street in New Haven, CT, at a total proposed capital cost of \$3,470,500, which does not include any capitalized financing costs.

Nature of Proceedings: On February 20, 2003, the Office of Health Care Access (“OHCA”) received the Applicant’s complete Certificate of Need (“CON”) application seeking authorization to acquire a 3T MRI Unit at 330 Orchard Street in New Haven, CT, at a total proposed capital cost of \$3,470,500, which does not include any capitalized financing costs. The Applicant is a health care facility or institution as defined by Section 19a-630, C.G.S.

A public hearing regarding the CON application was held on March 25, 2003. The Applicant was notified of the date, time, and place of the hearing, and a notice to the public was published prior to the hearing in the *New Haven Register*. Commissioner Mary M. Heffernan served as presiding officer for this case. The public hearing was conducted as a contested case in accordance with the provisions of the Uniform Administrative Procedure Act (Chapter 54 of the Connecticut General Statutes) and Section 19a-639, C.G.S.

The Presiding Officer heard testimony from witnesses for the Applicant and in rendering this decision, considered the entire record of the proceeding. 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 considered by OHCA in its review.

Findings of Fact

Clear Public Need

Impact on the Applicant’s Current Utilization Statistics

Contribution of the Proposal to the Accessibility of Health Care Delivery in the Region

Contribution of the Proposal to the Quality of Health Care Delivery in the Region

1. Saint Raphael Magnetic Resonance Center (“Applicant” or “SRMRC”) is a partnership between DePaul Health Service Corporation, a subsidiary of Saint Raphael Healthcare System, Inc., and Medical Imaging Associates, a subsidiary of New Haven Radiology Associates, P.C., which operates a freestanding imaging center located at 330 Orchard Street in New Haven, CT. (*CON Application, February 3, 2003, page 4*)
2. SRMRC consists of 11 full-time radiologists including three neuroradiologists who have incorporated MRA, spectroscopy and diffusion imaging into their routine clinical practice. (*CON Application, February 3, 2003, page 15*)
3. SRMRC is the MRI provider for the Hospital of Saint Raphael and offers a full range of neurological, vascular, and other specialized interventional services. (*CON Application, February 3, 2003, page 14*)
4. The Applicant is proposing to acquire a 3T MRI unit to replace one of the two existing 1.5T MRI units located at 330 Orchard Street in New Haven, CT. The proposed 3T MRI unit will be located in the exam room that currently houses the

1.5T MRI being replaced. (*Letter of Intent, October 7, 2003 and Responses to Completeness, February 20, 2003, page 1*)

5. SRMRC is currently operating two 1.5T MRI units. One is a short bore MRI unit that began operations in December 1999. The other 1.5T MRI unit that is proposed to be replaced was originally installed in 1988 and has a 15-year-old magnet. General Electric notified the Applicant that it will no longer be able to write service contracts for the 1988 unit after July 31, 2003 due to lack of spare parts. (*CON Application, February 3, 2003, pages 14&25*)
6. The Applicant stated that the proposed 3T MRI unit provides the following advantages when compared to the existing 1.5T MRI unit:
 - Improved image quality;
 - Increased speed of examination; and
 - Ability to perform new clinical applications.(*Letter of Intent, October 7, 2003*)
7. Moving from a 1.5T to 3T system doubles the signal to noise ratio without incurring any time penalty. The more the signal can be strengthened and the noise can be reduced, the clearer the image becomes. (*CON Application, February 3, 2003, pages 15&433*)
8. 3T MRI technology allows for 50% shorter scan times for many tumor patients who may have trouble holding still. (*CON Application, February 3, 2003, page 5*)
9. New clinical applications of 3T imaging include cardiac MRA, brain mapping, cervical spine and upper thoracic spine scans, fiber tracking, small stroke detection, arterial spin labeling, prostate spectroscopy, breast imaging, and studies of small body parts, specifically knee cartilage. (*CON Application, February 3, 2003, pages 16-19*)
10. According to an article titled "Multivoxel 3D Proton Spectroscopy in the Brain at 1.5 Versus 3.0 T: Signal-to-Noise Ratio ("SNR") and Resolution Comparison" by Gonen et al in the *American Journal of Neuroradiology* 22:1727-1731, October 2001, improvements of about 20-50% can be realized in SNR per unit time and spectral resolution through the use of a 3T MRI. These advantages allow shorter examinations and better quantification. (*CON Application, February 3, 2003, page 635*)
11. According to the article titled "Diffusion-Tensor MR Imaging at 1.5 and 3.0 T: Initial Observations" by Hunsche et al in *Radiology* November 2001, diffusion-tensor magnetic resonance imaging at 3.0 T offers better image resolution (MR) or shorter imaging time than that at 1.5 T because of a 40% increase in SNR. This may facilitate diffusion-tensor MRI imaging for clinical use. (*CON Application, February 3, 2003, page 600*)

12. The Applicant based the need for the replacement and upgrade of the MRI unit on clinical, operational and financial considerations as follows:

- Improved patient care with greater speed and higher resolution;
- Replacement of outdated equipment; and
- Improved cost efficiency and longevity of equipment.

(CON Application, February 3, 2003, page 14)

13. The Applicant asserts that the proposed 3T MRI unit will produce higher quality images and improved diagnostic capabilities for SRMRC's radiologists in MR Angiography, Functional MRI, Diffusion and Perfusion Imaging, Spectroscopy, Virtual Colonoscopy, and Conventional Anatomical Imaging. *(CON Application, February 3, 2003, pages 16-19)*

14. The Applicant stated that the ability to perform scans with greater speed and higher resolution will assist clinicians in making definitive diagnoses, expedite appropriate treatment regimens, and reduce the number of unnecessary surgeries and other invasive procedures. *(CON Application, February 3, 2003, page 14)*

15. The additional cost of the 3T MRI exceeds that of comparable 1.5T MRI system by approximately \$400,000. The installation and operating costs of the 3T MRI are the same as those of a 1.5T MRI system. *(CON Application, February 3, 2003, page 14)*

16. The Applicant's historical and current utilization by type of category is as follows:

Table 1: Total Number of SRMRC MRI Procedures for Ten Fiscal Years

Type	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002
Neuro	2881	3023	3175	3313	3752	4075	4597	4832	5479	6378	7021
Body*	1557	1489	1630	1557	1565	1773	1965	2194	2584	2842	2916
Total	4438	4540	4841	4898	5343	5879	6580	7048	8101	9245	9994

* Includes chest, abdomen, pelvis, knee, shoulder, hips, TMJ, neck, elbow, wrist, foot, ankle, angiography, and miscellaneous. *(CON Application, February 3, 2003, page 99)*

17. Specifically, over the past three years brain studies have grown at an average annual rate of 15.5%; neurological MRA or angiography has averaged 10.5% annual growth; body MRA studies have grown by an average of 9%; and abdominal studies by 6%. *(CON Application, February 3, 2003, page 22)*

18. SRMRC projects an average annual growth rate of 5.7% and 10.2% for brain and neurological MRA studies, respectively, from FYs 2004-2006. The average annual growth rate for body MRA and abdominal studies is projected to be 9.7% and 9.5%, respectively over the three-year period. *(CON Application, February 3, 2003, page 22)*

19. The Applicant projects the following volume statistics for the current year and the first three full fiscal years of operation with the 3T MRI unit based on historical trends and new applications of 3T technology, as follows:

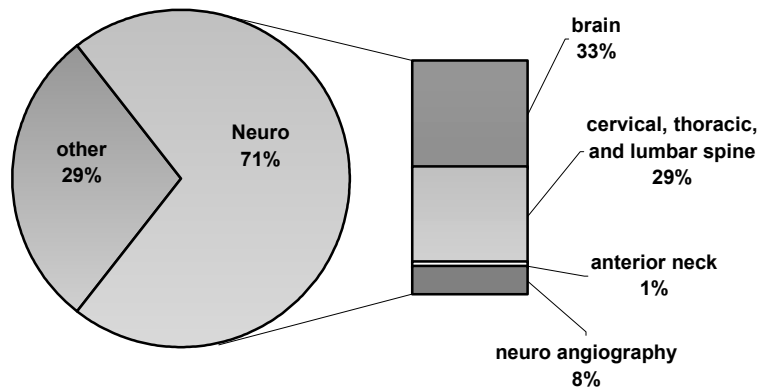
Table 2: Projected Total Number of Scans

Type	2003	2004	2005	2006
Neuro	6952	7603	8109	8350
Body	2700	3066	3244	3419
Total	9652	10669	11353	11769

(CON Application, February 3, 2003, Exhibits P&Q)

20. The projected total percentage of scans for neurological and other applications is 71% and 29%, respectively and is shown graphically in the following chart:

Figure 1: Types of Scans Performed in 2002



(CON Application, February 3, 2003, Exhibits P&Q)

21. The Applicant anticipates that the combination of the proposed 3T MRI unit with the existing 1.5T short bore MRI unit will improve throughput, reduce maintenance-related downtime and increase patient satisfaction. *(CON Application, February 3, 2003, page 14)*

22. The Applicant testified to the following regarding its relationship with HSR:

- All of SRMRC's radiologists are members of HSR's medical staff.
 - SRMRC currently provides all MRI scanning for inpatients of HSR.
 - SRMRC is physically located in the same building with HSR's Emergency Room.
- (March 20, 2003, Prefile Testimony of AnnaMarie Rose, page 6 and Hearing Testimony on March 25, 2003)*

Financial Feasibility 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 Payers for Such Services

23. The proposal has a total capital cost of \$3,470,500 which includes:

Table 3: Total Capital Cost

Project Components	Cost
Construction/Renovation	\$ 500,000
Other: Sales Tax	145,500
Total Capital Expenditure	\$645,500
Medical Equipment (Lease FMV)	2,825,000
Total Capital Cost	\$3,500,000

(CON Application, February 3, 2003, page 11)

24. For informational purposes only, the capitalized financing costs associated with the project are \$440,807. *(CON Application, February 3, 2003, page 7)*

25. The lease agreement for the 3T MRI unit includes \$400,000 for future upgrades to be expended at the Applicant's discretion over the five-year lease term. *(CON Application, February 3, 2003, page 7)*

26. The proposal will be financed through lease financing, a construction loan and the Applicant's operations. *(CON Application, February 3, 2003, page 10 and Responses to Completeness, February 20, 2003, page 1)*

27. The Applicant projects the 3T MRI unit will commence operation by October 1, 2003. *(CON Application, February 3, 2003, page 8)*

28. The Applicant projects excess revenues incremental to the project of \$402,128, \$457,996, and \$831,151 for FYs 2004, 2005, and 2006. *(CON Application, February 3, 2003, page 342)*

29. The Applicant will bill for all outpatient scans. The Hospital of Saint Raphael ("HSR") bills the facility fee (and reimburses the Applicant for these charges) for scans performed on inpatients of HSR. New Haven Radiology Associates bills the professional component. *(CON Application, February 3, 2003, page 6)*

30. The Applicant's rates are sufficient to cover the proposed capital cost and operating costs associated with the Applicant's proposal. *(CON Application, February 3, 2003, page 342)*

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

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

31. There is no State Health Plan in existence at this time. *(CON Application, February 3, 2003, page 2)*
32. The Applicant has adduced evidence that this proposal is consistent with the Applicant's long-range plan. *(CON Application, February 3, 2003, page 2)*
33. The Applicant has improved productivity and contained costs through application of technology. *(CON Application, February 3, 2003, page 5)*
34. The proposal will result in changes to the Applicant's teaching and research responsibilities. It will expose radiologists performing residencies and fellowships in the Hospital of Saint Raphael's graduate medical education program and radiology department to the latest clinical and technological advancements in MR. *(CON Application, February 3, 2003, page 5)*
35. The unique patient/physician mix characteristic related to this proposal is Applicant's physicians, in collaboration with the Hospital of Saint Raphael, have adopted a unique MRI-dependent protocol for the treatment of acute stroke patients. The protocol is one of the few in the Northeast that combines MRI evaluations using diffusion/perfusion techniques and the use of thrombolytic therapies to reduce the risk of hemorrhage. *(CON Application, February 3, 2003, page 5)*
36. The Applicant has sufficient technical, financial and managerial competence to provide efficient and adequate services to the public. *(CON Application, February 3, 2003, page 4 and Exhibit W)*

Rationale

Saint Raphael Magnetic Resonance Center (“SRMRC”) proposes to acquire a 3T MRI to replace one of the two existing 1.5T MRI units located at 330 Orchard Street in New Haven. SRMRC currently provides all MRI scanning for inpatients of the Hospital of Saint Raphael (“HSR”). All of SRMRC’s radiologists are members of HSR’s medical staff. SRMRC is physically located in the same building with HSR’s Emergency Room. The proposed 3T MRI unit will produce higher quality images and improved diagnostic capabilities for SRMRC’s radiologists in the areas of MR angiography, functional MR, perfusion and diffusion imaging, spectroscopy, virtual colonoscopy and conventional anatomical scans. SRMRC’s radiologists are currently performing MRA, spectroscopy and diffusion imaging. The Applicant based its proposal on clinical, operational, and financial considerations, including improving patient care with greater speed and higher resolution imaging, replacing outdated equipment, and improving the cost effectiveness of the equipment.

Clinically, the ability to perform scans with greater speed and higher resolution will assist clinicians in making definitive diagnoses, expedite appropriate treatment regimens, and reduce the number of unnecessary surgeries and other invasive procedures. Moving from a 1.5T to 3T system doubles the signal to noise ratio and maintains image quality while cutting exam time in half. Operationally, General Electric notified SRMRC that they would no longer be able to write service contracts after July 31, 2003 for the existing 1.5T MRI unit proposed to be replaced due to lack of spare parts. The combination of the proposed 3T MRI unit and the existing 1.5T short bore MRI unit will improve throughput, reduce maintenance-related downtime and increase patient satisfaction. Financially, the additional cost of the 3T MRI is approximately \$400,000 more than the 1.5T MRI. However, this additional cost is more than offset by the additional clinical applications proposed to be performed which require the 3T MRI’s higher signal to noise ratio.

Overall volume at SRMRC has more than doubled over the past ten years from 4,438 scans in FY 1992 to 9,994 scans in FY 2002. SRMRC has experienced an average annual growth rate of 14% in neurological exams over the past three years. In 2002, 70% of overall volume was neurological in nature. The proposed 3T MRI technology will compliment SRMRC’s expertise in neuro imaging and other advanced MRI techniques by making it the first provider in CT to offer 3T MRI in an exclusively clinical setting. SRMRC projects increased volume growth in brain and neurological MRA and in abdomen and body MRI based on historical trends and advances in 3T clinical technology. SRMRC also anticipates future growth in knee exams and scans of smaller parts of the body and extremities due to the higher resolution of the 3T magnet. Expanded applications include the areas of cardiac MRA, brain mapping, cervical spine and upper thoracic spine scans, fiber tracking, small stroke detection, arterial spin labeling, prostate spectroscopy, and breast imaging. OHCA concludes that the proposed 3T MRI unit will meet the needs of a large number of patients suffering from cardiac and neurological disorders who are referred to the SRMRC. Therefore, OHCA finds that the

Applicant's proposal will improve access to new clinical applications of these disorders, thereby improving the quality of life for these populations.

The proposal is financially feasible. The proposal has a total capital cost of \$3,470,500, which will be financed through lease financing, a construction loan, and the Applicant's operations. The lease agreement for the 3T MRI unit includes \$400,000 for future upgrades to be expended at the Applicant's discretion over the five-year lease term. The Applicant projects excess revenues incremental to the project of \$402,128, \$457,996, and \$831,151 for FYs 2004, 2005, and 2006. The Applicant will bill for all outpatient scans. The Hospital of Saint Raphael bills the facility fee for scans performed by the Applicant's physicians on inpatients and reimburses the Applicant for these charges. New Haven Radiology Associates bills the professional component. Based on the above findings, the financial projections appear to be reasonable and achievable. Therefore, the Applicant's proposal is in the best interests of consumers and payers. If volume projections are achieved, the Applicant's rates are sufficient to cover the proposed capital cost and operating costs associated with the project.

Based upon the foregoing Findings and Rationale, the Certificate of Need application of Saint Raphael Magnetic Resonance Center to acquire a 3T MRI Unit at 330 Orchard Street in New Haven, CT, at a total proposed capital cost of \$3,470,500, which does not include any capitalized financing costs, is hereby GRANTED.

Order

Saint Raphael Magnetic Resonance Center is hereby authorized to acquire a 3T MRI Unit at 330 Orchard Street in New Haven, CT, at a total proposed capital cost of \$3,470,500, which does not include any capitalized financing costs, subject to the following conditions:

1. This authorization shall expire on June 24, 2004, unless the Applicant presents evidence to OHCA that the 3T MRI unit has become operational by that date.
2. The Applicant shall not exceed the approved capital cost of \$3,470,500, which does not include any capitalized financing costs. In the event that the Applicant learns of potential cost increases or expects that final project costs will exceed those approved, the Applicant shall file with OHCA, a request for approval of the revised project budget.
3. This authorization requires the removal of the Applicant's existing 1988 MRI unit for certain disposition, such as sale or salvage, outside of and unrelated to the Applicant's New Haven location or any other affiliated locations. Furthermore, the Applicant will provide evidence to OHCA of the disposition of the existing MRI unit no later than six months after the replacement MRI scanner has become operational.

All of the foregoing constitutes the proposed final order of the Office of Health Care Access in this matter.

By Order of the
Office of Health Care Access

Date Signed
March 31, 2003

Signed by:
Mary M. Heffernan
Commissioner

Table Descriptions

Figure 1 shows the types of scans that were performed in 2002. 71% of the scans were neurological and 29% were for other purposes. The neurological scans were reported by type: 33% were brain scans, 29% were cervical, thoracic, and lumbar spine scans, 8% were neuroangiographic scans, and 1% were scans of the anterior neck.

Table 1 is the Applicant's historical and current MRI volume by type of category for the past ten fiscal years. Neurological studies have increased from 2,881 procedures in 1992 to 7,021 in 2002. Body procedures increased from 1,557 in 1992 to 2,916 in 2002.

Table 2 is the Applicant's projected number of scans for 2003 to 2006 by type of category. Neurological studies are projected to increase from 6,952 in 2003 to 8,350 in 2006. Body procedures are projected to increase from 2,700 in 2003 to 3,419 in 2006. The total number of scans projected are 9,652, 10,669, 11,353 and 11,769 in 2003, 2004, 2005, and 2006, respectively.