



Office Of Health Care Access Certificate of Need Application

Final Decision

Applicant: Yale-New Haven Hospital

Docket Number: 04-30283

Project Title: Acquire a 3.0 Tesla MRI Unit

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

Filing Date: August 2, 2004

Decision Date: August 18, 2004

Default Date: October 31, 2004

Staff Assigned: Harold M. Oberg

Project Description: Yale-New Haven Hospital (“Hospital”) proposes to acquire a 3.0 tesla Magnetic Resonance Imaging (“MRI”) unit, at a total capital expenditure of \$4,574,775. The Hospital is currently operating four 1.5 tesla MRI scanners and is proposing to acquire a fifth MRI scanner, which would be a high field 3.0 tesla fixed MRI unit and would enable the Hospital to meet current and projected MRI service demand.

Nature of Proceedings: On August 2, 2004, the Office of Health Care Access (“OHCA”) received a completed Certificate of Need (“CON”) application from Yale-New Haven Hospital to acquire a 3.0 tesla MRI unit, at a total capital expenditure of \$4,574,775. The Hospital is a health care facility or institution as defined by Section 19a-630 of the Connecticut General Statutes (“C.G.S.”).

On April 23, 2004, the Hospital was informed that a notice to the public regarding OHCA’s receipt of the Hospital’s Letter of Intent (“LOI”) to file its CON application would be published in the *New Haven Register* pursuant to Section 19a-639, C.G.S. as amended by Section 1 of Public Act 03-17. OHCA received no comments from the public concerning the Applicant’s LOI or CON application.

OHCA's authority to review and approve, modify or deny the CON application 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 Applicant'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. Yale-New Haven Hospital ("Hospital") is an acute care general hospital located at 20 York Street in New Haven, Connecticut. The Hospital's total licensed bed capacity of 944 beds and bassinets includes 852 licensed general hospital beds and 92 licensed bassinets. *(June 21, 2004 CON Application, Page 135)*
2. The Hospital proposes to acquire a 3.0 tesla Magnetic Resonance Imaging ("MRI") unit, at a total capital expenditure of \$4,574,775. The Hospital is currently operating four 1.5 tesla MRI scanners and is proposing to acquire a fifth MRI scanner, which would be a high field 3.0 tesla fixed MRI unit that would enable the Hospital to meet current and projected MRI service demand. *(June 21, 2004 CON Application, Pages 4 and 5)*
3. The Hospital intends to acquire and operate a GE Medical Systems Signa Excite 3.0 Tesla System fixed MRI unit, at a capital expenditure of \$2,250,000. *(June 21, 2004 CON Application, Appendix 11, Pages 139 - 146)*
4. The Hospital's existing four MRI units are experiencing a high level of utilization that places them near or above their individual operating capacities. The Hospital believes that it is essential that the four MRI units have excess capacity to handle the current and projected high volume of inpatient and emergency as well as outpatient MRI scans. The Hospital's current waiting time for an MRI exam ranges from 3 days to 14 days for a body or orthopedic MRI exam and from 7 days to 52 days for a neurological (head and spine) MRI exam. Future MRI volume is projected to grow due to the aging of the population, recent new uses for MRI and continued technological advancement. *(June 21, 2004 CON Application, Page 7)*
5. Compared to 1.5 tesla MRI scanners, 3.0 tesla MRI scanners offer the following advantages: *(April 19, 2004 Letter of Intent, Project Description)*
 - a. an improvement in the image quality and speed for certain MRI applications;
 - b. the provision of new clinical diagnostic capabilities that are not available with lower field strength MRI scanners; and
 - c. a more patient friendly exam period for most patients.
6. A 3.0 tesla MRI unit offers the following clinical and diagnostic capabilities when compared to a 1.5 tesla MRI unit: *(August 2, 2004 Completeness Responses, Pages 1 and 2)*

- a. Improved advanced brain imaging using techniques that permit improved localization and characterization of a wide range of neurological and cognitive ailments resulting in improved medical, surgical and minimally invasive therapies.
 - b. Improved proton and non-proton spectroscopy, which will improve the diagnosis of prostate and breast cancer. This will also help to determine whether a particular chemotherapeutic regimen is working at a very early stage so that therapies can be optimized and tailored for individual patients.
 - c. Higher spatial and temporal resolution images of the abdomen and pelvis will provide more detailed images and more accurate and early diagnosis and staging of diseases including liver, pancreatic, endometrial and ovarian cancers.
 - d. MRI of the heart will be improved so that MRI can be used routinely for the evaluation of ischemic heart disease and coronary arteries. It will also provide improved evaluation of complex congenital heart cases in the pediatric population, including quantification gradients and flow in shunts.
 - e. The 3.0 tesla MRI unit will make possible the use of techniques such as arterial spin labeling to non-invasively evaluate the perfusion of various organs such as the kidney and liver. This will aid in the evaluation of renal failure and renal and liver transplants, and could provide valuable information about various therapeutic regimens. The proposed MRI unit will also improve the sensitivity and specificity of MRI for the diagnosis of breast and prostate cancer.
 - f. Magnetic Resonance Angiography (“MRA”) will be faster and more detailed and will permit MR to replace conventional angiography for almost every diagnostic application, even in patients who cannot cooperate for extended periods of time, such as children and the elderly. Atherosclerotic plaque composition and burden will be evaluated non-invasively and will help determine the risk of heart attacks.
 - g. Improved evaluation of cartilage so that the efficacy of drug therapies for rheumatoid arthritis can be assessed and tailored for individual patients. In many cases, the capabilities provided by a 3.0 tesla MRI unit will result in new and improved therapies, which may be limited or not possible with a 1.5 tesla MRI unit.
7. The Hospital’s actual MRI scan volume was 11,281 scans in FY 2001, 13,515 scans in FY 2002 and 13,546 scans in FY 2003. *(August 2, 2004 Completeness Responses, Page 2)*
 8. The Hospital’s projected MRI scan volume for FY 2004, FY 2005, FY 2006 and FY 2007 is as follows: *(August 2, 2004 Completeness Responses, Pages 2, 9 and 10)*

Table 1: Hospital’s Projected MRI Scans for FY 2004 through FY 2007

Description	FY 2004	FY 2005	FY 2006	FY 2007
MRI Scans: With the CON Proposal	14,373	17,185	18,123	18,123
MRI Scans: Without the CON Proposal	14,373	14,373	14,373	14,373
MRI Scans: Incremental to CON Prop.	0	2,812	3,750	3,750

9. The Hospital estimates that the proposed MRI unit will be operational for nine months only in FY 2005, and that annually thereafter, the proposed MRI unit will operate 50 weeks per year with two weeks of downtime due to holidays, inclement weather and equipment maintenance. The proposed MRI unit will operate on a 12 shift per week basis including two shifts each day on Monday through Friday, plus one shift each on Saturday and Sunday. *(August 10, 2004 Supplemental Completeness Response, Page 1)*

10. The Hospital's calculation of its projected incremental MRI scans for FY 2005, FY 2006 and FY 2007 is as follows: *(August 10, 2004 Supplemental Completeness Response, Page 2)*

Table 2: Hospital's Calculation of Projected Incremental MRI Scans

<u>Description</u>
<u>FY 2005 Projected Incremental MRI Scans (January 2005 – September 2005)</u>
12 operating shifts per week x 6.25 MRI scans on average per shift = 75 MRI scans per week 50 operating weeks per year x .75 (9 months in FY 2005) = 37.5 weeks in operation in FY 2005 75 MRI scans per week x 37.5 weeks in operation in FY 2005 = 2,812 MRI scans
<u>FY 2006 Projected Incremental MRI Scans</u>
12 operating shifts per week x 6.25 MRI scans on average per shift = 75 MRI scans per week 75 MRI scans per week x 50 weeks in operation in FY 2006 = 3,750 MRI scans
<u>FY 2007 Projected Incremental MRI Scans</u>
12 operating shifts per week x 6.25 MRI scans on average per shift = 75 MRI scans per week 75 MRI scans per week x 50 weeks in operation in FY 2007 = 3,750 MRI scans

11. With regard to the current operating days and times of the Hospital's four existing MRI units, three MRI units operate on Monday through Friday from 7:00 a.m. until 11:30 p.m. and on Saturday and Sunday from 7:00 a.m. until 4:00 p.m. One MRI unit operates on Monday through Friday from 7:00 a.m. until 11:30 p.m. and on Saturday from 7:00 a.m. until 4:00 p.m. *(June 21, 2004 CON Application, Page 6)*

**Financial Feasibility and Cost Effectiveness 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 the Payers for Such Services**

12. The CON proposal's total capital expenditure of \$4,574,775 includes \$2,250,000 for the 3.0 tesla MRI unit and \$2,324,775 for building renovations. *(June 21, 2004 CON Application, Pages 13 and 15)*
13. The total renovation capital expenditures of \$2,324,775 include the following capital cost components: *(June 21, 2004 CON Application, Page 15)*

Table 3: Hospital's Total New Construction and Renovation Capital Expenditures

<u>Description</u>	<u>New Construction</u>	<u>Renovation</u>	<u>Total</u>
Building Work Costs	\$0	\$1,633,000	\$1,633,000
Architectural and Engineering Costs	0	231,832	231,832
Contingency Costs	0	309,383	309,383
Inflation Adjustment	0	15,000	15,000
Project Management Fee	0	135,560	135,560
Total Capital Expenditures	\$0	\$2,324,775	\$2,324,775

14. The CON proposal includes 3,824 square feet of major space renovations plus 232 square feet of minor space renovations for a total of 4,056 square feet of building renovations, which will provide upgraded and expanded operational and support space for the proposed 3.0 tesla MRI unit. *(June 21, 2004 CON Application, Page 14)*
15. The Hospital estimates that building renovations will commence upon CON approval and will be completed in November 2004, and that the proposed 3.0 tesla MRI unit will commence operation in January 2005. *(June 21, 2004 CON Application, Page 15, and August 2, 2004 Completeness Responses, Page 3)*
16. The total capital expenditure for the CON proposal of \$4,574,775 will be financed entirely by an equity contribution consisting of \$914,955 from the Hospital's operating funds and \$3,659,820 from the Hospital's funded depreciation. *(June 21, 2004 CON Application, Page 16)*
17. The Hospital projects incremental revenue from operations, total operating expense and gains from operations associated with the CON proposal for FY 2004, FY 2005, FY 2006 and FY 2007 as follows: *(August 2, 2004 Completeness Responses, Pages 9 and 10)*

Table 4: Hospital's Incremental Financial Projections for FY 2004 through FY 2007

Description	FY 2004	FY 2005	FY 2006	FY 2007
Incremental Revenue from Operations	\$0	\$2,844,000	\$3,905,000	\$4,022,000
Incremental Total Operating Expense	0	1,358,000	2,173,000	2,220,000
Incremental Gain from Operations	\$0	\$1,486,000	\$1,732,000	\$1,802,000

18. The Hospital's projected payer mix during the first three years of implementation and operation of the proposed 3.0 tesla MRI unit is as follows: *(June 21, 2004 CON Application, Page 17)*

Table 5: Hospital's Three-Year Projected Payer Mix with the CON Proposal

Payer Mix	Year 1	Year 2	Year 3
Medicare	33.82%	33.92%	33.68%
Medicaid	12.55%	12.36%	12.07%
TriCare (CHAMPUS)	0.36%	0.36%	0.36%
Total Government	46.73%	46.64%	46.11%
Commercial Insurers	51.11%	51.19%	51.57%
Self-Pay	1.31%	1.29%	1.42%
Workers Compensation	0.85%	0.88%	0.90%
Total Non-Government	53.27%	53.36%	53.89%
Uncompensated Care	0.00%	0.00%	0.00%
Total Payer Mix	100.00%	100.00%	100.00%

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

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

19. There is no State Health Plan in existence at this time. *(June 21, 2004 CON Application, Page 5)*
20. The Hospital has adduced evidence that the proposal is consistent with the Hospital's long-range plan. *(June 21, 2004 CON Application, Page 5)*
21. The Hospital has improved productivity and contained costs by undertaking energy conservation, group purchasing, reengineering and activities involving the application of new technology. *(June 21, 2004 CON Application, Page 11)*
22. The proposal will not result in any change to the Hospital's teaching and research responsibilities. *(June 21, 2004 CON Application, Page 12)*
23. There are no distinguishing or unique characteristics of the Hospital's patient/physician mix related to the proposal. *(June 21, 2004 CON Application, Page 12)*
24. The Hospital has sufficient technical, financial and managerial competence and expertise to provide efficient and adequate service to the public. *(June 21, 2004 CON Application, Appendix 6, Pages 35 - 112)*

Rationale

Yale-New Haven Hospital ("Hospital") proposes to acquire a 3.0 tesla Magnetic Resonance Imaging ("MRI") unit, at a total capital expenditure of \$4,574,775. The Hospital is currently operating four 1.5 tesla MRI scanners and is proposing to acquire a fifth MRI scanner, which would be a high field 3.0 tesla fixed MRI unit that would enable the Hospital to meet current and projected MRI service demand. The Hospital intends to acquire and operate a GE Medical Systems Signa Excite 3.0 Tesla System fixed MRI unit, at a capital expenditure of \$2,250,000.

The Hospital's existing four MRI units are experiencing a high level of utilization that places them near or above their individual operating capacities. The Hospital believes that it is essential that the four MRI units have excess capacity to handle the current and projected high volume of inpatient and emergency as well as outpatient MRI scans. The Hospital's current waiting time for an MRI exam ranges from 3 days to 14 days for a body or orthopedic MRI exam and from 7 days to 52 days for a neurological (head and spine) MRI exam. Future MRI volume is projected to grow due to the aging of the population, recent new uses for MRI and continued technological advancement.

Compared to 1.5 tesla MRI scanners, 3.0 tesla MRI scanners offer significant advantages including an improvement in the image quality and speed for certain MRI applications, the provision of new clinical diagnostic capabilities that are not available with lower field strength MRI scanners, and a more patient friendly exam period for most patients especially children and the elderly. Therefore, the proposed MRI unit acquisition will enhance the quality of health care delivery in the region.

The Hospital projects incremental volume increases of 0 MRI scans in FY 2004, 2,812 MRI scans in FY 2005, 3,750 MRI scans in FY 2006 and 3,750 MRI scans in FY 2007 due to the increased operating capacity and new clinical applications that are associated with the CON proposal. Based on the foregoing reasons, OHCA finds that there is a clear public need for the CON proposal, and that the CON proposal will improve both the quality and accessibility of existing MRI services in the New Haven region.

The total capital expenditure for the CON proposal of \$4,574,775 will be financed entirely by an equity contribution consisting of \$914,955 from the Hospital's operating funds and \$3,659,820 from the Hospital's funded depreciation. The Hospital projects incremental gains from operations of \$0 in FY 2004, \$1,486,000 in FY 2005, \$1,732,000 in FY 2006 and \$1,802,000 in FY 2007 associated with the CON proposal. The Hospital's volume projections and the 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 Yale-New Haven Hospital to acquire a 3.0 tesla MRI unit, at a total capital expenditure of \$4,574,775, is hereby GRANTED.

Order

Yale-New Haven Hospital (“Hospital”) is hereby authorized to acquire a 3.0 tesla MRI unit, at a total capital expenditure of \$4,574,775, subject to the following conditions:

1. This authorization shall expire on August 31, 2006. Should the Hospital’s 3.0 tesla MRI unit acquisition 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 total capital expenditure of \$4,574,775. In the event that the Hospital learns of potential cost increases or expects that final project costs will exceed those approved, the Hospital shall file with OHCA a request for approval of the revised CON project budget.

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

August 18, 2004

Signed by Cristine A. Vogel
Commissioner

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