



Office of Health Care Access Certificate of Need Application

Final Decision

Applicant: Yale-New Haven Hospital

Docket Number: 08-31217-CON

Project Title: Acquisition and Operation of a Fixed-Based, 1.5 Tesla-Strength Magnetic Resonance Imaging (“MRI”) Scanner , Replacing an Existing Fixed-Based, 1.5 Tesla-Strength MRI Scanner

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

Filing Date: December 3, 2008

Decision Date: February 17, 2009

Default Date: March 3, 2009

Staff: Jack A. Huber

Project Description: Yale-New Haven Hospital proposes to acquire and operate a fixed-based, 1.5 tesla-strength magnetic resonance imaging (“MRI”) scanner, replacing an existing fixed-based 1.5 tesla-strength MRI scanner, at a total capital expenditure of \$4,400,000.

Nature of Proceedings: On December 3, 2008, the Office of Health Care Access (“OHCA”) received a Certificate of Need (“CON”) application from Yale-New Haven Hospital (“Hospital”) seeking authorization to acquire and operate a fixed-based, 1.5 tesla-strength magnetic resonance imaging (“MRI”) scanner, replacing an existing fixed-based, 1.5 tesla-strength MRI scanner, at a total capital expenditure of \$4,400,000. 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 August 16, 2008. OHCA received no response 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 December 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. *(December 3, 2008, Initial CON application, page 10)*
2. The Hospital is requesting the acquisition and operation of a fixed-based, 1.5 tesla-strength magnetic resonance imaging scanner ("MRI"), which will replace the existing fixed-based, 1.5 tesla-strength Signa 3 MRI scanner. The proposal also includes renovations necessary to accommodate the new scanner in the Hospital's on-campus MRI center. *(December 3, 2008, Initial CON application, page 10)*
3. The Signa 3 MRI scanner was installed in 1990 by Yale University ("YU") adjacent to the Yale-New Haven Hospital clinical scanners. The scanner was used originally by YU as a research scanner. The Hospital acquired the MRI scanner from YU in 2003, at an amount that was under the \$400,000 Certificate of Need ("CON") capital expenditure threshold at the time of the acquisition. *(December 3, 2008, Initial CON application, pages 10 & 11 and Attachment II, page 27)*
4. The Hospital indicates the Signa 3 MRI scanner is quickly nearing the end of its useful life, with maintenance and part replacement availability issues occurring with greater frequency. In addition, the Hospital states many current applications of MRI imaging cannot be adequately performed with the Signa 3 system. *(December 3, 2008, Initial CON application, page 10)*
5. The Hospital indicates the proposed replacement will:
 - a. Insure its ability to provide continued access to MRI services for its patients;
 - b. Provide higher quality and greatly improved resolution that will benefit patients through more detailed and accurate imaging, thereby improving diagnosis and subsequently optimizing therapies; and
 - c. Support its goals of continuously improving clinical quality and patient care safety. *(December 3, 2008, Initial CON application, page 10)*
6. The Hospital plans to acquire and operate a fixed-based, 1.5 tesla-strength Siemens Magnetom Espree as its replacement equipment. *(December 3, 2008, Initial CON application, page 20 and Attachment XIV, pages 219 through 272)*

7. The Hospital indicates the replacement scanner will serve the Hospital's existing patient population and the equipment replacement will have no effect on existing service area MRI providers. *(December 3, 2008, Initial CON application, pages 12 & 14)*
8. The Signa 3 MRI scanner's actual service volumes for fiscal years ("FYs") 2006 through 2008 are as follows:

Table 1: Actual MRI Scans for the Signa 3 Scanner

Description	FY 2006	FY 2007	FY 2008
Signa 3 MRI Scanner	4,400	4,635	4,925

(December 3, 2008, Initial CON application, page 12)

9. The Hospital's actual service volumes by the number of MRI scans performed per scanner within the Hospital's on-campus MRI service is as follows:

Table 2: Actual Hospital MRI Service Volume

Description	FY 2006	FY 2007	FY 2008
Signa 1 (1.5T)	4,829	5,439	5,689
Signa 2 (1.5T)	3,810	3,798	4,173
Signa 3 (1.5T)	4,400	4,635	4,925
Signa 4 (mobile)	2,915	3,025	3,215
Signa 5 (3.0T)	3,666	4,460	4,721
Total MRI Scans	19,620	21,357	22,723

(December 3, 2008, Initial CON application, page 13)

10. The Hospital's projected service volumes by the anticipated number of MRI scans to be performed for the first three full fiscal years with the replacement MRI scanner are as follows:

Table 3: Projected Hospital MRI Service Volume***

Description	CFY 2009	FY 2010	FY 2011	FY 2012
Signa 1 (1.5T)	5,803*	5,919	6,037	6,158
Signa 2 (3.0T)	2,128**	4,256	4,342	4,428
Signa 3 (1.5T)	2,512**	5,024	5,124	5,226
Signa 4 (mobile)	3,279*	3,345	3,412	3,480
Signa 5 (3.0T)	4,815*	4,912	5,010	5,110
Total Number of Scans	18,537	23,456	23,925	24,402

Note: *Current fiscal year 2009 volume for Signa 1, 4 and 5 are based on projected growth of approximately 2.0% from FY 2008 volumes.

**Current fiscal year 2009 volume for Signa 2 and 3 represents actual first quarter volume beginning October 2008 through December 2008 and estimated second quarter volume beginning January 2009 through March 2009 and assumes a six month construction period for Signa 2, OCHA's approved upgrade from 1.5T to 3.0T under Docket Number: 08-31215-WVR and for the proposed Signa 3 replacement project.

***The growth in projected volume for fiscal years after 2009 represents an increase of approximately 2 percent each year.

(December 3, 2008, Initial CON application, page 13)

11. The Signa 3 MRI scanner, as well as the MRI service as a whole, operates Monday through Friday, 7:00 a.m. until 12:00 midnight; Saturday and Sunday, 8:00 a.m. until 5:00 p.m. *(December 3, 2008, Initial CON application, page 12)*

12. The Hospital states it will continue to meet the American College of Radiology guidelines through observance of clinical policies and procedures, medical staff credentialing and adherence to its quality assurance policies and procedures. *(December 3, 2008, Initial CON application, page 15)*

**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**

13. The proposal totals \$4,400,000 in capital expenditures and is itemized as follows:

Table 4: Total Capital Expenditure

Description	Component Cost
Major Medical Equipment	\$1,450,000
Renovation Work	\$2,400,000
Medical Equipment	\$550,000
Total Capital Expenditure	\$4,400,000

(December 3, 2008, Initial CON application, page 18)

14. The Hospital will fund the proposal through \$3,520,000 in funded depreciation and \$880,000 in operating funds. *(December 3, 2008, Initial CON application, page 20)*
15. Renovations totaling 5,745 square feet will commence immediately following the receipt OHCA's CON approval. *(December 3, 2008, Initial CON application, page 19)*
16. The project has been designed in a manner that will allow the Hospital to provide MRI services in an uninterrupted fashion. The Hospital proposes to employ a mobile-based 1.5 tesla-strength MRI scanner during the renovation and installation phases of the proposal. *(December 3, 2008, Initial CON application, page 19)*
17. The Hospital projects incremental operating losses of \$200,000, \$496,000 and \$496,000 due to non-cost depreciation expense in FYs 2010 through 2012, respectively. *(December 3, 2008, Initial CON application, page 22 and Attachment XVI, pages 278 through 281)*
18. The Hospital projects overall operating gains of \$26.3 million, \$27.9 million and \$32.2 million with the proposal in FYs 2010 through 2012, respectively. *(December 3, 2008, Initial CON application, page 22 and Attachment XVI, pages 278 through 281)*

19. 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%

(December 3, 2008, Initial CON application, pages 21 and 22)

20. There is no State Health Plan in existence at this time. *(December 3, 2008, Initial CON application, page 10)*
21. The Hospital has adduced evidence that this proposal is consistent with its long-range plan. *(December 3, 2008, Initial CON application, page 10)*
22. 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 by employing group purchasing practices in its procurement of supplies and equipment. *(December 3, 2008, Initial CON application, page 16)*
23. The proposal will not result in any change to the Hospital's teaching and research responsibilities. *(December 3, 2008, Initial CON application, page 17)*
24. 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. *(December 3, 2008, Initial CON application, page 17)*
25. The Hospital has sufficient technical and managerial competence to provide efficient and adequate services to the public. *(December 3, 2008, Initial CON application, pages 15 & 16 and Attachment VII, pages 57 through 108)*
26. The Hospital's rates are sufficient to cover the proposed capital expenditure and operating costs. *(December 3, 2008, Initial CON application, page 22 and Attachment XVI, pages 278 through 281)*

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 a new fixed-based, 1.5 tesla-strength magnetic resonance imaging (“MRI”) scanner, replacing an existing 19 year old fixed-based, 1.5 tesla-strength MRI scanner. The existing Signa 3 MRI scanner, which was installed in 1990 by Yale University adjacent to the Yale-New Haven Hospital clinical scanners, was used as a research scanner by the University. The Hospital acquired this MRI scanner from Yale University in 2003, at an expenditure that was below the \$400,000 Certificate of Need (“CON”) capital threshold at the time of the acquisition. The Hospital is requesting the replacement of the existing Signa 3 MRI scanner as the unit is quickly nearing the end of its useful life, with maintenance and part replacement availability issues occurring with greater frequency. In addition, the Hospital states many current applications of MRI imaging cannot be adequately performed with the Signa 3 scanner system. The Hospital performed 4,400, 4,635 and 4,925 scans with the Signa 3 MRI scanner in fiscal years (“FY”) 2006 through 2008, respectively.

The Hospital plans to acquire and operate a fixed-based, 1.5 tesla-strength Siemens Magnetom Espree as its replacement MRI equipment. This scanning equipment will provide higher quality and greatly improved image resolution that will benefit patients through more detailed and accurate imaging, resulting in improved diagnosis and subsequently optimizing therapies provided. The Hospital has provided sufficient evidence to support the need to maintain access to MRI scanning services in the area served by the Hospital. In addition, the CON proposal will improve the quality of MRI scanning services to Hospital patients.

The proposal’s capital expenditure totals is \$4,400,000 and consists of costs attributable to the replacement equipment and renovation work to accommodate the equipment. The project’s capital expenditure will be financed through a combination of Hospital funded depreciation and operating funds. In the initial years of operating the new Signa 3 MRI scanner, the Hospital projects operating losses from operation in each of the first three fiscal years due to non-cost 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 cost effective and is in the best interest of consumers and payers.

Order

Based on the foregoing Findings and Rationale, the Certificate of Need application of Yale-New Haven Hospital (“Hospital”) to acquire and operate a fixed-based, 1.5 tesla-strength magnetic resonance imaging (“MRI”) scanner, replacing an existing fixed-based, 1.5 tesla-strength MRI scanner, at a total capital expenditure of \$4,400,000, is hereby **granted**, subject to the following conditions.

1. This authorization shall expire on March 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 \$4,400,000. 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. This authorization allows the Applicant to lease a temporary mobile MRI scanner during installation of the replacement MRI scanner.
4. The Applicant may only operate one Signa 3 MRI scanner at all times; therefore, the temporary mobile MRI scanner may only be operated during installation of the replacement MRI scanner. The contractual arrangement for the temporary mobile MRI scanner must be terminated effective the date the new Signa 3 authorized MRI scanner becomes fully operational.
5. With respect to the acquisition of the new fixed-based, 1.5 tesla strength MRI scanner, the Hospital shall notify OHCA regarding the following information in writing by no later than one month after the scanner becomes operational:
 - a) The name of the MRI scanner manufacturer;
 - b) The model name and description of the MRI system; and
 - c) The initial date of the operation of the MRI scanner.
6. This authorization requires the removal, such as sale or salvage, outside of and unrelated to the Hospital’s Connecticut service locations, for the following:
 - a) The Hospital’s existing fixed-based, 1.5 Tesla MRI scanner; and
 - b) The temporary mobile MRI scanner authorized the condition number 3 above.

Furthermore, the Hospital shall provide evidence to OHCA of the disposition of the above listed MRI scanners to be removed by no later than six months after the new MRI scanner has become operational.

7. Should the Hospital propose any change in its magnetic resonance imaging 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 February 17, 2009

Date

Cristine A. Vogel
Commissioner

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