



## Office of Health Care Access Certificate of Need Application

### Final Decision

**Applicant:** Yale-New Haven Hospital

**Docket Number:** 08-31215-WVR

**Project Title:** Request to Waive CON Requirements for the Replacement of the Existing 1.5 Tesla MRI Scanner with a 3.0 Tesla MRI Scanner

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

**Filing Date:** August 4, 2008

**Decision Date:** August 25, 2008

**Staff:** Diane Duran

**Project Description:** Yale-New Haven Hospital requests a waiver of Certificate of Need (“CON”) requirements for replacement equipment for the purpose of replacing its existing 1.5 Tesla magnetic resonance imaging (“MRI”) scanner equipment with a 3.0 Tesla MRI scanner at 20 York Street in New Haven, at a total capital expenditure of \$4,605,633.

**Nature of Proceedings:** On August 4, 2008, the Office of Health Care Access (“OHCA”) received the completed waiver of Certificate of Need (“CON”) request for replacement equipment from Yale-New Haven Hospital (“Hospital”). The Hospital proposes to replace its 1.5 Tesla MRI scanner equipment with a 3.0 Tesla MRI scanner at 20 York Street in New Haven, at a total capital expenditure of \$4,605,633.

OHCA’s authority to review and approve, modify or deny the requested waiver of CON requirements for replacement equipment is established by Section 19a-639c 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 is an acute care hospital located at 20 York Street in New Haven, Connecticut. *(August 4, 2008, CON Waiver Form 2040, page 1)*
2. On May 23, 1989 in an Agreed Settlement under the Docket Number 89-505, Yale-New Haven Hospital (“Hospital”) received Certificate of Need (“CON”) authorization from the Commission on Hospitals and Health Care (“CHHC”), predecessor to the Office of Health Care Access (“OHCA”), to acquire a GE Signa, 1.5 Tesla magnetic resonance imaging (“MRI”) scanner at 20 York Street in New Haven, at a capital expenditure of \$4,343,867. *(August 4, 2008, CON Waiver Form 2040, page 2, and Appendix 1, May 23, 1989, Agreed Settlement under DN: 89-505, pages 9 and 12)*
3. The Hospital is requesting a waiver of CON requirements in order to replace its existing GE Signa 1.5 Tesla MRI scanner authorized by OHCA located at 20 York Street in New Haven. *(August 4, 2008, CON Waiver Form 2040, page 2)*
4. The Hospital operates two 1.5 Tesla MRI scanner located at 20 York Street in New Haven. *(August 4, 2008, CON Waiver Form 2040, page 2 and Cover Letter)*
5. Pursuant to Section 19a-639c of the Connecticut General Statutes (“C.G.S”), a proposal may be eligible for a waiver of replacement equipment from the CON process when a provider has previously received Certificate of Need authorization from OHCA for the equipment to be replaced and when the cost or value of the replacement equipment will not exceed \$3 million. *(Section 19a-639c, C.G.S.)*
6. The Hospital plans to acquire and operate a GE Signa HDx, 3.0 Tesla MRI scanner as its replacement equipment located at 20 York Street in New Haven. *(August 4, 2008, CON Waiver Form 2040, page 2 and Appendix II, Quotation, page 19)*
7. The Hospital states that the existing 1.5 Tesla MRI scanner equipment needs to be replaced with a 3.0 Tesla MRI scanner for the following reasons: *(August 4, 2008, CON Waiver Form 2040, page 5)*
  - a) The existing equipment is 19 years old and is outdated;
  - b) The equipment is nearing the end of its useful life, service issues and part replacement availability problems are occurring with greater frequency, resulting in significant downtime; and
  - c) The equipment also does not provide the same quality diagnostic exams.
8. Additionally, the Hospital states that the replacement of the existing 1.5 Tesla MRI scanner equipment with a new 3.0 Tesla MRI will result in the following benefits: *(August 4, 2008, CON Waiver Form 2040, pages 5 & 6)*
  - a) Improved imaging and resolution: Compared to the 1.5 Tesla, the 3.0 Tesla MRI scanner provides enhanced imaging quality and resolution. For example, the existing 1.5 Tesla scanner can only perform unilateral exams, which provides sub-optimal

- image quality, versus the proposed replacement equipment which is capable of bilateral breast MRI examinations with isotropic submillimeter resolution. Greater imaging and resolution capability will also improve evaluation of various complex cases such as complex congenital heart cases in the pediatric population, which involve non-invasive quantification gradients and flow in shunts;
- b) Facilitated use of advanced techniques: The new equipment will support the use of techniques such as arterial spin labeling to non-invasively evaluate the perfusion of various organs such as the kidney and liver, evaluate renal failure and liver transplants, and provide valuable information of various therapeutic regimens; and
  - c) Improved contrast-enhanced and non-contrast-enhanced magnetic resonance angiography (MRA): The new equipment will allow for faster and more detailed contrast-enhanced MRA, which is particularly important for pediatric and elderly patients. In addition, non-contrast-enhanced MRA will be significantly improved.
9. The Hospital states that by providing safe, high quality imaging services it is essential by supporting YNHH's goals of continuously improving clinical quality and patient safety. *(August 4, 2008, CON Waiver Form 2040, page 6)*
10. The total capital expenditure for the replacement project is \$4,605,633, which consists of the following components:
- a) \$1,895,000 for the associated major medical equipment; and
  - b) \$2,710,633 for construction and renovation work associated with the installation of the new equipment. *(August 4, 2008, CON Waiver Form 2040, page 3)*
11. During the construction and installation phase of the proposal, the Hospital will lease a mobile 1.5 Tesla MRI scanner, which will allow the Hospital to bridge the gap between the removal of the existing unit and the start of the new MRI scanner. *(August 4, 2008, CON Waiver Form 2040, Cover Letter)*
12. The capital cost of \$1,895,000 for the replacement 1.5 Tesla MRI scanner equipment is below the \$3 million threshold used to determine whether a request is eligible to receive a waiver of CON requirements for replacement equipment pursuant to Section 19a-639c, C.G.S. *(August 4, 2008, CON Waiver Form 2040, page 3)*
13. The Hospital will fund the proposal through its equity and depreciation funds. *(August 4, 2008, CON Waiver Form 2040, page 3)*
14. The Hospital intends to begin operating the new 3.0 Tesla MRI scanner upon CON approval. *(August 4, 2008, CON Waiver Form 2040, page 2)*
15. The replacement MRI scanner equipment will serve the Hospital's existing patient population and with no anticipated changes in the payer mix due to the proposal. *(August 4, 2008, CON Waiver Form 2040, pages 5 & 6)*

## **Rationale**

Yale-New Haven Hospital (“Hospital”) is requesting a waiver of Certificate of Need (“CON”) requirements for replacement equipment, pursuant to Section 19a-639c, of the C.G.S. The Hospital is seeking to replace its existing 1.5 Tesla magnetic resonance imaging (“MRI”) scanner with a 3.0 Tesla MRI scanner in New Haven and undertake renovations to accommodate the new equipment. The new MRI scanner replacement equipment will be located at 20 York Street in New Haven, Connecticut.

The Hospital is requesting that the existing 1.5 Tesla MRI scanner be replaced as the existing equipment is 19 years old and is outdated. The equipment is nearing the end of its useful life, service issues and part replacement availability problems have occurred with greater frequency, resulting in significant downtime. The new equipment will support the use of advanced techniques such as arterial spin labeling to non-invasively evaluate of the perfusion of various organs. The proposed MRI scanner will allow for faster and more detailed contrast-enhanced MRA. In addition, non-contrast-enhanced MRA will be significantly improved.

The capital cost for the proposed replacement MRI scanner equipment is \$1,895,000 which is below the \$3 million threshold for determining eligibility for a waiver of CON requirements for replacement equipment pursuant to Section 19a-639c, C.G.S. The Hospital will fund the replacement project through an equity and depreciation funds.

## **Order**

Based on the foregoing Findings and Rationale, OHCA has determined that the Yale-New Haven Hospital (“Applicant” or “Hospital”) request for a waiver of CON requirements for replacement equipment in order to replace its existing 1.5 Tesla magnetic resonance imaging (“MRI”) scanner with a 3.0 Tesla MRI scanner located at 20 York Street in New Haven, at a total capital cost of \$4,605,633, meets the requirements for waiver of the CON process pursuant to Section 19a-639c, C.G.S. and is hereby Approved subject to the following conditions .

1. This authorization shall expire on August 15, 2009. 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 total capital cost of \$4,605,633. 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.
3. This authorization allows the Applicant to lease a temporary mobile MRI scanner during installation of the new MRI scanner.
4. The Applicant may only operate one MRI scanner at all times; therefore, the temporary mobile MRI scanner may only be operated during installation of the new MRI scanner. The contractual arrangement for the temporary mobile MRI scanner must be terminated effective the date the new authorized MRI scanner becomes fully operational.
5. With respect to the acquisition of the new 3.0 Tesla MRI scanner, the Hospital shall notify OHCA regarding the following information in writing prior to the expiration date noted in Stipulation number 1:
  - a) The name of the system manufacturer;
  - b) The model name and description of the system; and
  - c) The initial date of the operation of the system.
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 1.5 Tesla MRI scanner; and
  - c) The temporary mobile MRI scanner authorized the condition #3.

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 the MRI scanner service, the Hospital shall file with OHCA a Certificate of Need Determination Request 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 August 25, 2008*

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Date

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Cristine A. Vogel  
Commissioner