



Office of Health Care Access Certificate of Need Application

Final Decision

Applicant: Yale-New Haven Hospital

Docket Number: 09-31335-WVR

Project Title: Request to Waive CON Requirements for the Replacement of an Existing 3.0 Tesla-Strength, Fixed-Based MRI Scanner in New Haven

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

Filing Date: March 17, 2009

Decision Date: March 26, 2009

Staff: Jack A. Huber

Project Description: Yale-New Hospital requests a waiver of Certificate of Need requirements for replacement equipment for the purpose of replacing its existing 3.0 tesla-strength, fixed-based magnetic resonance imaging scanner, at a total capital expenditure of \$2,496,501.

Nature of Proceedings: On March 17, 2009, 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”) in New Haven. The Hospital proposes to replace its existing 3.0 tesla-strength, fixed-based magnetic resonance imaging scanner (“MRI”) scanner with a 3.0 tesla-strength, fixed-based MRI scanner, at a total capital expenditure of \$2,496,501. The Hospital is a health care facility or institution as defined in Section 19a-630 of the Connecticut General Statutes (“C.G.S.”).

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, 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 hospital located at 20 York Street, New Haven, Connecticut. *(March 17, 2009, CON Waiver Form 2040, page 2)*
2. On August 18, 2004, in a Final Decision rendered under Docket Number: 04-30283, the Hospital received Certificate of Need (“CON”) authorization from the Office of Health Care Access (“OHCA”) to acquire and operate a 3.0 tesla-strength, fixed based MRI scanner. The new scanner, which represented the acquisition of a fifth scanner to its MRI complement of four existing 1.5 tesla-strength, was designated by the Hospital as the Signa 5 MRI unit. *(August 18, 2004, Final Decision, Docket Number: 04-30283 and March 17, 2009, CON Waiver Form 2040, page 2)*
3. The Hospital is requesting a waiver of CON requirements for the purpose of replacing its existing General Electric, 3.0 tesla-strength, fixed-based Signa 5 MRI scanner. The Hospital proposes to acquire and operate a Siemens 3.0 tesla-strength MAGNETOM Verio open bore, fixed-based system as its replacement equipment. *(March 17, 2009, CON Waiver Form 2040, pages 2 and 3 and Appendix II, pages 19 through 29)*
4. 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 health care facility has previously received CON authorization from OHCA for the equipment to be replaced and when the expenditure or value of the replacement equipment will not exceed \$3 million. *(Section 19a-639c, C.G.S.)*
5. The Hospital states that the Signa 5 MRI scanner requires replacement based on its plan to contract with a single equipment vendor for all of the scanners operating within its MRI service. The Hospital indicates its initiative will provide a standard platform for MRI services, standardize software levels across various scanners and will lead to consistency in imaging quality, standard protocols and training for technicians and physicians, and increase quality standards for the MRI services at its imaging center. *(March 17, 2009, CON Waiver Form 2040, page 5)*
6. The Hospital indicates the new Siemens wide bore MRI system will provide the following advantages:
 - a. Will enhance the Hospital’s ability to provide services to the bariatric population;
 - b. Will enhance the Hospital’s ability to minimize anxiety experienced by those patients who are claustrophobic;
 - c. Will produce whole body imaging for oncology patients during a single visit;
 - d. Will provide more detailed and versatile non-contrast magnetic resonance angiography (“MRA”) techniques for those patients who are at risk in receiving contrast; and
 - e. Will produce many cardiac imaging techniques better than the current scanner.*(March 17, 2009, CON Waiver Form 2040, pages 5 and 6)*

7. The proposed replacement will be used for similar services, examinations, and procedures as the current scanner. These include routine imaging of the brain, spine and upper and lower musculoskeletal system; neck; chest; abdomen; pelvis; breast; contrast enhanced MRA; and imaging of the heart. *(March 17, 2009, CON Waiver Form 2040, page 5)*
8. Relative to the following CON authorizations by OHCA, the Hospital has begun the transition of its MRI scanners to a single equipment vendor platform:
 - a. Signa 2 unit –approved in DN: 08-31215-WVR - will be a Siemens MRI scanner;
 - b. Signa 3 unit –approved in DN: 08-31217-CON - will be a Siemens MRI scanner;
 - c. Signa 4 unit –approved in DN: 08-31290-WVR - will be a Siemens MRI scanner; and
 - d. The Hospital’s two Smilow Cancer Center MRIs approved in DN: 04-30410-CON will be Siemens scanners.
9. In a separate matter, the Hospital on March 17, 2009, filed a request before OHCA seeking a waiver of CON for the replacement of its existing Signa 1, 1.5 tesla-strength MRI scanner with a new Siemens 1.5 tesla-strength MRI scanner, at a total capital expenditure of \$2,012,238.
10. The total capital expenditure for the Signa 1 project is \$2,496,501 and is itemized as follows:
 - a. \$1,500,046 for the purchase of the replacement MRI scanner; and
 - b. \$996,455 for renovation work associated with the installation of the new scanner. *(March 17, 2009, CON Waiver Form 2040, page 3)*
11. The replacement equipment project will be financed through equity and funded depreciation. *(March 17, 2009, CON Waiver Form 2040, page 3)*
12. The replacement expenditure for the proposal 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. *(March 17, 2009, CON Waiver Form 2040, page 2)*
13. The Hospital intends to proceed with its proposal upon authorization from OHCA. *(March 17, 2009, CON Waiver Form 2040, page 2)*
14. The replacement MRI scanner will serve the Hospital’s existing patient population. *(March 17, 2009, CON Waiver Form 2040, page 5)*
15. The Hospital anticipates no changes in the payer mix due to the proposal. *(March 17, 2009, CON Waiver Form 2040, page 5)*

Rationale

Yale-New Haven 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 General Electric 3.0 tesla-strength, fixed-based magnetic resonance imaging scanner (“MRI”) scanner with a Siemens 3.0 tesla-strength, fixed-based MRI scanner.

The Hospital is requesting the equipment replacement in order to achieve its plan to develop a standardized platform for the delivery of its MRI services. To accomplish its initiative the Hospital has begun the process of contracting with a single MRI equipment vendor. The Hospital’s efforts will standardize software levels across various scanners and will lead to consistency in imaging quality, standard protocols and training for technicians and physicians, and increase quality standards for the MRI services at its imaging center. In addition, the Hospital indicates that the proposed wide bore MRI scanner will enhance the Hospital’s ability to provide services to the bariatric population as well as claustrophobic individuals; will produce whole body imaging for oncology patients during a single visit; will provide more detailed and versatile non-contrast MRA techniques for those patients who are at risk in receiving contrast; and will produce many cardiac imaging techniques better than the current scanner.

The replacement expenditure for the proposed MRI scanner is \$1,500,046, 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 equity and funded depreciation.

Order

Based on the foregoing Findings and Rationale, the Office of Health Care Access (“OHCA”) has determined that Yale-New Haven Hospital’s (“Hospital’s”) request for a waiver of Certificate of Need (“CON”) requirements for replacement equipment in order to replace a 3.0 tesla-strength, fixed-based magnetic resonance imaging (“MRI”) scanner, at a total capital expenditure of \$2,496,501, 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 March 26, 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 \$3 million in replacement equipment expenditure or value for the proposed replacement equipment. In the event that the Hospital learns of potential cost increases or expects the replacement equipment expenditure or value will exceed \$3 million, the Hospital shall notify OHCA in writing.

3. With respect to the acquisition of the new MRI scanner, the Hospital shall notify OHCA regarding the following information in writing prior to the March 26, 2010, CON expiration date:
 - 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.
4. This authorization requires the removal of the Hospital's existing Signa 5 MRI scanner for certain disposition, such as sale or salvage, outside of and unrelated to the Hospital's Connecticut service locations. Furthermore, the Hospital shall provide evidence to OHCA of the disposition of the existing Signa 5 MRI scanner to be replaced by no later than six months after the replacement scanner has become operational.
5. Should the Hospital propose any change in MRI scanning services, 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 March 26, 2009

Date

Cristine A. Vogel
Commissioner

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