



## Office of Health Care Access Certificate of Need Application

### Final Decision

**Applicant:** Yale-New Haven Hospital

**Docket Number:** 07-31071-WVR

**Project Title:** Request to Waive CON Requirements for the Replacement of Two 4-Slice CT Simulator in Guilford and New Haven to Upgrade Radiation Therapy Capabilities

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

**Filing Date:** December 5, 2007

**Hearing:** Waived

**Decision Date:** January 24, 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 two computed tomography (“CT”) simulator scanners in Guilford and New Haven with no associated capital expenditure.

**Nature of Proceedings:** On December 5, 2007, the Office of Health Care Access (“OHCA”) received the waiver of Certificate of Need (“CON”) request for replacement equipment from Yale-New Haven Hospital (“Hospital”). The Hospital proposes to replace its existing two CT simulator scanner in Guilford and New Haven to upgrade radiation therapy capabilities, with no associated capital expenditure. 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 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. On December 6, 2002 in a Final Decision under Docket Number 02-549, Yale-New Haven Hospital (“Hospital”) and Yale New-Haven Ambulatory Services Corporation (“YNHASC”), received Certificate of Need (“CON”) authorization from the Office of Health Care Access (“OHCA”), to acquire and operate a 4-Slice computed tomography (“CT”) simulator scanner in Guilford, at a total capital cost of \$600,000. *(December 5, 2007, CON Waiver Form 2040, page 2, and December 6, 2002, Office of Health Care Access, Final Decision, Docket Number: 02-549, pages 17 and 22)*
2. On October 17, 2003 in a Final Decision under Docket Number 03-30083, Yale-New Haven Hospital (“Hospital”) received Certificate of Need (“CON”) authorization from the Office of Health Care Access (“OHCA”) to acquire CT simulator in New Haven that combines CT scanner functions that used Radiation Therapy patient treatment to support the use of Intensity Modulated Radiation Therapy (“IMRT”), at a total capital cost of \$1,179,950. *(December 5, 2007, CON Waiver Form 2040, page 2, and October 17, 2003, Final Decision for Docket Number: 03-30083, pages 10 and 12)*
3. The Hospital is requesting a waiver of CON requirements for the purpose of replacement of two existing GE LightSpeed Plus, 4-Slice CT simulator scanners, currently located at the Hospital’s Shoreline Medical Center at 111 Goose Lane in Guilford and at the Hospital 20 York Street in New Haven, acquired by the Hospital, which was authorized by the OHCA, through a Final Decision approved under Docket Numbers: 02-549 and 03-30083. *(December 5, 2007, CON Waiver Form 2040, page 2 and December 6, 2002 and October 17, 2003, the Office of Health Care Access, CON Final Decision, Docket Numbers: 02-549 and 03-30083)*
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 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.)
5. The Hospital plans to acquire and operate the GE LightSpeed RT 16 Systems, 16-Slice CT simulators as its replacement equipment at the Hospital’s Shoreline Medical Center at 111 Goose Lane in Guilford and the Hospital at 20 York Street in New Haven. *(December 5, 2007, CON Waiver Form 2040, pages 1 & 3 and Vendor Quotation, Appendix II)*
6. According to the Hospital the original purchase of the 4-Slice CT simulators for the Shoreline Medical Center and the Hospital, included a free upgrade to an 8-Slice simulators at no additional cost to the Hospital. *(December 5, 2007, CON Waiver Form 2040, pages 1 & 3 and Vendor Quotations, Appendix II and III)*

7. The delay in obtaining the upgrade was due to the non-availability of the 8-Slice technology and pending availability of the 16-Slice upgrade, which GE agreed to substitute for the non-available 8-Slice machine. *(December 5, 2007, CON Waiver Form 2040, Cover Letter, page 3 and Vendor Quotation, Appendix II)*
8. The Hospital indicates the two 4-Slice CT simulators in Guilford and New Haven provides the following: *(December 5, 2007, CON Waiver Form 2040, page 5)*
  - Functions as a combined CT scanner and is used for radiation therapy patients;
  - CT delineates the tumor and the simulator verifies accuracy of tumor localization and field placement; and
  - Procedures for all types of cancers (e.g., lung prostate, breast, head and neck, etc).
9. The Hospital states that the two 4-Slice CT simulators need to be replaced due to the following: *(December 5, 2007, CON Waiver Form 2040, pages 4 and 5)*
  - Inability to perform high quality images and resolution does not meet the standard practice to accommodate respiratory gating needs; and
  - Inability to monitor a more accurate and compensation of the respiratory beam for tumor movement within the body for the patients.
10. The Hospital states that the new two 16-Slice CT simulators will provide the following: *(December 5, 2007, CON Waiver Form 2040, page 6)*
  - Faster patient throughput;
  - Improved monitoring and compensation of the radiation beam, which enables the physician to maximize treatment dose while minimizing radiation exposure to the surrounding healthy tissues;
  - Improved tumor measuring methods, vascular and anatomical details;
  - Enhance clinical productivity, image clarity and computer processing speed;
  - Reduced scan time resulting which lowers the possibility of patient motion during the exam; and
  - Improved patient accessibility by providing a larger table and supporting large patients.
11. Even though there is no associated expenditure for the acquisition of the two proposed CT simulators, the upgrade to a higher slice was included in the original cost of the 4-Slice CT simulators. The fair market value for each of the proposed CT simulators is \$707,400. *(December 5, 2007, CON Waiver Form 2040, pages 1 & 3 and Vendor Quotations, Appendix II and III, January 16, 2007, Additional Vendor Quotation, page 5)*
12. There is no associated capital expenditure for the replacement project, due to the replacement equipment being included in the purchase of the existing CT simulators. *(December 5, 2007, CON Waiver Form 2040, page 3)*
13. The individual fair market value of the replacement CT simulators 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. *(December 5, 2007, CON Waiver Form 2040, page 3)*

14. The Hospital intends to begin operating the new CT simulator scanners upon CON approval. *(December 5, 2007, CON Waiver Form 2040, page 2)*
  
15. The replacement CT simulator will serve the Hospital's existing patient population with no anticipated changes in the payer mix due to the proposal. *(December 5, 2007, CON Waiver Form 2040, page 4)*

## **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 two 4-Slice computed tomography (“CT”) scanner with the GE LightSpeed RT 16 Systems CT simulator, with advanced radiation therapy capability.

The Hospital’s existing CT simulators at 111 Goose Lane in Guilford and at 20 York Street in New Haven need to be replaced due to the fact that the current CT simulators lack of ability to perform high quality images and the resolution does not meet the standard practice that accommodates respiratory gating needs. Additionally, the current CT simulators lack the ability to monitor and compensate of the respiratory beam for tumor movement within the body of the patients.

The Hospital’s proposed CT simulators will enhance clinical productivity, image clarity and computer processing speed. The CT simulators will offer faster patient throughput, improved resolution and image quality, tumor measuring methods, and vascular and anatomical details. The reduction of the CT simulator scan time will result in lowering the possibility of patient motion during the exams. It will also improve patient accessibility by providing a larger table and supporting large patients. The Hospital states that the new two 16-Slice CT simulators will provide improvement in monitoring and compensation of the radiation beam, which enables the physician to maximize treatment dose while minimizing radiation exposure to the surrounding healthy tissues.

There is no associated capital cost to the Hospital for the proposed replacement of the CT simulators due to the vendor including the upgrade to an 8-Slice CT simulator as part of the original purchase of the 4-Slice CT simulator. Due to the delay from the vendor in obtaining the 8-Slice CT simulator, the vendor is providing a free upgrade to a 16-Slice simulator at no additional cost to the hospital. The fair market value of each CT simulator scanner proposed is \$707,400 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.

## **Order**

Based on the foregoing Findings and Rationale, OHCA has determined that Yale-New Haven Hospital's ("Hospital") request for a waiver of CON requirements for replacement equipment in order to its two existing computed tomography ("CT") simulator scanners located at 111 Goose Lane in Guilford and at 20 York Street in New Haven, to upgrade radiation therapy capabilities with no associated capitol expenditure, the fair market value of each proposed 16-Slice CT simulators is \$707,400 which meets the requirements for waiver of the CON process pursuant to Section 19a-639c, C.G.S. and is hereby Granted subject to the following conditions.

1. This authorization shall expire on June 24, 2008. 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. There is no associated capital expenditure with this proposal. 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. With respect to the acquisition of the new CT simulator scanners, the Hospital shall notify OHCA regarding the following information in writing by no later than two months after the system becomes operational:
  - 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 CT simulator scanners at 111 Goose Lane in Guilford and at 20 York Street in New Haven 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 two CT Simulator to be replaced by no later than August 24, 2008.
5. Should the Hospital propose any change in the CT simulator 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 January 24, 2008*

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Date

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Cristine A. Vogel  
Commissioner

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