

Office of Health Care Access Certificate of Need Application

Final Decision

Applicant: Yale-New Haven Hospital

Docket Number: 06-30688-WVR

Project Title: Request to Waive CON Requirements for the

Replacement of Yale-New Haven Hospital's Linear

Accelerator

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

Filing Date: February 6, 2006

Hearing: Waived

Decision Date: April 3, 2006

Staff Assigned: Tillman Foster

Project Description: Yale-New Haven Hospital ("Hospital") requests a waiver of Certificate of Need ("CON") requirements for replacement equipment in order to replace its existing Linear Accelerator with a replacement Linear Accelerator capable of performing Stereotactic Radiosurgery (SRS), Intensity Modulated Radiation Therapy (IMRT) and Image Guided Radiotherapy (IGRT), at a total capital expenditure of \$2,796,851.

Nature of Proceedings: On February 6, 2006, the Office of Health Care Access ("OHCA") received the waiver of CON requirements request for replacement equipment from Yale-New Haven Hospital to replace its existing Linear Accelerator, at a total capital expenditure of \$2,796,851. 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, Inc. ("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 includes 852 licensed beds and 92 licensed bassinets. (February 6, 2006 Letter of Intent/Waiver Form 2030, Project Description Page 12)
- 2. 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 Connecticut General Statutes ("C.G.S.") to replace its existing Linear Accelerator, at a total capital expenditure of \$2,796,851. (February 6, 2006 Letter of Intent/Waiver Form 2030, Page 3)
- 3. On August 29, 1989, the Hospital received CON authorization from the Commission on Hospitals and Health Care ("CHHC"), predecessor agency to the Office of Health Care Access ("OHCA"), under Docket Number 89-533 for the purchase of its existing Linear Accelerator system, at a total capital expenditure of \$1,530,630. (August 29, 1989 Commission on Hospitals and Health Care Agreed Settlement, Yale-New Haven Hospital, Docket Number 89-533)
- 4. The Hospital's primary service area includes the following municipalities:

Ansonia	Derby	Madison	Orange
Bethany	East Haven	Meriden	Oxford
Branford	Essex	Milford	Seymour
Cheshire	Guilford	New Haven	Wallingford
Clinton	Hamden	North Branford	Westbrook
Deep River	Killingworth	North Haven	West Haven
		Old Saybrook	Woodbridge

(February 6, 2006 Letter of Intent/Waiver Form 2030, Project Description Page 9)

- 5. The Hospital proposes to replace its existing linear accelerator, a Varian 2100 C with an Elekta Synergy S System Linear Accelerator with IMRT, SRS and IGRT capabilities. (February 6, 2006 Letter of Intent Waiver Form 2030, Project Description, Page 8)
- 6. IMRT is an advanced form of external beam irradiation that delivers sharp dose gradients with a high degree of conformity
- 7. The Hospital's existing Linear Accelerator is fourteen years old, outdated, can not perform IMRT or SRS and does not have IGRT capabilities. (February 6, 2006 Letter of Intent Waiver Form 2030, Project Description, Page 9)
- 8. The benefits of the replacement Linear Accelerator will be that it can:
 - Perform IMRT or SRS and does have IGRT capabilities;
 - Increase dosage to certain tumor types (i.e., prostate, head & neck, spinal cord lesions, previously treated areas, children with cancer) while reducing dosage to normal tissue;

- Patients will experience fewer side effects and have potentially improved cure rates; and
- SRS capabilities coupled with the IGRT will provide treatment to patients with recurrent disease of the spinal cord.(February 6, 2006 Letter of Intent/Waiver Form 2030, Project Description Page 9)
- 9. The total capital expenditure for the replacement Linear Accelerator proposal is \$2,796,851 which includes \$1,974,070 for the replacement Linear Accelerator Unit and related software, \$725,581 for building renovations, and \$97,200 in other related costs. (February 6, 2006 Letter of Intent/Waiver Form 2030, Page 3)
- 10. The Hospital will fund the total capital expenditure of \$2,796,851 for the replacement equipment proposal through an equity contribution and funded depreciation. (February 6, 2006 Letter of Intent/Waiver Form 2030, Page 4)
- 11. The replacement expenditure of \$1,974,070 for the replacement equipment is below the \$2,000,000 threshold for determining eligibility for a waiver of CON requirements for replacement equipment pursuant to Section 19a-639c, C.G.S. (February 6, 2006 Letter of Intent/Waiver Form 2030, Page 3)
- 12. The replacement expenditure of \$1,974,070 for the replacement equipment is less than the original cost of the equipment to be replaced, plus an increase of ten percent for each twelve-month period that has elapsed since OHCA's original CON authorization date of August 29, 1989 under Docket Number 89-533. (February 6, 2006 Letter of Intent/Waiver Form 2030, Page 5)
- 13. The Hospital anticipates commencing the replacement equipment project upon OHCA Approval. (February 6, 2006 Letter of Intent/Waiver Form 2030, Page 2)

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 Connecticut General Statutes ("C.G.S.") to replace the equipment in the Linear Accelerator at a total capital expenditure of \$2,796,851. On August 29, 1989, the Hospital originally received CON authorization from the Commission on Hospitals and Health Care ("CHHC"), predecessor agency to the Office of Health Care Access ("OHCA"), under Docket Number 89-533 for the replacement of its existing Linear Accelerator equipment, at a total capital expenditure of \$1,530,630.

The Hospital plans to install an Elekta Synergy S System Linear Accelerator as its replacement Linear Accelerator equipment. The benefits of the replacement Linear Accelerator will be that it can perform IMRT or SRS and does have IGRT capabilities. It will increase dosage to certain tumor types (i.e., prostate, head & neck, spinal cord lesions, previously treated areas, children with cancer) while reducing dosage to normal tissue. Patients will experience fewer side effects and have potentially improved cure rates. SRS capabilities coupled with the IGRT will provide treatment currently not available to Connecticut patients with recurrent disease of the spinal cord.

The total capital expenditure for the replacement Linear Accelerator equipment is \$2,796,851, which includes \$1,974,070 for the replacement Linear Accelerator Unit and related software, \$725,581 for building renovations, and \$97,200 in other related costs. The Hospital will fund the total capital expenditure of \$2,796,851 for the replacement equipment proposal through an equity contribution.

The replacement expenditure of \$1,974,070 for the replacement equipment is below the \$2,000,000 threshold for determining eligibility for a waiver of CON requirements for replacement equipment pursuant to Section 19a-639c, C.G.S. Furthermore, the replacement expenditure of \$1,974,070 for the replacement equipment is less than the original cost of the equipment to be replaced, plus an increase of ten percent for each twelve-month period that has elapsed since the CHHC's original CON authorization date of August 29, 1989 under Docket Number 89-533.

Based on the foregoing Findings and Rationale, OHCA has determined that the Yale-New Haven Hospital's request for a waiver of CON requirements for replacement equipment to replace the existing Linear Accelerator with a Linear Accelerator capable of performing Stereotactic Radiosurgery (SRS), Intensity Modulated Radiation Therapy (IMRT) and Image Guided Radiotherapy (IGRT) at 20 York Street in New Haven, Connecticut, at a total capital expenditure of \$2,796,851, meets the requirements for waiver of the CON process pursuant to Section 19a-639c, C.G.S., and is hereby GRANTED.

Order

Yale-New Haven Hospital ("Hospital") is hereby authorized to replace its existing Linear Accelerator laboratory with a Linear Accelerator capable of performing Stereotactic Radiosurgery (SRS), Intensity Modulated Radiation Therapy (IMRT) and Image Guided Radiotherapy (IGRT) at 20 York Street in New Haven, Connecticut, at a total capital expenditure of \$2,522,281, subject to the following conditions:

- 1. This authorization shall expire on April 3, 2007. Should the Hospital's Linear Accelerator 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 expenditure of \$2,796,851. 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.
- 3. This authorization requires the removal of the Hospital's existing Linear Accelerator for certain disposition, such as sale or salvage, outside of and unrelated to the Hospital's various service provider locations. Furthermore, the Hospital will provide evidence to OHCA of the disposition of the existing Linear Accelerator to be replaced by no later than six months after the replacement Linear Accelerator has become operational.

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

April 3, 2006

Signed by Cristine A. Vogel Commissioner

CAV:tf