



Office of Health Care Access Certificate of Need Application

Final Decision

Applicant: The Harold Leever Regional Cancer Center

Docket Number: 08-31111-WVR

Project Title: Request to Waive CON Requirements for the Replacement of Two Linear Accelerators

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

Filing Date: February 27, 2008

Hearing: Waived

Decision Date: March 26, 2008

Staff: Laurie K. Greci

Project Description: The Harold Leever Regional Cancer Center requests a waiver of Certificate of Need (“CON”) requirements for replacement equipment for the purpose of replacing its two existing linear accelerators in Waterbury, at a total capital cost of \$3,850,000.

Nature of Proceedings: On February 27, 2008, the Office of Health Care Access (“OHCA”) received the completed waiver of Certificate of Need (“CON”) request for replacement equipment from The Harold Leever Regional Cancer Center (“Center”). The Center proposes to replace its two existing linear accelerators in Waterbury, at a total capital expenditure of \$3,850,000. The Center 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. The Harold Leever Regional Cancer Center (“Center”), a not-for-profit corporation, is a joint venture of Saint Mary’s Hospital and Waterbury Hospital. The Center is located at 1075 Chase Parkway. *(February 27, 2008, CON Waiver Form 2040, page 1)*
2. On June 5, 2001 the Office of Health Care Access (“OHCA”) authorized the establishment of the Center under Docket Number 00-562. The Center was authorized to include in its two-story building two linear accelerator vaults. *(June 5, 2001, Final Decision for Docket Number 00-562, page 4)*
3. The Center purchased two Varian 2199 SCX linear accelerators in October 2002 for \$1.1 million each. *(February 27, 2008, CON Waiver Form 2040, page 3)*
4. The Center is requesting a waiver of CON requirements for the purpose of replacing its two existing Varian 2100 SCX linear accelerators with two Elekta Synergy linear accelerators. *(February 27, 2008, CON Waiver Form 2040, page 3)*
5. The Center will use the existing linear accelerators as trade-ins to offset the acquisition cost of the two replacements. *(February 27, 2008, CON Waiver Form 2040, page 3)*
6. 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.)*
7. The Center states that the existing linear accelerators need to be replaced for the following reasons:
 - a) The technology available in the market has changed substantially since the original equipment was acquired six years ago;
 - b) Patients are currently imaged in one location and then moved to receive treatment at a different location and time.
(February 27, 2008, CON Waiver Form 2040, pages 5 and 6)
8. The Center states the new linear accelerators will provide the following advantages:
 - a) The ability of the Center to provide three-dimensional conformal and Intensity Modulated, external beam radiation therapy¹;
 - b) The equipment will incorporate cone beam computed tomography for real time imaging;
 - c) The equipment has the capability to perform stereotactic radiosurgery. This technique treats tumors with a precise delivery of a high dose of radiation in 1 to 5 days, rather than the normal 4 to 6 week course.

¹ Also commonly referred to as IMRT.

- d) The equipment will aid in minimizing the side effects of radiation therapy by reducing the margins previously set to account for uncertainties of target dimension, location, and movement.

(February 4, 2008, CON Waiver Form 2040, pages 5 and 6)

9. The total capital expenditure for the replacement project is \$3,850,000, which consists of the following components:

Item	Cost	Total
Two Elekta Synergy linear accelerators IMPAC Medical System connectivity kit	\$1,800,000 per unit	\$3,600,000
Renovations to accommodate installation of the new equipment	\$250,000	250,000
Grand Total		\$3,850,000

(February 4, 2008, CON Waiver Form 2040, page 3)

10. The capital expenditure of \$1,800,000 for each linear accelerator 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. *(February 27, 2008, CON Waiver Form 2040, page 3)*
11. The Center will fund the proposal through its equity funds. *(February 17, 2008, CON Waiver Form 2040, page 4)*
12. The Center proposes to remove the first existing linear accelerator and have the existing vault renovated to accommodate the first new linear accelerator. Within 4 to 5 months after the removal of the first existing linear accelerator, the Center anticipates that the first new linear accelerator will be operational. After a 4 to 6 week transition period, the second existing linear accelerator will be removed, required renovations performed and the second new linear accelerator installed. *(March 20, 2008, Completeness Response, page 1)*
13. Under the Center's proposal, the two new linear accelerators will be installed and operational by March 2009. *(March 20, 2008, Completeness Response, page 1)*
14. The replacement equipment will serve the Center's existing patient population and with no anticipated changes in the payer mix due to the proposal. *(February 4, 2008, CON Waiver Form 2040, page 6)*

Rationale

The Harold Leever Regional Cancer Center (“Center”) is requesting a waiver of Certificate of Need (“CON”) requirements for replacement equipment, pursuant to Section 19a-639c, C.G.S. The Center is seeking to replace its two existing linear accelerators.

The Center indicated that the two linear accelerators need to be replaced, as the existing equipment is not able to provide the technology available in the market today. Also, patients are currently imaged in one location and then must be moved to receive their radiation treatment at a different location and time. With the new linear accelerators, the Center will be able to provide three-dimensional conformal and Intensity Modulated external beam radiation therapy. The new equipment will incorporate cone beam computed tomography for real time imaging allowing for the performance of stereotactic radiosurgery. The stereotactic radiosurgery technique treats tumors with a precise delivery of a high dose of radiation in 1 to 5 days, rather than the customary 4 to 6 week course. The equipment will aid in minimizing the side effects of radiation therapy by reducing the margins previously set to account for uncertainties of target dimension, location, and movement.

The capital expenditure required to replace each linear accelerator 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 Center will fund the replacement project through its equity funds.

Order

Based on the foregoing Findings and Rationale, OHCA has determined that The Harold Leever Regional Cancer Center's ("Center") request for a waiver of CON requirements for replacement equipment in order to replace its two existing linear accelerators with a total capital cost of \$3,850,000 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 September 26, 2009. Should the Center's replacement project not be completed by that date, the Center must seek further approval from OHCA to complete the project beyond that date.
2. The Center shall not exceed the approved total capital cost of \$3,850,000 for two new linear accelerators, the IMAC Medical System, and the required renovations. In the event that the Center learns of potential cost increases or expects that final project costs will exceed those approved, the Center shall notify OHCA.
3. With respect to the acquisition of the two new linear accelerators, the Center shall notify OHCA regarding the following information in writing by no later than two months after the respective equipment becomes operational:
 - a) The name of the manufacturer;
 - b) The model name and description of the linear accelerator; and
 - c) The initial date of the operation of the linear accelerator; and
4. This authorization requires the removal of each existing linear accelerator for certain disposition, such as sale or salvage, outside of and unrelated to the Center's Connecticut service locations. Furthermore, the Center shall provide evidence to OHCA of the disposition of each existing linear accelerator to be replaced by no later than six months after each respective linear accelerator has become operational.
5. Should the Center propose any change in its proposal to replace the two linear accelerators, the Center shall file with OHCA a Certificate of Need Determination Request regarding the proposed service change.

Should the Center 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, 2008

Date

CAV:lkq

Cristine A. Vogel
Commissioner