



Office of Health Care Access Certificate of Need Application

Final Decision

Applicant: Saint Francis Hospital and Medical Center

Docket Number: 07-31048-WVR

Project Title: Request to Waive CON Requirements for the Replacement of an Existing 18 MEV 2300 Linear Accelerator

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

Filing Date: October 4, 2007

Hearing: Waived

Decision Date: October 29, 2007

Staff: Diane Duran

Project Description Saint Francis Hospital and Medical Center requests a waiver of Certificate of Need (“CON”) requirements for replacement equipment for the purpose of replacing an existing linear accelerator, at a total capital cost of \$2,489,523.

Nature of Proceedings: On October 4, 2007, the Office of Health Care Access (“OHCA”) received the waiver of Certificate of Need (“CON”) request for replacement equipment from Saint Francis Hospital and Medical Center (“Hospital”). The Hospital proposes to replace its existing linear accelerator, at a total capital cost of \$2,489,523. 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 August 15, 1991, in a Final Decision under Docket Number: 91-506, Saint Francis Hospital and Medical Center, (“Hospital”) received Certificate of Need (“CON”) authorization from the Commission on Hospital’s and Health Care (“CHHC”), predecessor to the Office on Health Care Assess (“OHCA”), for the initial price acquisition and operation of a linear accelerator, at a capital expenditure of \$1,101,051. *(October 4, 2007, CON Waiver Form 2040, page 2, and October 26, 2007, Additional Responses, and August 15, 1991, Commission on Hospital’s and Health Care, Final Decision, Docket Number: 91-506)*
2. The Hospital is requesting a waiver of CON requirements for the purpose of replacing an existing 18MEV 2300 Linear Accelerator manufactured by Varian Clinac iX, acquired by the Hospital, which was authorized by the CHHC, predecessor to the OHCA, through a Final Decision approved under Docket Number: 91-506. *(October 4, 2007, CON Waiver Form 2040, pages 2 & 3 and August 15, 1991, Commission on Hospital’s and Health Care, Final Decision, Docket Number: 91-506)*
3. 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.)*
4. The Hospital plans to acquire and operate a Varian Clinac iX, 18 MEV 2300 linear accelerator as its replacement equipment currently located on the first floor of its Cancer Center called Saint Francis/Mount Sinai Regional Cancer Center (“SFMSRCC”) of the Hospital’s Radiology Therapy Department. *(October 4, 2007, CON Waiver Form 2040, pages 3, 4 & 6 and Vendor Quotation, page 2)*
5. SFMSRCC houses the Hospital’s two linear accelerators in the radiation therapy department. *(October 4, 2007, CON Waiver Form 2040, page 4 and August 15, 1991, Commission on Hospital’s and Health Care, Final Decision, Docket Number: 91-506)*
6. The Hospital states the existing linear accelerator needs to be replaced for the following reasons: *(October 4, 2007, CON Waiver Form 2040, page 5)*
 - The equipment is over 15 years old and has exceeded its useful life for present day Hospital use;
 - Increasing breakdowns caused by a cracked waveguide;
 - Parts for the existing system have become difficult, if not impossible, to obtain;
 - Out of service for 203 hours in the last two years affecting 425 visits to reschedule; and
 - Radiation therapy equipment is operating more at its capacity per year.

7. The Hospital's two existing linear accelerators currently treat approximately 725 new patients per year or approximately 363 new patients per machine. This equates to the Hospital's existing radiation therapy equipment operating at approximately 113% of capacity. *(October 4, 2007, CON Waiver Form 2040, page 4)*
8. According to the Hospital's the new linear accelerator will enhance the delivery of radiation therapy treatment as follow: *(October 4, 2007, CON Waiver Form 2040, pages 5 and 6)*
 - Enhances treatment accuracy;
 - Improve field verification of the tumor; and
 - Improve capabilities to treat the smallest of lesions.
9. The total capital cost for the replacement project is \$2,489,523, which consists of the following components: *(October 4, 2007, CON Waiver Form 2040, page 3)*
 - \$2,189,523 the purchase price of the replacement linear accelerator equipment; and
 - \$300,000 for renovation work associated with the installation of the new equipment.
10. The capital cost of \$2,189,523, for the replacement linear accelerator 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. *(October 4, 2007, CON Waiver Form 2040, pages 2 and 3)*
11. The Hospital will fund the proposal through their equity. *(October 4, 2007, CON Waiver Form 2040, page 3)*
12. The Hospital intends to begin operating the new linear accelerator six months after CON approval. *(October 4, 2007, CON Waiver Form 2040, page 2)*
13. The replacement linear accelerator will serve the Hospital's existing patient population and there is no anticipated changes in the payer mix due to the proposal. *(October 4, 2007, CON Waiver Form 2040, pages 2 and 7)*

Rationale

Saint Francis Hospital and Medical Center (“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 an existing linear accelerator and to undertake renovations to accommodate the new equipment.

The Hospital indicates that the existing linear accelerator needs to be replaced as the existing system is 15 years old and has exceeded its useful life for present day Hospital use. Additionally, the current linear accelerator has increasing breakdowns and parts for the existing system are difficult to obtain. It has been out of service for 203 hours in the last two years affecting 425 visits to reschedule. The Hospital states that the proposed linear accelerator will enhance the delivery of radiation therapy treatment and improve field verification of the tumor and capabilities to treat the smallest of lesions. The replacement equipment will also enhance treatment accuracy.

The capital cost for the proposed replacement linear accelerator equipment is \$2,189,523, 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 funded depreciation.

Order

Based on the foregoing Findings and Rationale, OHCA has determined that Saint Francis Hospital and Medical Center’s request for a waiver of CON requirements for replacement equipment in order to replace an existing linear accelerator, at a total capital cost of \$2,489,523, 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 October 29, 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. The Hospital shall not exceed the approved capital cost of \$2,489,523. 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. With respect to the acquisition of the new linear accelerator, the Hospital shall notify OHCA regarding the following information in writing by no later than one month 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 linear accelerator 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 linear accelerator to be replaced by no later than six months after the replacement system has become operational.
5. Should the Hospital propose any change in the radiation therapy 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 October 29, 2007

Date

Cristine A. Vogel
Commissioner

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