



Office of Health Care Access Certificate of Need Application

Final Decision

Applicant: Saint Francis Hospital and Medical Center

Docket Number: 08-31129-WVR

Project Title: Request to Waive CON Requirements for the Replacement of the Existing Linear Accelerator

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

Filing Date: June 13, 2008

Decision Date: June 13, 2008

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 its existing linear accelerator equipment in Hartford, at a total capital cost of \$2,706,538.

Nature of Proceedings: On June 13, 2008, the Office of Health Care Access (“OHCA”) received the completed waiver of Certificate of Need (“CON”) request for replacement equipment from Saint Francis Hospital and Medical Center (“Hospital”). The Hospital proposes to replace its linear accelerator equipment, at a total capital cost of \$2,706,538.

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. Saint Francis Hospital and Medical Center (“Hospital”) is an acute care hospital located at 114 Woodland Street in Hartford, Connecticut. *(May 29, 2008, CON Waiver Form 2040, page 1)*
2. On August 15, 1991, in an Agreed Settlement under the Docket Number 91-506, Saint Francis Hospital and Medical Center (“Hospital”), and Mount Sinai Hospital (“MSH”), both “Co-Applicants”, received Certificate of Need (“CON”) authorization from the Commission on Hospitals and Health Care (“CHHC”), predecessor to the Office of Health Care Access (“OHCA”) for the outpatient portion of the medical oncology/hematology departments of both the Hospital and MSH to be combined and relocated to the new replacement Cancer Center, and that in addition, all radiation therapy candidates at MSH be directed to the Cancer Center located at the Hospital on Woodland Street in Hartford, at a total capital expenditure of \$11,535,000. *(May 29, 2008, CON Waiver Form 2040, pages 2 & 3 and August 15, 1991, Agreed Settlement, Docket Number: 91-506, pages 2 and 4)*
3. Additionally, on August 15, 1991, in an Agreed Settlement under the Docket Number 91-506, the Hospital was approved to acquire and operate an 18 MEV high energy linear accelerator, at a capital cost of \$1,101,051 and a 6 MEV low energy linear accelerator, at a capital cost of \$525,472 located on Woodland Street in Hartford. *(May 29, 2008, CON Waiver Form 2040, page 2, August 15, 1991, Agreed Settlement, Docket Number: 91-506, pages 2)*
4. On October 29, 2007, in the Final Decision under the Docket Number 07-31048-WVR, the Hospital was authorized by OHCA, to replace its first 18 MEV high energy linear accelerator as its replacement equipment located on the first floor of its Cancer Center in Hartford, at a capital cost of \$2,189,523. *(October 29, 2007, Office of Health Care Access, Final Decision, Docket Number: 07-31048-WVR, page 2)*
5. The Hospital houses two linear accelerators in the radiation therapy department located at 114 Woodland Street in Hartford. *(May 29, 2008, CON Waiver Form 2040, pages 2 and 5)*
6. The Hospital is requesting a waiver of CON requirements in order to replace its second existing Varian, 6 MEV low energy linear accelerator authorized by OHCA. *(May 29, 2008, CON Waiver Form 2040, page 3)*
7. 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.)*

8. The Hospital plans to acquire and operate a Varian Clinac iX Silhouette, 6C linear accelerator, as its replacement equipment located at 114 Woodland Street in Hartford. *(May 29, 2008, CON Waiver Form 2040, page 3)*
9. The Hospital indicates that its current operating hours for the linear accelerator service are Monday through Friday, 6 a.m. – 7 p.m., since January 2008. *(May 29, 2008, CON Waiver Form 2040, page 5 and June 13, 2008, Additional Responses)*
10. The Hospital states that the existing linear accelerator equipment needs to be replaced for the following reasons: *(May 29, 2008, CON Waiver Form 2040, page 5)*
- The equipment is over 15 years old and has exceeded its useful life;
 - Increasing breakdowns;
 - Replacement parts for the existing system have become difficult, if not impossible, to obtain;
 - Out of service for 46.02 hours in FY 2007 affecting 94 visits to reschedule; and
 - The difficulty to schedule additional cases on the one remaining linear accelerator given the high volume.
11. According to the Hospital the new linear accelerator will enhance the delivery of radiation therapy treatment as follows: *(May 29, 2008, CON Waiver Form 2040, pages 5 and 6)*
- Enhances on board imaging system to render optimal tumor views while maintaining coincidence between imaging and treatment isocenters;
 - Enhances treatment accuracy;
 - Enhances respiratory gating and fluoroscopic field verification of the tumor;
 - Improves multileaf collimators capabilities to treat the smallest of lesions;
 - Improves full motion robotics capabilities; and
 - Enhances the treatment of cancer patients.

12. The Hospital states that the volume of the existing linear accelerator is as follows:

<u>Fiscal Year</u>	<u>Linear Accelerator Volume</u>
2005	6,883
2006	6,766
2007	6,706
2008*	6,376

Note: * The increased treatment of volume for FY 2008 through April was due to the first removal of the 18 MEV linear accelerator.

(June 13, 2008, Additional Responses)

13. The Hospital states that on December 27, 2007, the radiation therapy department started transferring patients from the first, 18 MEV linear accelerator to the existing 6 MEV linear accelerator, on the date above there were 35 patients a day being seen on the first linear accelerator. Additionally, the patients were transferred over the next two weeks and the process was completed on January 3, 2008. *(June 13, 2008, Additional Responses)*

14. The total capital expenditure for the replacement project is \$2,706,538, which consists of the following components:
 - a) \$2,231,538 for the associated medical equipment purchase; and
 - b) \$475,000 for construction and renovation work associated with the installation of the new equipment.
(May 29, 2008, CON Waiver Form 2040, page 3 and Attachment III)

15. The capital cost of \$2,231,538 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. *(May 29, 2008, CON Waiver Form 2040, page 2)*

16. The Hospital will fund the proposal through its equity funds. *(May 29, 2008, CON Waiver Form 2040, page 4)*

17. The Hospital intends to begin operating the new linear accelerator six months after CON approval. *(May 29, 2008, CON Waiver Form 2040, page 2)*

18. The Hospital states that its proposed change of operating hours for the linear accelerator service is to return to its normal operating hours upon replacement of the linear accelerator which are Monday through Friday, 8 a.m. – 4:30 p.m. *(May 29, 2008, CON Waiver Form 2040, page 4)*

19. The replacement linear accelerator equipment will serve the Hospital's existing patient population and with no anticipated changes in the payer mix due to the proposal. *(May 29, 2008, CON Waiver Form 2040, page 5)*

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, C.G.S. The Hospital is seeking to replace its second existing linear accelerator in Hartford and to undertake renovations to accommodate the new equipment. The new linear accelerator replacement equipment will be located at 114 Woodland Street in Hartford.

The Hospital is requesting that the second existing linear accelerator be replaced as the existing equipment is over 15 years old and has exceeded its useful life. The equipment cannot be maintained due to increasing breakdowns. The Hospital indicates that the replacement parts for the existing system have become difficult, if not impossible, to obtain. The linear accelerator has been out of service for 46.02 hours in FY 2007 affecting 94 visits to reschedule. It has caused difficulty to schedule additional cases on the one remaining linear accelerator given the high volume. The new linear accelerator will enhance board imaging system to render optimal tumor views while maintaining coincidence between imaging and treatment isocenters. The delivery of radiation therapy treatment and treatment accuracy will also be enhanced.

The capital cost for the proposed replacement linear accelerator equipment is \$2,231,538 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 its equity funds.

Order

Based on the foregoing Findings and Rationale, OHCA has determined that the Saint Francis Hospital and Medical Center request for a waiver of CON requirements for replacement equipment in order to replace its existing linear accelerator in Hartford, at a total capital cost of \$2,706,538, 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 June 13, 2009. 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 total capital cost of \$2,706,538. 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 linear accelerator, 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 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 linear accelerator 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 June 13, 2008

Date

CAV: dd

Cristine A. Vogel
Commissioner