



Office of Health Care Access Certificate of Need Application

Final Decision

Applicant: Danbury Hospital

Docket Number: 06-30659-WVR

Project Title: Request to Waive CON Requirements for the Replacement of Danbury Hospital's Linear Accelerators

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

Filing Date: April 3, 2006

Hearing: Waived

Decision Date: April 6, 2006

Staff Assigned: Kim Martone

Project Description: Danbury Hospital ("Hospital") requests a waiver of Certificate of Need ("CON") requirements for replacement equipment in order to replace its two existing Linear Accelerators with replacement Linear Accelerators capable of performing Stereotactic Radiosurgery (SRS), Intensity Modulated Radiation Therapy (IMRT) and Image Guided Radiotherapy (IGRT), at a total capital expenditure of \$5,396,777.

Nature of Proceedings: On December 21, 2005 with additional information on April 3, 2006, the Office of Health Care Access ("OHCA") received the waiver of CON requirements request for replacement equipment from Danbury Hospital to replace its two existing Linear Accelerators, at a total capital expenditure of \$5,396,777. 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. Danbury Hospital, Inc. (“Hospital”) is an acute care general hospital located at 24 Hospital Avenue in Danbury, Connecticut. *(December 21, 2005 Letter of Intent/Waiver Form 2030, Project Description Page 12)*
2. Danbury 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 two existing Linear Accelerators, at a total capital expenditure of \$5,396,777. *(December 21, 2005 Letter of Intent/Waiver Form 2030, Page 2)*
3. On February 29, 1984, 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 83-538 for the purchase of one of the existing Linear Accelerators, at a capital expenditure of \$2,218,380. The Hospital was approved for a replacement of this Linear Accelerator on August 28, 2002 under Docket Number 02-1505, at a capital expenditure of \$621,136. On July 30, 1992, the Hospital received CON authorization under Docket Number 92-511CRF for the acquisition of a second Linear Accelerator, at a fair market value of \$1,123,370. *(February 29, 1984 and July 30, 1992 Agreed Settlements, Danbury Hospital, Docket Numbers 83-538 and 92-511CRF)*
4. The Hospital proposes to replace its existing two linear accelerators with two state-of-the-art Varian EX, and iX linear accelerators with IMRT, SRS and IGRT capabilities. Consistent with the replacement of the linear accelerators is the concurrent replacement of the Hospital’s record and verify system. Construction upgrades to the two existing treatment rooms are also included in the Hospital’s proposal in order to meet today’s standards for safety. *(December 21, 2005 Letter of Intent Waiver Form 2030, Project Description, Page 10)*
5. Both machines will have IMRT capability used to increase radiation dose to the target tissue, maximizing cure, while decreasing dose and damage to surrounding tissues thereby minimizing side effects. One of the replacement accelerators will be equipped with IGRT respiratory gating and SRS allowing further daily localization of target tissues, sparing of adjacent healthy cells and permitting both single fraction and fractionated stereotactic radiotherapy capabilities. *(December 21, 2005 Letter of Intent Waiver Form 2030, Project Description, Page 10)*
6. The Hospital stated that the existing two Linear Accelerators have been subject to multiple breakdowns and continued maintenance issues, which frequently disrupt patients’ treatment schedules. During Fiscal Year 2005, twenty-nine down days were documented interrupting hundreds of patient treatments. *(December 21, 2005 Letter of Intent Waiver Form 2030, Project Description, Page 9)*

7. The Hospital's replacement proposal is based on the following:
 - Ages of the existing equipment;
 - Increasing periods of down time;
 - Difficulty in maintaining the equipment; and
 - Limitations on replacement parts.

(April 3, 2006, Additional information received)
8. The total capital expenditure for the replacement Linear Accelerator proposal is \$5,396,777 which includes \$3,275,182 for the replacement Linear Accelerators and related software, \$366,544 for non-medical equipment and other and \$1,755,051 in construction upgrades. *(December 21, 2005 Letter of Intent/Waiver Form 2030, Page 3)*
9. The Hospital will fund the total capital expenditure of \$5,396,777 for the replacement equipment proposal through an equity contribution. *(December 21, 2005 Letter of Intent/Waiver Form 2030, Page 4)*
10. The replacement expenditure of \$1,880,792 for the Varian Clinac iX and \$924,400 for the Varian Clinac EX-d are each below the \$2,000,000 threshold for determining eligibility for a waiver of CON requirements for each piece of replacement equipment pursuant to Section 19a-639c, C.G.S. *(April 3, 2006, Additional information received)*
11. The replacement expenditure of \$1,880,792 for the Varian Clinac iX and \$924,400 for the Varian Clinac EX-d are each 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 dates on August 28, 2002 under Docket Number 02-1505 and on July 30, 1992 under Docket Number 92-511CRF. *(December 21, 2005 Letter of Intent/Waiver Form 2030, Page 5 and April 3, 2006, Additional information received)*
12. The Hospital anticipates commencing the replacement equipment project upon OHCA Approval. *(December 21, 2005 Letter of Intent/Waiver Form 2030, Page 2)*

Rationale

Danbury 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 two existing Linear Accelerators at a total capital expenditure of \$5,396,777. On February 29, 1984, 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 83-538 for the purchase of one of the existing Linear Accelerators, at a capital expenditure of \$2,218,380. The Hospital was approved for a replacement of this Linear Accelerator on August 28, 2002 under Docket Number 02-1505, at a capital expenditure of \$621,136. On July 30, 1992, the Hospital received CON authorization under Docket Number 92-511CRF for the acquisition of a second Linear Accelerator, at a fair market value of \$1,123,370.

The Hospital proposes to replace its existing two linear accelerators with two state-of-the-art Varian EX, and iX linear accelerators with IMRT, SRS and IGRT capabilities. Consistent with the replacement of the linear accelerators is the concurrent replacement of the Hospital’s record and verify system. Construction upgrades to the two existing treatment rooms are also included in the Hospital’s proposal in order to meet today’s standards for safety. Both machines will have IMRT capability used to increase radiation dose to the target tissue, maximizing cure, while decreasing dose and damage to surrounding tissues thereby minimizing side effects. One of the replacement accelerators will be equipped with IGRT respiratory gating and SRS allowing further daily localization of target tissues, sparing of adjacent healthy cells and permitting both single fraction and fractionated stereotactic radiotherapy capabilities.

The Hospital stated that the existing two Linear Accelerators have been subject to multiple breakdowns and continued maintenance issues, which frequently disrupt patients’ treatment schedules. During Fiscal Year 2005, twenty-nine down days were documented interrupting hundreds of patient treatments. The Hospital’s replacement proposal is based on the ages of the existing equipment; increasing periods of down time; difficulty in maintaining the equipment; and limitations on replacement parts.

The total capital expenditure for the replacement Linear Accelerator proposal is \$5,396,777 which includes \$3,275,182 for the replacement Linear Accelerators and related software, \$366,544 for non-medical equipment and other and \$1,755,051 in construction upgrades. The Hospital will fund the total capital expenditure of \$5,396,777 for the replacement equipment proposal through an equity contribution.

The replacement expenditure of \$1,880,792 for the Varian Clinac iX and \$924,400 for the Varian Clinac EX-d are each below the \$2,000,000 threshold for determining eligibility for a waiver of CON requirements for each piece of replacement equipment pursuant to Section 19a-639c, C.G.S. Furthermore, the replacement expenditure of \$1,880,792 for the Varian Clinac iX and \$924,400 for the Varian Clinac EX-d are each 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 dates on August 28, 2002 under Docket Number 02-1505 and on July 30, 1992 under Docket Number 92-511CRF.

Based on the foregoing Findings and Rationale, OHCA has determined that Danbury Hospital's request for a waiver of CON requirements for replacement equipment to replace the existing two Linear Accelerators at 24 Hospital Avenue in Danbury, Connecticut, at a total capital expenditure of \$5,396,777, meets the requirements for waiver of the CON process pursuant to Section 19a-639c, C.G.S., and is hereby GRANTED.

Order

Danbury Hospital ("Hospital") is hereby authorized to replace its existing two Linear Accelerators at 24 Hospital Avenue in Danbury, Connecticut, at a total capital expenditure of \$5,396,777, subject to the following conditions:

1. This authorization shall expire on April 6, 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 \$5,396,777. 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 two Linear Accelerators 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 two Linear Accelerators 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 6, 2006

Signed by Cristine A. Vogel
Commissioner

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