

M. JODI RELL
GOVERNOR

STATE OF CONNECTICUT
OFFICE OF HEALTH CARE ACCESS

CRISTINE A. VOGEL
COMMISSIONER

May 5, 2009

IN THE MATTER OF:

A modification of a previous Certificate of
Need authorization as allowed by
Section 4-181a(b), Connecticut General Statutes

Notice of Modification Final Decision
Office of Health Care Access
Docket Number 09-30874-MDF

Greenwich Hospital

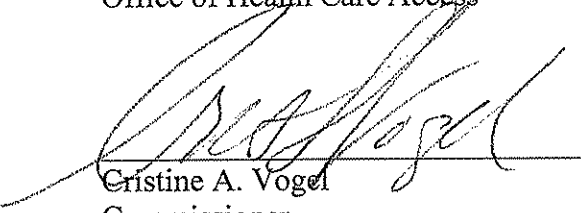
A request to modify Docket Number 06-
30874-CON

To: Ms. Nancy Hamson
Director of Planning
Greenwich Hospital
5 Perryridge Road
Greenwich, CT 06830

Dear Ms. Hamson:

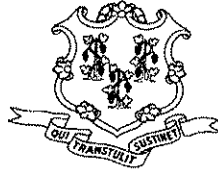
This letter will serve as notice of the Final Decision of the Office of Health Care Access in the above matter as provided by Section 4-181a(b), C.G.S. On May 5, 2009, this Modification was rendered as the revised order of the Office of Health Care Access. A copy of the Final Decision is attached hereto for your information.

By Order of the
Office of Health Care Access



Cristine A. Vogel
Commissioner

CAV:kr



Office of Health Care Access

A Modification of a Previously Authorized Certificate of Need

Applicant: Greenwich Hospital

Modification Docket Number: 09-30874-MDF

Modification Project Title: A request to modify a previous Certificate of Need authorization in order to revise the Order wording and allow the back up linear accelerator to be used on a regular basis for a limited selection of radiation therapy patients.

Original Project Docket Number and Title: Docket Number 06-30874-CON;
The Acquisition of a New Radiation Oncology Linear Accelerator and the Construction of a New Vault to Accommodate the Equipment

Statutory Reference: Sections 4-181a(b), Connecticut General Statutes

Filing Date: April 20, 2009

Decision Date: May 5, 2009

Staff: Karen Roberts

Project Description: Greenwich Hospital requests a modification of the Certificate of Need authorization under Docket Number 06-30874-CON in order to revise the Order wording and allow the back up linear accelerator to be used on a regular basis for a limited selection of radiation therapy patients.

Findings of Fact

1. On June 18, 2007, under Docket Number 06-30874-CON, the Office of Health Care Access (“OHCA”) granted a Certificate of Need (“CON”) pursuant to Section 19a-639 of the Connecticut General Statutes to Greenwich Hospital (“Hospital”) to acquire a new radiation oncology linear accelerator, construct a new vault to accommodate the new equipment, and retain the existing linear accelerator for back-up purposes, at a total capital expenditure of \$10,090,025. The location of this authorized project is the Hospital’s Bendheim Cancer Center at 77 LaFayette Place in Greenwich. On September 16, 2008, under Docket Number 08-30874-MDF, OHCA granted a modification of this Certificate of Need in order to extend the CON expiration date set forth in Condition #1 to March 30, 2010.
2. On April 20, 2009, the Hospital filed a request for modification of the CON order in order to revise the Order wording and allow the back up linear accelerator to be used on a regular basis for a limited selection of radiation therapy patients. The following information was provided in the Hospital’s modification request to explain the proposed change in the use of the back up unit:
 - a) The Hospital indicates that *“Since the original CON Final Decision, Greenwich Hospital has decided that in order to offer optimal patient care the Hospital should avail itself of the state of the art technology that recently became available on linear accelerators made by Varian Medical Systems. The new Varian Novalis TX linear accelerator that the Hospital plans to own¹ is equipped with a high definition 120 multi-leaf collimator (MLC) which can better shape the tumor dose using 64 central 2.5 mm wide computerized blades and 56 peripheral 5 mm blades.”*
 - b) The Hospital further indicates that *“90% of patients will benefit from the higher resolution MLC, but the maximum rectangular field size when utilizing the MLC is 40 X 22 cm.”* Therefore, the Hospital anticipates that there will be approximately 10% of patients that will *“require a larger field size and not need the HD MLC”*.
 - c) The Hospital identifies this limited selection of patients as including large breast patients that need an IMRT delivery, lymphoma patients that require large mantle fields or inverted Y field treating abdomen and pelvis, and large para-aortic fields for seminoma cancer patients.
 - d) The Hospital indicates that it *“would operate the two units with the same staff and run them sequentially and not concurrently.”*
3. The Hospital indicated in its original CON application that the new linear accelerator was to replace the existing unit and that the existing unit was to be maintained for back up purposes only. This is evidenced by the following statements from the Hospital’s CON application filing:

¹ As noted by OHCA in Finding of Fact #6 of the authorized Certificate of Need under Docket Number 06-30874-CON, the Hospital proposed *“to purchase a Varian High Energy Clinac iX linear accelerator that incorporates image guided radiation therapy (“IGRT”) capabilities.”* The acquisition of this particular equipment model was not specifically required in the CON Order or Conditions.

- a) On Page 2 of the CON application, the Hospital lists the new linear accelerator as a replacement.
 - b) On page 8 of the CON application, the Hospital states that *“The Linear Accelerator replacement will require a new poured concrete vault ...”*
 - c) On page 12 of the CON application, the Hospital states that *“The replacement of the radiation oncology linear accelerator at Greenwich Hospital will enable the delivery of state-of-the-art easily accessible, excellent quality care to oncology patients.”*
 - d) On page 18 of the CON application, the Hospital states that *“After construction is complete and the new radiation oncology linear accelerator is operational, the Hospital would discontinue use of the current radiation oncology linear accelerator except as a back-up during any downtime of the new radiation oncology linear accelerator.”*
 - e) On page 180 of the CON application, the Hospital states that *“As this is replacement equipment for a present service, the only new incremental revenue calculated will be the new component provided by this new technology which is the IGRT component.”*
 - f) On page 2 of the May 25, 2007 completeness responses, the Hospital states that *“The replacement of the current radiation oncology linear accelerator offering state of the art clinical care will increase volume”*
 - g) On page 6 of the May 25, 2007 completeness responses, the Hospital states that *“The staffing increases ... are not related to the radiation oncology linear accelerator replacement.”*
4. The Hospital is not requesting an increase in the authorized capital expenditure nor a further extension of the CON expiration date related to this modification request.

Discussion

OHCA has reviewed this request for a modification to a previously authorized CON and finds that the relationship of the CON authorized under Docket Number 06-30874-CON, to Section 19a-637, C.G.S., is not significantly altered by this request for a modification under Docket Number 09-30874-MDF, as such request is specifically clarified in the following revised CON Order. It is the Hospital's intent to complete the project as reviewed and authorized by OHCA which is to acquire and operate a new state of the art linear accelerator with IGRT capabilities for the Hospital's radiation therapy patient base. This new unit had been represented in the original CON application to be a replacement unit as evidenced by Finding of Fact #4 above and, as such, OHCA authorized the retention of the existing unit for only back up purposes and not a secondary full service unit.

In reviewing the Hospital's modification request, OHCA finds that the new unit will still replace the existing unit for a vast majority of the Hospital's radiation therapy patient base and that the existing unit will be retained as a back up unit but could also be used for a limited number of patients whose radiation therapy treatment requires a larger field size. The Hospital estimates that this may total approximately 10% of the radiation therapy patient population. OHCA finds that this change in the use of the back up unit does not significantly impact the authorized project scope and does not impact the authorized capital expenditure or the project implementation timeframe. The new unit will be the Hospital's primary unit for service provision and the back up unit will be specifically limited in its use. OHCA finds that the Hospital has sufficiently explained the reasoning for its request and OHCA concludes that the request for modification is reasonable.

Order

Based on the above discussion and the reasons provided in the Hospital's modification request, OHCA hereby grants the request and modifies the CON authorized under Docket Number 06-30874-CON, as previously modified by Docket Number 08-30874-MDF. The wording of the Certificate of Need Order issued under Docket Number 06-30874-CON is revised as follows:

Greenwich Hospital ("Hospital") is hereby authorized to acquire and operate a new radiation oncology linear accelerator, construct a new vault to accommodate the new equipment, and retain the existing linear accelerator as a back up unit to the new equipment during downtime on the new equipment and for specific and limited purposes, at a total capital expenditure of \$10,090,025, subject to the following conditions:

OHCA further modifies this Certificate of Need authorization to add the following conditions:

5. In authorizing this project, OHCA considers the new linear accelerator to be a full-service replacement of the existing unit. The existing unit may be retained on site for the following specific and limited purposes only:
 1. As a back up unit to the new unit during scheduled and unscheduled downtime; and
 2. As a back up unit for patients who cannot be appropriately served on the new unit. This would specifically be limited to radiation therapy patients requiring a larger field size. Such patients would include large breast patients that need an IMRT delivery, lymphoma patients that require large mantle fields or inverted Y field treating abdomen and pelvis, and large para-aortic fields for seminoma cancer patients.
6. As the Hospital proposed the project as a replacement project, and such proposal was authorized by OHCA under Docket Number 06-30874-CON, the Hospital may not utilize 19a-639c in the future to seek to replace this back up/limited usage linear accelerator with a full service replacement linear accelerator.

All other conditions set forth in the CON authorization issued under Docket Number 06-30874-CON, as previously modified by Docket Number 08-30874-MDF, not further modified herein, will remain in full effect.

By Order of the
Office of Health Care Access


Cristine A. Vogel
Commissioner

5-5-09
Date

CAV/kr