



Office of Health Care Access

A Modification of Previously Authorized Certificate of Need

Applicant: Hospital of Saint Raphael

Modification Docket Number: 08-30450-MDF

Modification Project Title: A request to modify a previous Certificate of Need authorization to extend the CON expiration date and change the wording of Condition #3 of the CON Order

Original Project Docket Number and Title: Docket Number 05-30450-CON
McGivney Cancer Center Equipment Replacements and Upgrades, and Establishment of a Radiation Therapy Satellite Facility in Hamden, Connecticut.

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

Filing Date: August 25, 2008

Decision Date: September 10, 2008

Staff: Karen Roberts

Project Description: Hospital of Saint Raphael requests a modification of the Certificate of Need authorization under Docket Number 05-30450-CON, in order to extend the CON expiration date from June 1, 2008 to June 30, 2009 and revise the wording in Condition #3 of the CON Order.

Findings of Fact

1. On December 21, 2005, under Docket Number 05-30450-CON, the Office of Health Care Access (“OHCA”) granted a Certificate of Need (“CON”) pursuant to Sections 19a-638 and 19a-639 of the Connecticut General Statutes to Hospital of Saint Raphael (“Hospital”) to replace and upgrade radiation therapy equipment at its Father Michael J. McGivney Center for Cancer Care and to establish a radiation therapy satellite facility in Hamden, at a total capital expenditure of \$12,207,916.

2. Conditions #1 and #3 of the CON Order under Docket Number 05-30450-CON state the following:

“1. This authorization shall expire June 1, 2008. Should the Hospital’s radiation therapy project not be completed by that date, the Hospital must seek further approval from OHCA to complete the project beyond that date.”

“3. The Hospital is authorized to acquire the following medical equipment systems and perform the following medical equipment upgrades as identified by each project component:

- a. McGivney Center: Two Replacement Acquisitions and Two System Upgrades:*
- i. Replacing an older unit for a new TomoTherapy Hi-Art linear accelerator system;*
 - ii. Replacing an older unit for a new Varian Clinac iX linear accelerator system;*
 - iii. Multilease¹ collimator upgrade to the existing retrofitted linear accelerator; and*
 - iv. Phillips computed tomography scanner upgrade from 1 to 16 slice capability.*
- b. Hamden Outpatient Satellite Facility: Two Equipment Acquisitions*
- i. A new Varian Clinac iX linear accelerator system; and*
 - ii. A refurbished Siemens Volume Zoom 8 slice CT scanner.”*

3. On May 30, 2008, the Hospital notified OHCA of its request to extend the CON expiration date and on June 3, 2008, OHCA received the Hospital’s Form 2050 filing of a request to modify the CON Order to extend the CON expiration date from June 1, 2008 to June 30, 2010 and to change the specific wording in Condition #3 of the CON Order. Additional information was received from the Hospital on July 7, 2008 and August 25, 2008. In its August 25, 2008 submission, the Hospital revised its request from a two year extension to a one year extension from June 1, 2008 to June 30, 2009.

4. The Hospital requests that Condition #3 be revised to the following wording:

3. The Hospital is authorized to acquire the following medical equipment systems and perform the following medical equipment upgrades as identified by each project component:

- a. McGivney Center: Two Replacement Acquisitions and One System Upgrade:
- i. Replacing an older unit for a new TomoTherapy Hi-Art linear accelerator system;
 - ii. Replacing an older unit for a new Elekta Synergy linear accelerator system; and
 - iii. Phillips computed tomography scanner upgrade from 1 to 16 slice capability.
- b. Hamden Outpatient Satellite Facility: Two Equipment Acquisitions
- i. A new Elekta Synergy linear accelerator system; and
 - ii. A new Siemens Volume Zoom Wide Bore 24 slice CT scanner.

¹ Note that “Multilease” as quoted here should say Multi-Leaf.

5. This proposal will not result in an increase the authorized total capital expenditure.
6. One of the requested wording changes to Condition #3 is to change the equipment vendor from Varian to Elekta for the authorized linear accelerator at the Hamden location and one of the authorized linear accelerators at the McGivney Center. Subsequent to the initial CON authorization, the Hospital evaluated various linear accelerators vendors and found that Elekta, Inc. had significantly improved its linear accelerator product. The Hospital states that this product is superior to the Varian model with regard to patient imaging. In addition, Elekta is now the owner of the company and technology which the Hospital uses for developing patient radiation treatment plans. Choosing Elekta as the vendor instead of Varian for these two linear accelerators will allow the Hospital to better integrate the treatment planning system with their linear accelerators.
7. Another of the requested wording changes to Condition #3 is to delete the reference to a multi-leaf collimator upgrade at the McGivney location. The Hospital has chosen not to go forward with the addition of a multi-leaf collimator as originally proposed. The Hospital states that IMRT² has not expanded significantly into other treatment areas such as breast, lung, and liver and that other treatment options, such as stereotactic radiosurgery, mammosite and brachytherapy have made the expansion of the IMRT capabilities beyond the new linear accelerators unnecessary.
8. Another of the requested wording changes to Condition #3 is to allow for a new 24 slice CT scanner as opposed to the refurbished 8 slice unit originally proposed and authorized for the Hamden location. The Hospital provides the following information regarding this change in project component:
 - a) Since the initial CON application and decision, the Hospital has determined that the refurbished unit could not be purchased. The Hospital states that *“After discussion with Philips and Siemens Medical, it was determined that neither Philips nor Siemens manufacture an eight slice large bore system.”*
 - b) A significant portion of the Hospital’s patient population require a large bore multi-slice CT scanner in order to support the need for a wide gantry to allow for proper positioning in simulations of lung and breast patients and quicker scan times for respiratory gating and improved targeting for 4-D planning.
 - c) The Hospital also states that *“there were no refurbished 16 slice Philips or 24 slice Siemens systems available in the market”* and that Phillips did not have a large bore multi-slice refurbished unit available. The smallest wide bore unit by Philips was a 16 slice unit for \$790,000 and the smallest wide bore unit by Siemens was 24-slice for \$600,000.
 - d) The Hospital has signed a contract in place for the 24-slice CT large bore scanner with Siemens. The anticipated deliver date is in late November or early December, 2008.

² IMRT is Intensity-Modulated Radiation Therapy.

9. The Hospital provides the following information regarding project implementation to date:
 - a) The replacement of one of the older linear accelerator at the McGivney Center with a new Elekta Linear Accelerator unit was completed in April 2007. The existing multi-leaf collimator was taken out of service in 2007 with the installation of this new Elekta unit.
 - b) The upgrade of the Philips CT scanner at the McGivney Center from 1 to 16 slices was completed in May of 2006.
 - c) A lease for physical space was entered into on April 15, 2008 with Twenty Eighty Limited Partnership for the Hamden satellite location.
 - d) The Hospital had received planning and zoning approval for special permit on April 29, 2008 as well as the building permit for this 2080 Whitney Avenue, Hamden construction project. The Hospital indicates that the interior tenant improvements were issued for construction by the architect on June 13, 2008 and will be submitted to the town of Hamden for "permit sets" immediately.
 - e) The project was significantly delayed beyond the originally planned timeframe due to delays encountered in obtaining the required zoning and construction permits from the City of Hamden and the State of Connecticut for the Hamden location. The State Traffic Commission and the Department of Transportation took more than nine months to address parking permit and right of way issues.
 - f) The Hospital has worked with their "*vendors and construction contractors to tighten this schedule*" and the Hospital anticipates that the Hamden Center will be operational no later than March 31, 2009.
 - g) The Hospital has spent and/or entered into non-lease commitments of \$5,763,674 to date. In addition, the fifteen year initial lease term carries a total base cost of \$3,023,614.
 - h) The Hospital has signed a contract with Elekta and rendered a deposit for the linear accelerators.

10. The replacement of an older linear accelerator with a new TomoTherapy Hi-Art linear accelerator system at the McGivney Center location has not occurred as yet. The Hospital plans to start decommissioning the older unit and begin installation of the new unit two months after the go live date for the Hamden Center. The Hospital indicates that this will allow patients being treated on the older unit to complete their treatments on the system without interruption.

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 05-30450-CON, to Section 19a-637, C.G.S., is not altered by this request for a modification under Docket Number 08-30450-MDF. It is the Hospital's intent to complete the project as reviewed and authorized by OHCA and the Hospital indicates that the remaining project implementation should be June 30, 2009. The additional time needed to complete the project will not result in a change to project scope or the authorized capital expenditure and the Hospital has sufficiently explained the barriers that have occurred which have prevented the Hospital from fully completing the authorized project in the timeframe previously authorized. OHCA also concludes that the requested wording changes to Condition #3 are fully explained and justified.

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 05-30450-CON.

Condition #1 of the previous authorization under Docket Number 05-30450-CON is modified as follows:

1. This authorization shall expire June 30, 2009. Should the Hospital's radiation therapy project not be completed by that date, the Hospital must seek further approval from OHCA to complete the project beyond that date.

Condition #3 of the previous authorization under Docket Number 05-30450-CON is modified as follows:

3. The Hospital is authorized to acquire the following medical equipment systems and perform the following medical equipment upgrades as identified by each project component:
 - a. McGivney Center: Two Replacement Acquisitions and One System Upgrade:
 - i. Replacing an older unit for a new TomoTherapy Hi-Art linear accelerator system;
 - ii. Replacing an older unit for a new Elekta Synergy linear accelerator system; and
 - iii. Phillips computed tomography scanner upgrade from 1 to 16 slice capability.
 - b. Hamden Outpatient Satellite Facility: Two Equipment Acquisitions
 - i. A new Elekta Synergy linear accelerator system; and
 - ii. A new Siemens Volume Zoom Wide Bore 24 slice CT scanner.

All other conditions set forth in the CON authorization issued under Docket Number 05-30450-CON, not modified herein, will remain in full effect.

By Order of the
Office of Health Care Access

Signed by Commissioner Vogel on September 10, 2008

Date

Cristine A. Vogel
Commissioner

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