



## Office Of Health Care Access Certificate of Need Application

### Final Decision

**Applicant:** Norwalk Hospital

**Docket Number:** 04-30245

**Project Title:** Acquire a Replacement Linear Accelerator with IMRT Technology

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

**Filing Date:** June 15, 2004

**Decision Date:** June 24, 2004

**Default Date:** September 13, 2004

**Staff Assigned:** Harold M. Oberg

**Project Description:** Norwalk Hospital (“Hospital”) proposes to acquire a replacement linear accelerator with Intensity Modulated Radiation Therapy (“IMRT”) technology, at a total capital expenditure of \$4,100,000. The Hospital plans to replace an existing linear accelerator currently located at the Hospital’s Whittingham Cancer Center that is now approximately fourteen years old and has outlived its useful file. The Hospital’s existing linear accelerator has a low energy beam, is not equipped with a multileaf collimator attachment, and is incapable of providing IMRT types of treatments.

**Nature of Proceedings:** On June 15, 2004, the Office of Health Care Access (“OHCA”) received a completed Certificate of Need (“CON”) application from Norwalk Hospital to acquire a replacement linear accelerator with IMRT technology, at a total capital expenditure of \$4,100,000. The Hospital is a health care facility or institution as defined by Section 19a-630 of the Connecticut General Statutes (“C.G.S.”).

On February 11, 2004, the Hospital was informed that a notice to the public regarding OHCA’s receipt of the Hospital’s Letter of Intent (“LOI”) to file its CON application would be published in *The Hour* of Norwalk pursuant to Section 19a-639, C.G.S. as amended by Section 1 of Public Act 03-17. OHCA received no comments from the public concerning the Hospital’s LOI or CON application.

OHCA's authority to review and approve, modify or deny the CON application is established by Section 19a-639, 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

### Clear Public Need

#### Impact of the Proposal on the Applicant's Current Utilization Statistics Proposal's Contribution to the Quality of Health Care Delivery in the Region Proposal's Contribution to the Accessibility of Health Care Delivery in the Region

1. Norwalk Hospital ("Hospital") is an acute care general hospital located at 34 Maple Street in Norwalk, Connecticut. The Hospital's total licensed bed capacity of 366 beds and bassinets includes 328 licensed beds and 38 licensed bassinets. (*May 19, 2004 CON Application, Page 111*)
2. On July 18, 1989, the Commission on Hospitals and Health Care ("CHHC") granted Certificate of Need ("CON") authorization under Docket Number 89-549 to Norwalk Hospital for the acquisition of a 10 MEV linear accelerator with related new construction and renovations. The total capital expenditure for all components of the CON project authorized by CHHC under Docket Number 89-549 was \$3,095,342. (*July 18, 1989 CHHC Agreed Settlement, Norwalk Hospital, Docket Number 89-549 and May 19, 2004 CON Application, Page 3*)
3. The Hospital proposes to acquire a replacement linear accelerator with Intensity Modulated Radiation Therapy ("IMRT") technology, at a total capital expenditure of \$4,100,000. The Hospital plans to replace an existing linear accelerator currently located at the Hospital's Whittingham Cancer Center that is now approximately fourteen years old and has outlived its useful file. (*May 19, 2004 CON Application, Pages 1 and 3*)
4. The Hospital's existing linear accelerator has a low energy beam and is not equipped with a multileaf collimator attachment, which renders it incapable of providing IMRT types of treatments. The existing linear accelerator has experienced downtime for machine maintenance approximately two to three times per month. (*June 15, 2004 Completeness Responses, Page 1*)
5. The Hospital plans to purchase and install a Varian Medical Systems Clinac 21 EX linear accelerator with IMRT technology and a multileaf collimator attachment, treatment planning hardware and software, and a radiographic simulator. (*May 19, 2004 CON Application, Page 3 and Attachment 12*)
6. IMRT uses computer-generated images to deliver radiation doses to cancerous tumor sites that are more narrowly focused as compared to conventional radiation therapy. With this capability, physicians can pinpoint a precise dose of radiation to the size, shape and depth of the tumor, while significantly reducing the negative effects of the radiation on surrounding healthy tissue. (*May 19, 2004 CON Application, Page 4*)

7. The Hospital currently operates two linear accelerators, and one linear accelerator will remain operational during the performance of building renovation work and the installation of the replacement linear accelerator and related items of equipment. *(May 19, 2004 CON Application, Page 17)*
8. The Hospital believes the improvements in the quality of patient care to be obtained from the operation of the replacement linear accelerator with IMRT technology are as follows: *(May 19, 2004 CON Application, Page 5)*
  - a. IMRT will allow for the delivery of a higher quantity of radiation doses to tumor sites while sparing surrounding healthy tissue;
  - b. Combinations of IMRT fields will produce a conformal dose distribution of radiation to tumors with much improved precision in tumor targeting; and
  - c. IMRT is the most advanced approach to three dimensional conformal radiation therapy resulting in demonstrated improvements in the treatment of cancers of the head and neck, prostate, breast and lung.
9. The Hospital's actual Radiation Therapy treatments utilizing two linear accelerators were 9,036 in FY 2000, 8,990 in FY 2001, 9,738 in FY 2002 and 9,029 in FY 2003. *(June 15, 2004 Completeness Responses, Pages 2 and 5)*
10. The Hospital's projected Radiation Therapy treatments for FY 2004, FY 2005, FY 2006 and FY 2007 with, without and incremental to the CON proposal are as follows: *(June 16, 2004 Supplemental Completeness Responses, Pages 2 and 4)*

**Table 1: Hospital's Projected Radiation Therapy Treatments for FY 2004 through FY 2007**

Description	FY 2004	FY 2005	FY 2006	FY 2007
RT Treatments with CON Proposal	9,029	9,479	9,929	10,379
RT Treatments without CON Proposal	9,029	9,029	9,029	9,029
RT Treatments Incremental to CON Proposal	0	450	900	1,350

11. The Hospital's calculation of its projected incremental Radiation Therapy treatments assumes a shift from brachytherapy (seed implantation) for prostate cancer and external beam treatments for head and neck, breast, lung and brain cancer patients to IMRT treatments over a three-year period. The Hospital estimates that approximately 70 cancer patients would shift treatment modalities from brachytherapy and external beam treatment to IMRT treatment. The combined effect of this change in practice pattern will result in projected incremental volume increases in Radiation Therapy treatments of 400, 950 and 1,350 for FY 2005, FY 2006 and FY 2007, respectively. *(June 16, 2004 Supplemental Completeness Responses, Pages 1 and 5)*
12. The days and hours of operation of the Radiation Therapy service provided at the Hospital's Whittingham Cancer Center are Monday through Friday from 8:00 am to 5:00 pm, which would remain the same upon the commencement of operation of the replacement linear accelerator. *(May 19, 2004 CON Application, Page 6)*

**Financial Feasibility and Cost Effectiveness of the Proposal and its Impact on the Applicant's Rates and Financial Condition  
Impact of the Proposal on the Interests of Consumers of Health Care Services and the Payers for Such Services**

13. The Hospital's total capital expenditure of \$4,100,000 for the CON proposal includes \$2,052,580 for the purchase of the replacement linear accelerator with IMRT technology and a multileaf collimator attachment, \$1,310,904 for the purchase of a simulator and treatment planning hardware and software, \$650,000 for building renovations and \$86,516 for contingency costs. *(May 19, 2004 CON Application, Page 14)*
14. As part of the CON proposal, the Hospital proposes to renovate both clinical areas and public corridors within its Radiation Therapy Department. The approximate square footage to be renovated in both the clinical areas and public corridors is 3,885 total square feet. The building renovations for the CON proposal would commence on July 1, 2004, would be completed on September 30, 2004, and the replacement linear accelerator would commence operation on October 1, 2004. *(May 19, 2004 CON Application, Pages 15, 16 and 18)*
15. The Hospital's total capital expenditure for the CON proposal will be funded entirely by an equity contribution of \$4,100,000 from the Hospital's operating funds. *(May 19, 2004 CON Application, Page 19)*
16. The Hospital projects incremental revenue from operations, total operating expense and gains from operations associated with the CON proposal as follows: *(June 16, 2004 Supplemental Completeness Responses, Page 4)*

**Table 2: Hospital's Incremental Financial Projections for FY 2004 through FY 2007**

Description	FY 2004	FY 2005	FY 2006	FY 2007
Incremental Revenue from Operations	\$0	\$ 818,000	\$1,626,000	\$2,175,000
Incremental Total Operating Expense	0	794,000	1,122,000	1,213,000
<b>Incremental Gain from Operations</b>	<b>\$0</b>	<b>\$ 24,000</b>	<b>\$ 504,000</b>	<b>\$ 962,000</b>

17. The Hospital's projected payer mix during the first three years of the operation of the replacement linear accelerator is as follows: *(May 19, 2004 CON Application, Page 20)*

**Table 3: Hospital's Three-Year Projected Payer Mix**

Description	Year 1	Year 2	Year 3
Medicare	44.0%	44.0%	44.0%
Medicaid	11.0%	11.0%	11.0%
TriCare	0.0%	0.0%	0.0%
<b>Total Government</b>	<b>55.0%</b>	<b>55.0%</b>	<b>55.0%</b>
Commercial Insurers	42.0%	42.0%	42.0%
Self-Pay	3.0%	3.0%	3.0%
Workers Compensation	0.0%	0.0%	0.0%
<b>Total Non-Government</b>	<b>45.0%</b>	<b>45.0%</b>	<b>45.0%</b>
Uncompensated Care	0.0%	0.0%	0.0%
<b>Total Payer Mix</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>

## Consideration of Other Section 19a-637, C.G.S. Principles and Guidelines

The following findings are made pursuant to the principles and guidelines set forth in Section 19a-637, C.G.S.:

18. There is no state health plan in existence at this time. *(May 19, 2004 CON Application, Page 2)*
19. The Hospital has adduced evidence that the proposal is consistent with the Hospital's long-range plan. *(May 19, 2004 CON Application, Page 2)*
20. The Hospital has improved productivity and contained costs by undertaking energy conservation, reengineering, group purchasing and activities involving the application of new technology. *(May 19, 2004 CON Application, Page 11)*
21. The proposal will not result in any change to the Hospital's teaching and research responsibilities. *(May 19, 2004 CON Application, Page 12)*
22. There are no distinguishing or unique characteristics of the Hospital's patient/physician mix related to the proposal. *(May 19, 2004 CON Application, Page 12)*
23. The Hospital has sufficient technical, financial and managerial competence and expertise to provide efficient and adequate service to the public. *(May 19, 2004 CON Application, Pages 97 – 110 and June 15, 2004 Completeness Responses, Pages 9 - 12)*

## Rationale

Norwalk Hospital ("Hospital") proposes to acquire a replacement linear accelerator with Intensity Modulated Radiation Therapy ("IMRT") technology, at a total capital expenditure of \$4,100,000. The Hospital plans to replace an existing linear accelerator currently located at the Hospital's Whittingham Cancer Center that is now approximately fourteen years old and has outlived its useful life. The Hospital plans to purchase and install a Varian Medical Systems Clinac 21 EX linear accelerator with IMRT technology and a multileaf collimator attachment, treatment planning hardware and software, and a radiographic simulator.

On July 18, 1989, the Commission on Hospitals and Health Care ("CHHC") granted Certificate of Need ("CON") authorization under Docket Number 89-549 to Norwalk Hospital for the acquisition of a 10 MEV linear accelerator with related new construction and renovations. The total capital expenditure for all components of the CON project authorized by CHHC under Docket Number 89-549 was \$3,095,342. The Hospital's existing linear accelerator has a low energy beam and is not equipped with a multileaf collimator attachment, which renders it incapable of providing IMRT types of treatments. The existing linear accelerator has experienced downtime for machine maintenance approximately two to three times per month.

The Hospital currently operates two linear accelerators, and one linear accelerator will remain operational during the performance of building renovation work and the installation of the replacement linear accelerator and related items of equipment. The Hospital's calculation of its projected incremental Radiation Therapy treatments assumes a shift from brachytherapy (seed implantation) for prostate cancer and external beam treatments for head and neck, breast, lung and brain cancer patients to IMRT treatments over a three-year period. The Hospital estimates that approximately 70 cancer patients would shift treatment modalities from brachytherapy and external beam treatment to IMRT treatment. The combined effect of this change in practice pattern will result in projected incremental volume increases in Radiation Therapy treatments of 0 in FY 2004, 450 in FY 2005, 900 in FY 2006 and 1,350 in FY 2007 as a result of the implementation of the CON proposal.

The Hospital believes the improvements in the quality of patient care to be obtained from the operation of the replacement linear accelerator with IMRT technology are that: IMRT will allow for the delivery of a higher quantity of radiation doses to tumor sites while sparing surrounding healthy tissue; combinations of IMRT fields will produce a conformal dose distribution of radiation to tumors with much improved precision in tumor targeting; and IMRT is the most advanced approach to three dimensional conformal radiation therapy resulting in demonstrated improvements in the treatment of cancers of the head and neck, prostate, breast and lung. Based on the foregoing reasons, OHCA finds that there is a clear public need for the Hospital's CON proposal, and that the proposal will improve the quality and maintain the accessibility of Radiation Therapy services provided in the Norwalk region.

The CON proposal's total capital expenditure of \$4,100,000 will be funded entirely by an equity contribution of \$4,100,000 from the Hospital's operating funds. The Hospital projects incremental gains from operations of \$0 in FY 2004, \$24,000 in FY 2005, \$504,000 in FY 2006 and \$962,000 in FY 2007 due to the CON proposal. The Hospital's volume projections and the financial projections upon which they are based appear to be reasonable and achievable. Therefore, OHCA finds that the CON proposal is both financially feasible and cost effective.

Based upon the foregoing Findings and Rationale, the Certificate of Need application of Norwalk Hospital to acquire a replacement linear accelerator with IMRT technology, at a total capital expenditure of \$4,100,000, is hereby GRANTED.

## Order

Norwalk Hospital ("Hospital") is hereby authorized to acquire a replacement linear accelerator with Intensity Modulated Radiation Therapy ("IMRT") technology, at a total capital expenditure of \$4,100,000, subject to the following conditions:

1. This authorization shall expire on June 30, 2006. 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 \$4,100,000. 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 linear accelerator and related items of equipment to be replaced for certain disposition, such as sale or salvage, outside of and unrelated to the Hospital's service provider locations. Furthermore, the Hospital will provide evidence to OHCA of the disposition of the existing linear accelerator and related items of equipment to be replaced by no later than three months after the replacement linear accelerator with IMRT technology has commenced operation.

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

June 24, 2004

Signed by Cristine A. Vogel  
Commissioner

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