Office Of Health Care Access
Certificate of Need Application

Final Decision

Applicant: **Yale-New Haven Hospital**

Docket Number: **03-30083**

Project Title: **Acquire a CT Simulator**

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

Filing Date: **September 19, 2003**

Hearing: **Waived**

Decision Date: **October 17, 2003**

Default Date: **December 18, 2003**

Staff Assigned: **Harold M. Oberg**

Project Description: Yale-New Haven Hospital ("Hospital") proposes to acquire a CT simulator, at a total capital expenditure of $1,398,847. The Hospital's proposal includes the purchase of a CT simulator that combines CT scanner and simulator functions to be used in Radiation Therapy patient treatment to support the use of Intensity Modulated Radiation Therapy ("IMRT").

Nature of Proceedings: On September 19, 2003, the Office of Health Care Access ("OHCA") received a Certificate of Need ("CON") application from Yale-New Haven Hospital to acquire a CT simulator that combines CT scanner and simulator functions, at a total capital expenditure of $1,398,847. The Hospital is a health care facility or institution as defined by Section 19a-630 of the Connecticut General Statutes ("C.G.S.").

The Hospital requested a waiver of hearing for the CON application pursuant to Section 19a-643-45 of OHCA's Regulations, and claimed that the CON application is non-substantive as defined in Section 19a-643-95(3) of OHCA's Regulations. On September 26, 2003, the Hospital was informed that the CON application was eligible for consideration of waiver of public hearing, and a notice to the public was published in the *New Haven Register*. OHCA received no comments from the public concerning the

Hospital's request for waiver of hearing during the public comment period, and therefore on October 15, 2003, OHCA granted the Hospital's request for waiver of hearing.

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. Yale-New Haven Hospital ("Hospital") is an acute care general hospital located at 20 York Street in New Haven, Connecticut. The Hospital's total licensed bed capacity of 944 beds and bassinets includes 852 licensed beds and 92 licensed bassinets. *(September 19, 2003 CON Application, Page 356)*

2. The Hospital proposes to acquire a CT simulator, at a total capital expenditure of $1,398,847. The Hospital proposes to purchase a CT simulator that combines CT scanner and simulator functions to be used in Radiation Therapy patient treatment to support the use of Intensity Modulated Radiation Therapy ("IMRT"). *(September 19, 2003 CON Application, Pages 4 and 5)*

3. The Hospital is proposing to acquire a GE LightSpeed Plus CT simulator to replace a 14-year old CT scanner and to renovate its CT scanner room to accommodate the proposed unit. The proposed CT simulator, which will be utilized to localize tumor sites for radiation therapy, will support the delivery of IMRT. *(May 29, 2003 Letter of Intent, Project Description)*

4. The Hospital's existing CT scanner is outdated, the image detail is poor and it does not meet current imaging standards required to support IMRT treatment. The proposed CT simulator will provide a large bore size, increased image definition, reduced scanning time, and will possess the ability to interface with other imaging modalities. *(May 29, 2003 Letter of Intent, Project Description)*

5. IMRT is an advanced form of external beam irradiation that delivers sharp dose gradients and a high degree of conformity, permitting improved treatment of lesions located in between healthy and critical organs. IMRT better protects surrounding healthy tissue, so that higher doses (i.e., more treatments) can be delivered to tumor sites, thus improving disease control and advancing cure. *(September 19, 2003 CON Application, Page 6)*

6. Since IMRT allows more precise treatment, patients will experience fewer side effects. In addition, the rapid acquisition speed of the proposed unit reduces the need for sedation, especially in pediatric patients. *(September 19, 2003 CON Application, Page 6)*

7. The vital components required to perform IMRT are a linear accelerator, multileaf collimator, tumor delineation method (CT scanner) treatment planning system and a simulator to verify the accuracy of tumor localization and field placement. The CT simulator combines tumor delineation and simulation, which in turn reduces the number of trips patients are required to make in preparation of their treatment. It also eliminates the possibility of patient position variation between set up, simulation and treatment. *(September 19, 2003 CON Application, Page 8)*

8. The Hospital's actual Radiation Therapy volume for FY 2001, FY 2002 and FY 2003 is as follows: *(September 19, 2003 CON Application, Page 7)*

Table 1: Hospital's Actual Radiation Therapy Volume for FY 2001, FY 2002 and FY 2003

Description	FY 2001	FY 2002	FY 2003
Actual Radiation Therapy Treatments	20,713	18,089	22,885
Actual Radiation Therapy Simulations	1,262	1,112	1,309

9. The Radiation Therapy treatments and simulations for FY 2003 are estimated/actual numbers based on ten months of actual volume. The decline in Radiation Therapy volume in FY 2002 reflects the loss of volume due to a flood in the Radiation Therapy Department. *(September 19, 2003 CON Application, Page 7)*

10. The Hospital's projected Radiation Therapy volume for FY 2004, FY 2005 and FY 2006 is as follows: *(September 19, 2003 CON Application, Page 7)*

Table 2: Hospital's Projected Radiation Ther. Volume for FY 2004, FY 2005 and FY 2006

Description	FY 2004	FY 2005	FY 2006
Projected Radiation Therapy Treatments	24,716	26,693	28,829
Projected Radiation Therapy Simulations	1,414	1,541	1,695

11. The Hospital projects that no incremental volume increase in Radiation Therapy treatments or simulations will occur as a result of the implementation of the CON proposal. *(September 19, 2003 CON Application, Page 379)*

12. The Hospital's projections for FY 2004 through FY 2006 are based on annualized ten months of actual volume for FY 2003, changes in technology, the use of IMRT and the aging of the population. The Hospital estimates that the growth rate is expected to be higher than 8% annually with growth rates in FY 2005 and FY 2006 projected to be 9% and 10%, respectively. *(September 19, 2003 CON Application, Page 8)*

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 $1,398,847 includes the following capital expenditure components: *(September 19, 2003 CON Application, Pages 13 and 373)*

Table 3: Hospital's Total Capital Expenditure for the CON Proposal

Description	Total
GE LightSpeed Plus CT Simulator	$ 1,179,950
Laser Camera	51,190
CT Injector	23,700
Building Renovations	144,007
Total Capital Expenditure for the CON Proposal	**$1,398,847**

14. The total capital expenditure of $1,398,847 will be financed by an equity contribution consisting of $279,769 from the Hospital's operating funds and $1,119,078 from Hospital funded depreciation. *(September 19, 2003 CON Application, Page 14)*

15. The Hospital projects incremental revenue from operations, total operating expense and gain/(loss) from operations associated with the CON proposal as follows: *(September 19, 2003 CON Application, Page 378)*

Table 4: Hospital's Incremental Financial Projections for FY 2003, FY 2004 and FY 2005

Description	FY 2003	FY 2004	FY 2005
Incremental Revenue from Operations	$ 0	$ 0	$ 0
Incremental Total Operating Expense	0	130,000	387,000
Incremental Gain/(Loss) from Operations	**$ 0**	**$(130,000)**	**$(387,000)**

16. The projected incremental losses from operations are due to new operating expenses for depreciation and a service contract related to the purchase and implementation of the proposed CT simulator. *(September 19, 2003 CON Application, Page 379)*

17. The Hospital's projected payer mix during the first three years of implementation and operation of the CON proposal is as follows: *(September 19, 2003 CON Application, Page 15)*

Table 5: Hospital's Three-Year Projected Payer Mix

Payer Mix	Year 1	Year 2	Year 3
Medicare	37.31%	37.31%	37.31%
Medicaid	12.87%	12.87%	12.87%
TriCare	0.31%	0.31%	0.31%
Total Government	**50.49%**	**50.49%**	**50.49%**
Commercial Insurers	47.98%	47.98%	47.98%
Self-Pay	0.42%	0.42%	0.42%
Workers Compensation	1.11%	1.11%	1.11%
Total Non-Government	**49.51%**	**49.51%**	**49.51%**
Uncompensated Care	0.00%	0.00%	0.00%
Total Payer Mix	**100.00%**	**100.00%**	**100.00%**

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. *(September 19, 2003 CON Application, Page 5)*

19. The Hospital has adduced evidence that the proposal is consistent with the Hospital's long-range plan. *(September 19, 2003 CON Application, Page 5)*

20. The Hospital has improved productivity and contained costs by undertaking energy conservation, reengineering, application of new technology and group purchasing activities. *(September 19, 2003 CON Application, Page 11)*

21. The proposal will not result in any change to the Hospital's teaching and research responsibilities. *(September 19, 2003 CON Application, Page 11)*

22. There are no distinguishing or unique characteristics of the Hospital's patient/ physician mix related to the proposal. (*September 19, 2003 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. *(September 19, 2003 CON Application, Appendix VIII, Pages 123 through 165)*

Rationale

Yale-New Haven Hospital (" Hospital") proposes to acquire a CT simulator and undertake renovations to the CT scanner room, at a total capital expenditure of $1,398,847. The proposed scanner is a GE LightSpeed Plus CT simulator which will replace a 14-year old CT scanner. The Hospital proposes to purchase a CT simulator that combines CT scanner and simulator functions to be used in Radiation Therapy patient treatment to support the use of Intensity Modulated Radiation Therapy ("IMRT").

The Hospital's existing CT scanner has poor image detail and does not meet current imaging standards required to support IMRT treatment. The proposed CT simulator will provide a large bore size, increased image definition, reduced scanning time, and will possess the ability to interface with other imaging modalities. The CT simulator combines tumor delineation and simulation, which in turn reduces the number of trips patients are required to make in preparation of their treatment. It also eliminates the possibility of patient position variation between set up, simulation and treatment.

The proposed CT simulator will support the delivery of IMRT. IMRT is an advanced form of external beam irradiation that delivers sharp dose gradients and a high degree of conformity, permitting improved treatment of lesions located in between healthy and critical organs. IMRT better protects surrounding healthy tissue, so that higher doses (i.e.,

more treatments) can be delivered to tumor sites, thus improving disease control and advancing cure. Since IMRT allows more precise treatment, patients will experience fewer side effects. In addition, the rapid acquisition speed of the proposed unit reduces the need for sedation, especially in pediatric patients. Based on the foregoing reasons, OHCA finds that the CON proposal will improve both the quality and accessibility of the Hospital's existing Radiation Therapy treatment services.

The Hospital projects no incremental volume increase in Radiation Therapy treatments or simulations as a result of the implementation of the CON proposal. The Hospital's projections for FY 2004 through FY 2006 are based on annualized ten months actual volume for FY 2003, changes in technology, the use of IMRT and the aging of the population. The Hospital estimates that the growth rate is expected to be higher than 8% annually with growth rates in FY 2005 and FY 2006 projected to be 9% and 10%, respectively.

The proposal's total capital expenditure of $1,398,847 will be funded entirely by an equity contribution consisting of $279,769 from the Hospital's operating funds and $1,119,078 from Hospital funded depreciation. The Hospital projects minimal incremental losses from operations of $(130,000) in FY 2004 and $(387,000) in FY 2005. The projected minimal incremental losses from operations are due to new operating expenses for depreciation and a service contract related to the purchase and implementation of the proposed CT simulator. 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 Yale-New Haven Hospital to acquire a CT simulator that combines CT scanner and simulator functions, at a total capital expenditure of $1,398,847, is hereby GRANTED.

Order

Yale-New Haven Hospital ("Hospital") is hereby authorized to acquire a CT simulator that combines CT scanner and simulator functions, at a total capital expenditure of $1,398,847, subject to the following conditions:

1. This authorization shall expire on October 31, 2005. Should the Hospital's CT simulator acquisition 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 capital expenditure of $1,398,847. 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 CT scanner used in Radiation Therapy patient treatment 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 Hospital's existing CT scanner by no later than six months after the new CT simulator 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

Date signed:
October 17, 2003

Signed by:
Mary M. Heffernan
Commissioner

MMH:ho

Table Descriptions

Yale-New Haven Hospital
Acquire a CT Simulator
CON Final Decision, Docket Number 03-30083

Table 1

Title: Hospital's Actual Radiation Therapy Volume for FY 2001, FY 2002 and FY 2003

The Hospital's actual number of Radiation Therapy treatments is 20,713 in FY 2001, 18,089 in FY 2002 and 22,885 in FY 2003. The Hospital's actual number of Radiation Therapy simulations is 1,262 in FY 2001, 1,112 in FY 2002 and 1,309 in FY 2003. The decline in Radiation Therapy volume in FY 2002 reflects the loss of volume due to a flood in the Radiation Therapy Department.

Table 2

Title: Hospital's Projected Radiation Ther. Volume for FY 2004, FY 2005 and FY 2006

The Hospital's projected number of Radiation Therapy treatments with or without the CON proposal is 24,716 in FY 2004, 26,693 in FY 2005 and 28,829 in FY 2006. The Hospital's projected number of Radiation Therapy simulations with or without the CON proposal is 1,414 in FY 2004, 1,541 in FY 2005 and 1,695 in FY 2006. The Hospital projects that no incremental volume increase in Radiation Therapy treatments or simulations will occur as a result of the implementation of the CON proposal.

Table 3

Title: Hospital's Total Capital Expenditure for the CON Proposal

The total capital expenditure for the CON proposal is $1,398,847 and includes $1,179,950 for the GE LightSpeed Plus CT Simulator, $51,190 for a laser camera, $23,700 for a CT injector, and $144,007 for building renovations.

Table 4

Title: Hospital's Incremental Financial Projections for FY 2003, FY 2004 and FY 2005

The projected incremental revenue from operations for the proposal is $0 in FY 2003, $0 in FY 2004 and $0 in FY 2005. The projected incremental total operating expense for the proposal is $0 in FY 2003, $130,000 in FY 2004 and $387,000 in FY 2005. The projected incremental losses from operations for the proposal are $0 in FY 2003, $(130,000) in FY 2004 and $(387,000) in FY 2005.

Table 5

Title: Hospital's Three-Year Projected Payer Mix

The projected payer mix remains constant in each category for the first three years of implementation and operation of the CT simulator project. Total Government reimbursement is projected to account for 50.49% of total reimbursement with Medicare at 37.31%, Medicaid at 12.87% and TriCare (CHAMPUS) at 0.31%. Total Non-Government reimbursement is projected to account for 49.51% of total reimbursement with Commercial Insurers at 47.98%, Self-Pay Patients at 0.42% and Workers Compensation at 1.11%. Uncompensated Care is projected to be 0.00% of total reimbursement.