



STATE OF CONNECTICUT
DEPARTMENT OF PUBLIC HEALTH
Office of Health Care Access

September 21, 2010

IN THE MATTER OF:

An Application for a Certificate of Need
filed Pursuant to Sections 19a-639, C.G.S.
by:

Lawrence & Memorial Hospital

Notice of Final Decision
Office of Health Care Access
Docket Number: 10-31532-CON

Acquisition of a Replacement Linear
Accelerator

Crista Durand
Vice President, Strategic Planning
Lawrence & Memorial Hospital
365 Montauk Avenue
New London, CT 06320

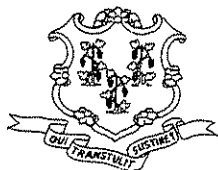
Dear Ms. Durand:

This letter will serve as notice of the Final Decision of the Office of Health Care Access in the above matter, as provided by Sections 19a-639, C.G.S. On September 21, 2010, the Final Decision was rendered as the finding and order of the Office of Health Care Access. A copy of the Final Decision is attached hereto for your information.

A handwritten signature in black ink, appearing to read "Kimberly R. Martone".

Kimberly R. Martone
Director of Operations

Enclosure
KRM:lkg



**Department of Public Health
Office of Health Care Access
Certificate of Need Application**

Final Decision

Applicant: Lawrence and Memorial Hospital
Docket Number: 10-31532-CON
Project Title: Acquisition of a Replacement Linear Accelerator

Project Description: Lawrence and Memorial Hospital ("Hospital" or "Applicant") is proposing to acquire a replacement Linear Accelerator ("LinAc") to be located at its Community Cancer Center at the Hospital, at a total capital cost of \$4,600,410.

Nature of Proceedings: On May 6, 2010, the Office of Health Care Access ("OHCA") received the initial Certificate of Need ("CON") application for the above-referenced project. The Hospital is a health care facility or institution as defined under Section 19a-630 of the Connecticut General Statutes ("C.G.S.").

A notice to the public regarding OHCA's receipt of the Hospital's Letter of Intent to file its CON Application was published in *The Day* on February 13, 2010. OHCA received no responses from the public concerning the Hospital's proposal. Pursuant to Section 19a-639, C.G.S., three individuals, or an individual representing an entity with five or more people, had until July 15, 2010, the twenty-first calendar day following the filing of the Hospital's CON application, to request that OHCA hold a public hearing on the Hospital's proposal. OHCA received no hearing requests from the public.

OHCA's authority to review and approve, modify or deny this proposal 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

1. The Applicant is a not-for-profit, acute care hospital located at 365 Montauk Avenue, New London, Connecticut. *(May 6, 2010 Initial CON Application, page 1)*
2. The Hospital currently operates a Community Cancer Center ("Center") on the Hospital's main campus. *(May 6, 2010 Initial CON Application, page 2)*
3. The Center is one of the Hospital's centers of excellence and in 2008 the Center received a 3-year approval as a Community Hospital Comprehensive Program and eight commendations by the American College of Surgeons. *(May 6, 2010 Initial CON Application, page 17)*
4. The Center's comprehensive program category ensures that multidisciplinary cancer care with supportive services and state-of-the-art equipment is provided to the Hospital's cancer patients. *(May 6, 2010 Initial CON Application, page 17)*
5. The comprehensive cancer services at the Center include chemotherapy, radiation oncology and GYN oncology. *(June 22, 2010, Completeness Letter Response, page 154)*
6. In the past few years, the Hospital has made several investments in its cancer program including the development of a new breast imaging center, the addition of Calypso Image Guided Radiation Therapy, and the addition of a new CT simulator. *(May 6, 2010 Initial CON Application, pages 17-18)*
7. The table below lists the Center's historical patient visits by type of service:

Table I: Hospital's Cancer Center's Historical Volume

	FY 2007	FY 2008	FY 2009	FY 2010*
Radiation Therapy	470	457	414	435
GYN Oncology	154	116	121	144
Chemotherapy			312	363
Total	624	673	847	942

*FY 2010, projected based on actual Jan.-April data.
(June 22, 2010, Completeness Letter Response, page 154)

8. The Hospital currently operates two LinAcs at the Center. Both LinAc models are Varian 2100. *(May 6, 2010 Initial CON Application, page 3)*
9. The Applicant is proposing to replace one of the existing LinAcs, a Varian 2100C (“Varian 2100C”), located at the Center. *(May 6, 2010, Initial CON Application, page 2)*
10. The Varian 2100C was acquired by the Hospital through authorization by the Commission on Hospitals and Health Care¹ under Docket No.: 90-568, as part of the Hospital’s master facility plan, which included establishment of the Center. *(Commission on Hospitals and Health Care, Agreed Settlement, September 5, 1991)*
11. The Hospital currently contracts with Yale-New Haven Hospital to provide its radiation therapy services, including staffing. Staff involved includes a chief therapist, radiation therapists, a physicist, dosimetrists, a resident physician and a physics technician. *(May 6, 2010 Initial CON Application, page 2)*
12. The Varian 2100C is over 15 years old and is at the point where it is experiencing excessive maintenance, repair down-time and patient rescheduling. The Hospital asserts that the Varian 2100C has exceeded its useful life. *(May 6, 2010 Initial CON Application, page 2)*
13. In FY 2009, the Varian 2100C experienced 33 problem situations compared to 30 problem situations to date for the 5.5 months (through March 15th) in 2010. *(May 6, 2010 Initial CON Application, page 2)*
14. The Applicant submitted a copy of its service log as evidence of the problem situations that the Varian 2100C has been experiencing. *(May 6, 2010 Initial CON Application, Exhibit 2)*
15. It has become difficult for the Hospital to locate replacement parts and the Hospital had to buy refurbished parts, which in turn experience short timeframes before they themselves need replacement. *(May 6, 2010 Initial CON Application, page 2)*
16. OHCA finds that the Applicant’s proposal is based on the need to replace its existing aging LinAc, which requires extensive repairs and down time.
17. The proposed LinAc, a Varian Medical Systems Novalis Tx (“Novalis Tx”) will provide greater efficiency, save money on supplies and will enable greater applications of use versus the Varian 2100C. *(May 6, 2010 Initial CON Application, page 2)*
18. The Novalis Tx’s multileaf collimation removes human error by communicating with the record and verifying the system to ensure the correct shielding is in place. In addition to that, it will provide Portal Vision, which will allow the therapists operating the unit to take verification x-rays and see them within seconds as opposed to the current use of films that need to be developed first before they can be viewed. *(May 6, 2010 Initial CON Application, page 2)*

¹ Commission on Hospitals and Health Care was the predecessor agency to the Office of Health Care Access.

19. Further, the Novalis Tx will allow for both Intensity Modulated Radiation Therapy (“IMRT”)² and Stereotactic Radiosurgery treatments (“SRS”)³. The Hospital asserts that these treatments allow the doctors to treat cancerous tumors to a high dose while sparing normal tissue. *(May 6, 2010 Initial CON Application, page 2)*
20. The Novalis Tx has the capability of on-board imaging (“OBI”) which is the device for imaging guided radiation therapy (“IGRT”). *(June 22, 2010, Completeness Letter Response, page 155)*
21. The Novalis Tx will also allow the patients that currently have to travel large distances for these highly specialized treatments to receive them at the Center, with their own physicians and familiar staff. *(May 6, 2010 Initial CON Application, page 2)*
22. Currently, approximately four patients per month travel elsewhere to receive treatment from a LinAc with IMRT and SRS, capabilities. *(May 6, 2010 Initial CON Application, page 2)*
23. The Novalis Tx will be housed in the Varian 2100C location in the Center on the Hospital campus, which provides a centralized location for oncology services and comprehensive cancer treatment. *(May 6, 2010 Initial CON Application, pages 3&4)*
24. The Novalis Tx will require specialized training for all staff involved including the physicians, physicist and other related staff. *(June 22, 2010, Completeness Letter Response, page 155)*
25. The per-patient treatment time will increase slightly as a result of performing some IMRT and SRS procedures; however, it is anticipated that the Applicant will be able to treat the same number of patients or slightly increase the number of patients. *(June 22, 2010, Completeness Letter Response, page 155)*
26. There is no anticipated change in populations to be served as a result of this proposal. *(May 6, 2010 Initial CON Application, page 4)*
27. There are no providers of similar services in the Hospital’s primary service area. *(May 6, 2010 Initial CON Application, page 5)*
28. OHCA finds this proposal will improve accessibility and quality of care for the Hospital’s cancer patients.

² A type of three-dimensional radiation therapy that uses computer-generated images to match radiation to the size and shape of a tumor. Source: medterms.com

³ Stereotactic radiosurgery is a form of radiation therapy that focuses high-powered x-rays on a small area of the body. Source: info.baylorhealth.com

29. The historical utilization for fiscal years (“FY”) 2007-2009 and current fiscal year (2010) for both of the Hospital’s LinAcs is as follows:

Table II: Hospital’s Historical Treatments for the Existing LinAcs

	FY 2007	FY 2008	FY 2009	FY 2010*
Varian 2100C <i>(To Be Replaced)</i>	5,022	4,389	4,517	4,883
Varian 2100D	5,668	6,487	7,158	7,272
Total	10,690	10,876	11,675	12,155

*FY 2010 is Annualized
(May 6, 2010 Initial CON Application, page 6)

30. The projected utilization for the existing and the proposed LinAc for partial FY 2011 and FYs 2012-2014 is as follows:

Table III: Hospital’s Projected Treatments for the Existing & Proposed LinAc:

	FY 2011*	FY 2012	FY 2013	FY 2014
Novalis Tx <i>(New LinAc)</i>	1,764	4,704	4,704	4,704
Varian 2100D <i>(Existing)</i>	10,056*	7,208	7,208	7,208
Total	11,820	11,912	11,912	11,912

* FY 2011 volume for the existing LinAc (Varian 2100D) includes increased volume due to additional volume to compensate for the time during the transition to the new LinAc.
(May 6, 2010 Initial CON Application, page 6)

31. The Applicant projects the replacement Novalis Tx to approximate the historical treatment levels of the Varian 2100c and the slight decrease in annual treatment utilization is due the additional time required for treatments involving IMRT and SRS.
(May 6, 2010 Initial CON Application, page 12)
32. During replacement of the Varian 2100C between August 25, 2010 and May 17, 2011, the Hospital will operate only the Varian 2100D, which will accommodate all patient volume until the Novalis Tx becomes operational. (May 6, 2010 Initial CON Application, page 12)
33. During the renovation period, the Varian 2100D will be scheduled late on weekdays as well as on weekends. Therefore, there is no anticipated loss of volume during this period and no increase in staffing costs. (May 6, 2010 Initial CON Application, page 12)
34. OHCA finds the Applicant’s projected utilization for the proposed Novalis Tx is reasonable.

35. The proposed total capital expenditure of \$4,600,410 includes the following:

Table IV: Projected Capital Expenditure

Linear Accelerator Equipment Purchase	\$3,619,987
Non-Medical Equipment Purchase	\$311,587
Medical Equipment Purchase	\$50,600
Construction/Renovation	\$526,236
Other-Non-Construction	\$92,000
Total	\$4,600,410

(May 6, 2010, Initial CON Application, page 14)

36. The Hospital will fund this proposal from operations. *(May 6, 2010, Initial CON Application, page 15)*
37. The Hospital projects a loss from operations incremental to the proposal for the first three years of the proposal of \$(206,504), \$(270,592) and \$(39,276), for FYs 2011-2013, respectively. *(May 6, 2010, Initial CON Application, page 145)*
38. The projected losses incremental to the proposal for the first three years of the proposal are attributed to depreciation of the Novalis Tx. *(May 6, 2010, Initial CON Application, page 17)*
39. The Hospital projects gains from operations with the proposal as follows:

Table V: Projected Overall Hospital Gain from Operations with the Project

	FY 2012	FY 2013	FY 2014
Revenues from Operations	\$293,432,606	203,432,605	293,432,605
Expenses from Operations	\$287,472,524	\$287,511,800	\$287,511,800
Gains from Operations	\$4,960,081	\$5,920,805	\$5,920,805

(May 6, 2010, Initial CON Application, page 145)

40. OHCA finds that the Hospital will experience an overall gain from its operations despite the incremental losses attributed to the proposal.

41. There is no change expected in the projected payer mix based on Patient Population, as illustrated below:

Table VI: Current & Three-Year Projected Payer Mix

	Current FY 2010	FY 2011	FY 2012	FY 2013
Medicare*	47.9%	47.9%	47.9%	47.9%
Medicaid*	3.7%	3.7%	3.7%	3.7%
Champus and TriCare	4.0	4.0	4.0	4.0
Total Government	55.6%	55.6%	55.6%	55.6%
Commercial Insurers*	43.7	43.7	43.7	43.7
Uninsured/Private Pay	0.7	0.7	0.7	0.7
Workers Compensation				
Total Non-Government	44.4	44.4	44.4	44.4
Total Payer Mix	100%	100%	100%	100%

* Includes managed care activity
(May 6, 2010, Initial CON Application, page 16)

42. This proposal is consistent with its long-range plan in that it elevates the level of radiation therapy services provided. (May 6, 2010, Initial CON Application, page 17)

Rationale

OHCA approaches community and regional need for CON proposals on a case by case basis. CON applications do not lend themselves to general applicability due to a variety of factors, which may affect any given proposal; e.g., the characteristics of the population to be served, the nature of the existing services, the specific types of services proposed to be offered, the current utilization of services and the financial feasibility of the proposal.

The Applicant is an acute care hospital located in New London, Connecticut and currently operates the Center on the hospital's main campus. The Center is one of the Hospital's Centers of Excellence and in 2008, the American College of Surgeons designated it as a Community Hospital Comprehensive Program. The Center provides comprehensive cancer care including chemotherapy, radiation oncology and GYN oncology [Findings 3&5]. The Hospital proposes to replace its existing Varian 2100C LinAc through the acquisition of Novalis Tx LinAc [Finding 9]. OHCA finds that the Applicant's proposal is based on the need to replace its existing aging LinAc, which requires extensive repairs and down time [Finding 16].

The Hospital currently operates 2 LinAcs at the Center and the existing LinAc proposed for replacement is over 15 years old and has been experiencing excessive maintenance and repair down-time [Findings 12-15]. Further, the existing LinAc is limited on the types of treatments that can be performed on it and currently up to 4 patients per month travel to providers outside the Hospital's primary service area to receive their services [Findings 22-24]. Compared to the Hospital's existing 15 year old LinAc, the Novalis Tx will offer the Hospital the ability to offer additional treatments including IMRT and SRS treatments, thereby improving the accessibility and quality of care for the Hospital's existing cancer patients. [Findings 17-21].

Furthermore, there is no change anticipated in the population to be served and there are no providers of similar services in the Hospital's primary service area [Findings 24 &25]. Although the Hospital has experienced increasing annual utilization on its current LinAcs, the Hospital anticipates only a slight increase in its projected utilization for the two LinAcs for the first year and thereafter utilization remains constant as there is no change in population to be served [Findings 24, 27&28]. The Hospital's volume projections appear to be reasonable and achievable.

The total capital cost associated with this proposal is \$4,600,410 [Finding 35]. The Hospital plans to fund the purchase of the proposed LinAc through its operations [Finding 36]. OHCA finds that the Hospital will experience an overall gain from its operations despite the incremental losses attributed to the proposal and volume and financial projections upon which they are based appear to be reasonable and achievable and therefore, the proposal is financially feasible [Findings 34&40].

Order

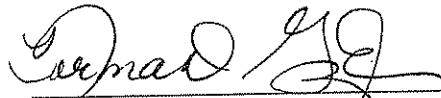
Based on the foregoing Findings and Rationale, the Certificate of Need application of Lawrence and Memorial Hospital ("Hospital") to acquire a Linear Accelerator ("LinAc") to be operated on its main campus in New London, Connecticut, with an associated capital cost of \$4,600,410 is hereby **GRANTED**, subject to the following condition:

1. The Applicant shall notify OHCA in writing the name of the manufacturer of the new LinAc by no later than one month after the scanner becomes operational.

Should the Hospital fail to comply with any of the aforementioned condition, OHCA reserves the right to take additional action as authorized by law. All of the foregoing constitutes the final order of the Office of Health Care Access in this matter.

By Order of the
Department of Public Health
Office of Health Care Access

Sept. 20, 2010
Date


Norma Gyle, R.N., Ph.D.
OHCA Deputy Commissioner

NG:swl

*** TX REPORT ***

TRANSMISSION OK

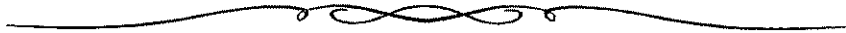
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**STATE OF CONNECTICUT
DEPARTMENT OF PUBLIC HEALTH
OFFICE OF HEALTH CARE ACCESS**

FAX SHEET

TO: CRISTA DURAND
FAX: (860) 444-3716
AGENCY: LAWRENCE AND MEMORIAL HOSPITAL
FROM: LAURIE GRECI
DATE: 9/21/10 **TIME:** _____
NUMBER OF PAGES: 11
(including transmittal sheet)



Comments: Docket 10-31532-CON Notice of Final Decision

PLEASE PHONE IF THERE ARE ANY TRANSMISSION PROBLEMS.