

M. JODI RELL  
GOVERNOR

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

CRISTINE A. VOGEL  
COMMISSIONER

May 14, 2009

**IN THE MATTER OF:**

An Application for a Certificate of Need  
filed pursuant to Section 19a-639, C.G.S. by

Notice of Agreed Settlement  
Office of Health Care Access  
Docket Number: 08-31262-CON

**Middlesex Hospital**

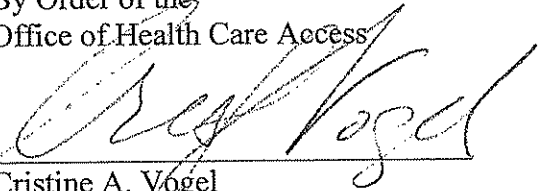
**Acquisition of a Second Linear Accelerator  
with Image-Guided Radiation Therapy at  
Middlesex Hospital**

Harry Evert  
Vice President  
Middlesex Hospital  
28 Crescent Street  
Middletown, CT 06457

Dear Mr. Evert:

This letter will serve as notice of the Agreed Settlement between the Office of Health Care Access and Middlesex Hospital in the above matter, as provided by Section 19a-639, C.G.S. On May 14, 2009, the Agreed Settlement was adopted as the finding and order of the Office of Health Care Access. A copy of the Agreed Settlement is attached hereto for your information.

By Order of the  
Office of Health Care Access



Cristine A. Vogel  
Commissioner

Enclosure  
CAV:agf



## Office of Health Care Access Certificate of Need Application

### Agreed Settlement

**Applicant:** Middlesex Hospital

**Docket Number:** 08-31262-CON

**Project Title:** Acquisition of a Second Linear Accelerator with Image-Guided Radiation Therapy at Middlesex Hospital

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

**Filing Date:** March 2, 2009

**Decision Date:** May 12, 2009

**Default Date:** May 31, 2009

**Staff:** Alexis G. Fedorjaczenko

**Project Description:** Middlesex Hospital (“Hospital”) proposes to acquire a second Linear Accelerator (“Linac”) with Image-Guided Radiation Therapy (“IGRT”) at Middlesex Hospital. The proposed total capital expenditure for the project is \$5,226,899.

**Nature of Proceedings:** On March 2, 2009, the Office of Health Care Access (“OHCA”) received the Certificate of Need (“CON”) application from the Hospital seeking authorization to acquire a second Linac (a Novalis TX System) equipped with IGRT at Middlesex Hospital at a proposed total capital expenditure of \$5,226,899. The Applicant is a health care facility or institution as defined by Section 19a-630 of the Connecticut General Statutes (“C.G.S.”).

Pursuant to Section 19a-639, C.G.S., a notice to the public concerning OHCA’s receipt of the Applicant’s Letter of Intent was published in the *Middletown Press* on November 18, 2008. 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 March 23, 2009, 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**

### **Clear Public Need**

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

1. It is found that Middlesex Hospital ("Hospital") is a 275-bed general hospital located at 28 Crescent Street in Middletown. *(February 2, 2009, Initial CON Application, page 172)*
2. It is found that the Hospital's Cancer Center is located at 536 Saybrook Road in Middletown. *(February 2, 2009, Initial CON Application, page 172)*
3. It is found that on April 5, 2001, the Hospital received CON authorization to develop a Cancer Center adjacent to and in conjunction with an expansion of the Hospital's Outpatient Center on Saybrook Road in Middletown. This included authorization to replace the Hospital's existing 15-year old linear accelerator ("Linac") and relocate the equipment to the Cancer Center. *(March 2, 2009, Completeness Response, page 183; April 5, 2002, Final Decision Docket Number 00-553)*
4. The Hospital contends that the Hospital's primary service area, from which 86% of the radiation therapy treatment volume is derived, will be the service area for the proposal. The towns include Cromwell, Durham, Haddam, Killingworth, Middlefield, Middletown, Colchester, East Haddam, East Hampton, Marlborough, Portland, Chester, Clinton, Deep River, Essex, Madison, Old Saybrook, and Westbrook. *(February 2, 2009, Initial CON Application, pages 6-7)*
5. The Hospital indicated that in addition to more traditional 3-D conformal radiation therapy, the current Linac is capable of providing intensity modulated radiation therapy ("IMRT") which allows for the delivery of higher doses of radiation to the tumor while sparing the surrounding normal tissue. The Hospital stated that image-guided radiation therapy ("IGRT") is the next step in the evolution of radiation therapy and that it can better localize the extent of a tumor before the radiation is delivered and then can deliver the optimal dose of radiation precisely to the localized tumor. *(February 2, 2009, Initial CON Application, page 35)*

6. It is found that the Hospital's historical number of radiation therapy treatments and patients, along with the average number of treatments per patient are as follows:

**Table 1: Historical Radiation Therapy Treatments, FYs 2006-2009**

	Actual FY 2006	Actual FY 2007	Actual FY 2008	Actual FY 2009*
Radiation Therapy Treatments	8,700	8,683	7,674	2,746
Total Patients	371	364	321	
Avg. Radiation Therapy Trtmt/Patient	23.45	23.85	23.91	

\*First four months of FY 2009, Oct 2008-Jan 2009

(February 2, 2009, Initial CON Application, page 47 and March 2, 2009, Completeness Response, page 185)

7. The Hospital stated that according to its Tumor Registry, the total number of diagnosed cancer cases reported at the Hospital in FYs 2006, 2007, and 2008 was 888, 868, and 895, respectively. (March 2, 2009, Completeness Response, page 188)
8. It is found that the historical number of total patients for radiation therapy treatments has been declining; and also the total number of diagnosed cancer cases according to the Hospital Tumor Registry has been relatively stable.
9. The Hospital contends that the following projections and estimates of new cancer incidence in the service area between 2008 and 2018 were obtained from Thomson Reuters and were utilized in the Hospital's development of projections.

**Table 2: Projected Service Area New Cancer Incidence Growth, by Age Group**

	Projected 2008	Projected 2013	Projected 2018	5-Year Growth	10-Year Growth
00-17	8	8	8	0.0%	0.0%
18-44	89	85	80	(4.49%)	(10.1%)
45-64	502	557	618	10.96%	23.1%
65+	760	889	1,039	16.97%	36.7%
<b>Total</b>	<b>1,359</b>	<b>1,539</b>	<b>1,745</b>	<b>13.25%</b>	<b>28.4%</b>

Note: Populations based on Thomson Reuters 2007 and 2012 estimates.

(February 2, 2009, Initial CON Application, page 31)

The following is a summary of the methodology used by the Hospital in developing its projections:

- In FY 2008, there were 321 new radiation therapy patients seen at the Hospital (actual number from the Hospital) out of a total of 1,359 new cancer cases in the service area (number estimated by Thomson Reuters);
- 1,359 cancer cases times 55% (a composite ratio estimated by the Hospital representing the proportion of cancer patients who will receive radiation therapy) equals 748 radiation therapy patients in the primary service area in FY 2008;
- With a 37.5% market share for the service area, 280 of these patients were estimated to have received treatment at the Hospital, and another 41 patients from outside the service area were also estimated to have received radiation therapy services at the Hospital, for a total of 321 patients (the actual number treated at the hospital);

- These calculations were applied to the FY 2013 projected cancer incidence (from Thomson Reuters) to project the number of patients for that year;
  - The Hospital estimated the proportion of patients that would receive different types of radiation therapy based on current treatment mix and introduction of IGRT;
  - The average number of treatments per patient was applied to determine a total projected number of treatments of 10,199 in FY 2013.
- (February 2, 2009, Initial CON Application, page 39-40, 43-44)*

10. It is found that there is no evidence to support these projections or the estimates upon which they are based.
11. The Hospital contends that the Hospital's actual and projected mix of radiation therapy treatment types are as follows:

**Table 3: Historical & Projected Treatments by Type of Radiation Therapy**

Trtmt. Type	Actual			Projected			
	FY 2006	FY 2007	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012
IGRT-IMRT	--	--	--	--	2,834	5,231	5,364
Non-IGRT IMRT	2,564	2,627	1,777	2,452	2,267	1,744	1,788
Conformal	5,957	5,943	5,639	6,040	3,812	2,324	2,383
Non-Conformal	179	113	258	182	186	191	196
<b>Total</b>	<b>8,700</b>	<b>8,683</b>	<b>7,674</b>	<b>8,674</b>	<b>9,099</b>	<b>9,490</b>	<b>9,731</b>

*(February 2, 2009, Initial CON Application, page 47)*

12. The Hospital contends the following historical and projected volumes by Linac machine:

**Table 4: Historical and Projected Treatment Volume with CON Approval**

	Actual			Projected			
	FY 2006	FY 2007	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012
Existing Linac	8,700	8,683	7,674	8,674	3,998	2,525	2,579
Proposed Linac	--	--	--	--	5,101	6,975	7,153
<b>Total Treatments</b>	<b>8,700</b>	<b>8,683</b>	<b>7,674</b>	<b>8,674</b>	<b>9,099</b>	<b>9,490</b>	<b>9,732</b>
Number Patients	371	364	321	329	337	345	354

*(February 2, 2009, Initial CON Application, pages 10-12, & 47 and March 2, 2009, Completeness Response, pages 186-7)*

13. It is found that the Applicants failed to demonstrate how the increase in treatments from 7,674 in FY 2008 to the estimated 8,674 in FY 2009 will be realized based on the projected increase in patients from 321 to 329.

14. The Hospital contends that when equipment need was calculated, the following number of Linacs determined to be necessary:

**Table 5: Calculated Need for Linac Machines at the Hospital**

	Actual				Projected								
	FY06	FY07	FY08	FY09	FY10	FY11	FY12	FY13	FY14	FY15	FY16	FY17	FY18
Total Trtmt Hours	2,181	2,186	1,866	2,162	2,799	3,303	3,387	3,549	3,640	3,734	3,829	3,927	4,028
# Linacs Needed	.9	.9	.8	.9	1.2	1.4	1.4	1.5	1.5	1.6	1.6	1.7	1.7

The Hospital calculated total projected treatment hours based on the number of patients expected to receive each type of treatment and the number of minutes per treatment. The Hospital used an annual average of 2,375 hours available per machine to determine the number of machines needed for each year. This is based on 9.5 hours per day x 5 days per week x 50 weeks per year x 100% efficiency. (February 2, 2009, Initial CON Application, pages 48, 50 & 51)

15. The Hospital conducted a study of unscheduled downtime on the current equipment and found that downtime has been increasing over the last three years. In FY 2006 the current machine experienced 18.25 hours of unscheduled downtime; this rose to 24.5 hours in FY 2007 and 29.0 hours in FY 2008. (February 2, 2009, Initial CON Application, page 37)
16. It is found that the existing Linac has been experiencing increasing downtime.
17. It is found that based on the Hospital's own calculations in Table 5, a second Linac may not necessarily be required at this time given the existing volume.

**Financial Feasibility of the Proposal and its Impact on the Hospital's Rates and Financial Condition**  
**Impact of the Proposal on the Interests of Consumers of Health Care Services and Payers for Such Services**  
**Consideration of Other Section 19a-637, C.G.S. Principles and Guidelines**

18. The Hospital contends that the total capital expenditure for the proposal of \$5,226,899 includes \$3,999,999 for purchase of an IGRT system, \$1,076,900 for construction of a vault to accommodate the IGRT equipment, and \$150,000 in contingency funds. (February 2, 2009, Initial CON Application, page 19)
19. The Hospital's projected three-year incremental revenue from operations, total operating expense and gain from operations associated with the proposal are as follows:

**Table 6: Hospital's Financial Projections Incremental to the Project**

Description	FY 2010	FY 2011	FY 2012
Incremental Revenue from Operations	\$1,648,764	\$2,978,216	\$3,237,373
Incremental Total Operating Expense	1,227,497	1,670,272	1,717,454
<b>Incremental Gain from Operations</b>	<b>\$421,268</b>	<b>\$1,307,944</b>	<b>\$1,519,918</b>

(February 2, 2009, Initial CON Application, page 25)

20. The Hospital contends that the existing total facility payer mix based on gross patient revenue is not expected to change as a result of this project:

**Table 7: Hospital's Current and Three-Year Projected Payer Mix with the Proposal**

<b>Payer</b>	<b>FY 2008 Actual FY 2009 Budget</b>	<b>Year 1 FY 2010</b>	<b>Year 2 FY 2011</b>	<b>Year 3 FY 2012</b>
Medicare*	44.41%	44.41%	44.41%	44.41%
Medicaid	9.72%	9.72%	9.72%	9.72%
TriCare & CHAMPUS	0.31%	0.31%	0.31%	0.31%
<b>Total Government</b>	<b>54.45%</b>	<b>54.45%</b>	<b>54.45%</b>	<b>54.45%</b>
Commercial Insurers	38.47%	38.47%	38.47%	38.47%
Uninsured	3.22%	3.22%	3.22%	3.22%
Workers Compensation	1.93%	1.93%	1.93%	1.93%
Other	1.93%	1.93%	1.93%	1.93%
<b>Total Non-Government</b>	<b>45.55%</b>	<b>45.55%</b>	<b>45.55%</b>	<b>45.55%</b>
<b>Total Payer Mix</b>	<b>100.00%</b>	<b>100.00%</b>	<b>100.00%</b>	<b>100.00%</b>

\* Includes managed care activity.

(February 2, 2009, Initial CON Application, page 22)

21. There is no State Health Plan in existence at this time. (February 2, 2009, Initial CON Application, page 5)
22. The Hospital has improved productivity and contained costs by undertaking energy conservation measures, group purchasing, and application of new technology. (February 2, 2009, Initial CON Application, page 17)
23. The proposal will not result in any change to the Hospital's teaching and research responsibilities. (February 2, 2009, Initial CON Application, page 18)
24. There are no characteristics of the Hospital's patient/physician mix that make the proposal unique. (February 2, 2009, Initial CON Application, page 18)

## Rationale

The Office of Health Care Access (“OHCA”) approaches community and regional need for Certificate of Need (“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.

Middlesex Hospital (“Hospital”) is a 275-bed general hospital located at 28 Crescent Street in Middletown. The Hospital operates a Cancer Center located at 536 Saybrook Road in Middletown. At the Cancer Center, the Hospital operates a linear accelerator (“Linac”) equipped with 3-D conformal radiation therapy as well as intensity modulated radiation therapy (“IMRT”). The Hospital proposes to acquire a second Linac equipped with image-guided radiation therapy (“IGRT”) to supplement the existing scanner.

The Hospital’s historical number of radiation therapy treatments was 8,700 in FY 2006; 8,683 in FY 2007; and 7,674 in FY 2008. The Hospital’s historical number of radiation therapy patients during the same period was 371, 364, and 321, respectively. The Hospital also stated that according to its Tumor Registry, during the period of FYs 2006 through 2008, the total number of diagnosed cancer cases reported at the Hospital was 888, 868, and 895, respectively. OHCA finds that the historical number of total patients for radiation therapy treatments has been declining; and also that the total number of diagnosed cancer cases according to the Hospital Tumor Registry has been relatively stable. At the same time as these volumes are declining, the Hospital contends that the current year (FY 2009) will experience an increase of 1,000 treatments based on an additional eight patients; and then projects increasing volume for the next three years following the current year. The Hospital has failed to demonstrate how this increase will be realized in FY 2009 and therefore OHCA is unable to conclude that the Hospital’s projections or estimates upon which they are based are reasonable. Accordingly, OHCA concludes that the Hospital has failed to demonstrate that a clear public need exists for the acquisition of a second Linac at the Hospital.

Nevertheless, OHCA finds that the Hospital has been experiencing increasing downtime on the existing scanner. According to the Hospital’s study of unscheduled downtime, such downtime increased from 18.25 hours in FY 2006, to 24.5 hours in FY 2007, and 29.0 hours in FY 2008. Therefore, OHCA concludes that replacement of the existing Linac would alleviate the growing problems related to its downtime, without creating excess capacity. Despite the lack of need for a second Linac, such a replacement would improve access to quality radiation therapy services for patients in the Hospital’s service area.



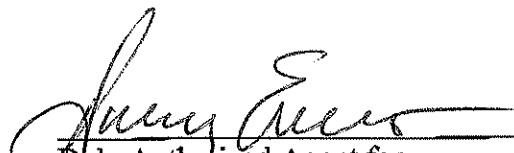
## Order

**NOW, THEREFORE**, the Office of Health Care Access (“OHCA”) and Middlesex Hospital (“Hospital”) hereby stipulate and agree to the terms of settlement with respect to the Hospital’s request to acquire a second Linear Accelerator (“Linac”) equipped with Image-Guided Radiation Therapy (“IGRT”) at Middlesex Hospital at a proposed total capital expenditure of \$5,226,899.

1. The Hospital’s request to acquire a second Linac equipped with IGRT at Middlesex Hospital at a proposed total capital expenditure of \$5,226,899 is **denied**.
2. The Hospital is hereby **approved** to replace the existing Linac, located at the Hospital’s Cancer Center at 536 Saybrook Road in Middletown, with the proposed Linac equipped with IGRT at Middlesex Hospital at a proposed total capital expenditure of \$5,226,899.
3. The Applicants and OHCA agree that the existing linear accelerator may be maintained as property owned by Middlesex Hospital. The Applicants agree that the existing unit shall not be used for purposes of any direct or indirect patient care. This unit shall not be used for the scheduling of radiation therapy services or for the purpose of a back up unit during scheduled or unscheduled downtime on the new unit. No radiation therapy treatments, nor any other diagnostic or therapeutic services, may be performed using the existing unit by Middlesex Hospital or any other entity.
4. At the time that the Hospital finds that it has sufficient utilization to warrant the reactivation of the existing unit as a functioning Linac providing patient care services, the Hospital shall then seek a determination from OHCA. This agreed settlement does not specifically guarantee OHCA authorization in the future regarding the reactivation of the existing unit.
5. This authorization shall expire on May 12, 2010. Should the approved Linac project not be completed by that date, the Hospital must seek further approval from OHCA to complete the project beyond that date.
6. The Hospital shall not exceed the approved capital expenditure of \$5,226,899. In the event that the Hospital learns of potential cost increases or expects that final project costs will exceed those approved, the Hospital shall notify OHCA immediately.
7. OHCA and Middlesex Hospital agree that this Agreed Settlement represents a final agreement between OHCA and the Hospital with respect to this request. The signing of this Agreed Settlement resolves all objections, claims and disputes, which may have been raised by the Applicants with regard to Docket Number: 08-31262-CON.

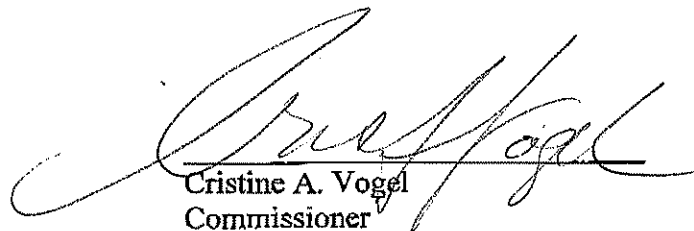
8. This Agreed Settlement is an order of the Office of Health Care Access with all the rights and obligations attendant thereto, and the Office of Health Care Access may enforce this Agreed Settlement pursuant to the provisions of Sections 19a-642 and 19a-653 of the Connecticut General Statutes at the Applicants' expense, if the Hospital fails to comply with its terms.

5/12/09  
Date

  
Duly Authorized Agent for  
Middlesex Hospital

The above Agreed Settlement is hereby accepted and so ordered by the Office of Health Care Access on May 12, 2009.

5-14-09  
Date

  
Cristine A. Vogel  
Commissioner

CAV:agf