

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

Agreed Settlement

Applicant: Middlesex Hospital
28 Crescent Street, Middletown, CT

Docket Number: 15-31985-CON

Project Title: Acquisition of a non-hospital based linear accelerator

Project Description: On March 11, 2015, Middlesex Hospital ("Applicant" or "Middlesex") submitted a certificate of need ("CON") application to the Office of Health Care Access ("OHCA") of the Department of Public Health seeking approval to acquire a non-hospital based linear accelerator to be located at its facility at 250 Flat Rock Place, Westbrook, CT ("Shoreline site"), with an associated capital cost of \$3,800,000.

Procedural History: The Applicant published notice of its intent to file a Certificate of Need ("CON") application in *The Middletown Press* (Middletown) on February 4, 5 and 6, 2015. On March 11, 2015, the Office of Health Care Access ("OHCA") received the CON application from the Applicant for the above-referenced project and deemed the application complete on July 9, 2015. OHCA received public responses concerning the proposal from Yale Therapeutic Radiology and Yale New Haven Health.

On July 24, 2015, the Applicant was notified of the date, time, and place of the public hearing. On August 6, 2015, a notice to the public announcing the hearing was published in *The Middletown Press*. Also on August 6, 2015, a public hearing was requested by three members of the public. Commissioner Jewel Mullen designated Attorney Kevin T. Hansted as the hearing officer in this matter.

On August 21, 2015, OHCA received a petition from Yale-New Haven Hospital to be designated as an intervenor with full rights of cross-examination. The Hearing Officer granted the petition of Yale-New Haven Hospital ("Intervenor" or "YNHH").

Thereafter, pursuant to Connecticut General Statutes ("Conn. Gen. Stat.") § 19a-639a(f), a public hearing regarding the CON application was held on August 27, 2015 at the discretion of OHCA. The hearing was conducted in accordance with the provisions of the Uniform Administrative Procedure Act (Chapter 54 of

the Conn. Gen. Stat.) and Conn. Gen. Stat. § 19a-639a and the Hearing Officer heard testimony from witnesses for the Applicant and the Intervenors. The public hearing record was closed on September 30, 2015. In rendering this final decision, Deputy Commissioner Brancifort considered the entire record and proceeding.

Findings of Fact and Conclusions of Law

1. Middlesex Hospital (the "Applicant" or "Hospital") is a not-for-profit, acute care hospital located at 28 Crescent Street in Middletown, CT. It is a subsidiary of Middlesex Health System, Inc. Exhibit B, p. 6.
2. Shoreline Medical Center ("Shoreline") is a satellite office of the Hospital located at 250 Flat Rock Place, Westbrook, CT, and offers emergency care, women's services, imaging and laboratory services, infusion therapy and chronic care management. Exhibit B, p. 11.
3. The Applicant operates the Middlesex Hospital Cancer Center at its main outpatient campus, located at 536 Saybrook Road, Middletown, where it currently operates two linear accelerators ("LINACs"), a 2002 Varian 2100SCX ("Varian") and a Novalis TX ("Novalis"). Exhibit B, pp. 10, 15-16.
4. In 2008, OHCA entered into an Agreed Settlement with the Applicant (docket number 08-31262-CON) approving the Applicant's acquisition of the Novalis. Included in the Agreed Settlement was a condition that, although the existing Varian could be kept, it could not recommence treating patients until the Hospital demonstrated sufficient demand for two LINACs. In 2010, OHCA approved a Modification of the Agreed Settlement (Docket Number 10-31262) based on the Hospital's assertion that ". . . although the Novalis TX delivers both IMRT [Intensity Modulated Radiation Therapy] and SBRT [Stereotactic Body Radiation Therapy], it was not designed as a standalone unit. The maximum field size on the Novalis TX is 22 x 40 cm compared to the 40 x 40 cm on the Varian 2100 SCX. Accordingly, patients with very large treatment volumes, such as those with Hodgkin's Lymphoma or ovarian or cervical cancer, cannot be treated on the Novalis TX." Docket Number 10-31262 FF 15,16.
5. The Applicant proposes disposing of its Varian and acquiring an Elekta Infinity LINAC ("Elekta"), selected for its image-guided radiation that includes Volumetric Modulated Arc Therapy that enables a more targeted dose around a tumor. The Applicant proposes locating the Elekta at its satellite Shoreline site. Only the Novalis would remain at Middlesex Hospital. Exhibit B, pp. 10, 31.
6. The Applicant asserts that the proposal would enable Middlesex to better provide more convenient access to its radiation therapy for a number of shoreline cancer patients. Mr. Vincent Capece, President and Chief Executive Officer of Middlesex Hospital, elaborated that the proposal will enable the Applicant to maximize convenience for its Shoreline-area patients by reducing the number of trips to Middletown for their treatment. Exhibit X, Tr. Testimony of Mr. Vincent Capece, pp. 10, 11.
7. Patients originating from Middletown represented the largest percentage (25.7%) of Connecticut residents receiving LINAC treatment from the Hospital in FY2014. Exhibit Y, pp. 7-8.
8. The Applicant's service area towns were categorized into either the "Shoreline Area" or "Middletown Area" based on their relative distance to either the Shoreline site or Middlesex Hospital.

TABLE 1
LINAC SERVICE AREA BY DISTANCE TO MIDDLESEX HOSPITAL AND WESTBROOK

Area	Town	Driving Miles to Middlesex*	Driving Miles to Westbrook**
Shoreline Area	Chester	14.1	11.2
	Clinton	19.9	5.6
	Deep River	17.9	8.6
	Essex	18.5	5.6
	Killingworth	16.1	11.1
	Madison	20.3	7.9
	Old Saybrook	24.8	5.3
	Westbrook	23.7	1.8
Middletown Area	Colchester	21.7	28.1
	Cromwell	4.5	27.7
	Durham	6.5	22.9
	East Haddam	15.4	19.9
	East Hampton	11.9	25.6
	Haddam	7.8	17.2
	Marlborough	16.2	36.2
	Middlefield	6.1	26.6
	Middletown	2.4	25.6
	Portland	3.7	26.9

*Estimated using Google Maps from town listed to 536 Saybrook Road, Middletown CT 06457

**Estimated using Google Maps from town listed to 250 Flat Rock Place, Westbrook, CT 06498

9. From FY2012 through FY2014, an average of almost 3 out of 4 patients originated from the Middletown Area.

TABLE 2
HISTORIC PATIENT VOLUME BY SERVICE AREA *

	FY 2012	% of total	FY 2013	% of total	FY 2014	% of total	3 year average	% of average
Shoreline Area	111	32%	99	26%	100	26%	103	28%
Middletown Area	239	68%	286	74%	279	74%	268	72%
Total	350		385		379		371	

* Excludes out-of-state patients and patients outside of the Applicant's service area.
Exhibit Y, pp. 7-8.

10. From FY2012 through FY2014, 78% of LINAC treatments were administered to patients originating from the Middletown Area.

TABLE 3
HISTORIC TREATMENT*VOLUME BYSERVICE AREA**

	FY 2012		FY 2013		FY 2014		Average	
	Treatments	% of total	Treatments	% of total	Treatments	% of total	Treatments	% of average
Shoreline Area	1,487	24%	1,634	23%	1,226	19%	1,449	22%
Middletown Area	4,760	76%	5,542	77%	5,168	81%	5,157	78%
Total	6,247		7,176		6,394		6,606	

* Treatment volumes reflect only radiation therapy treatments and do not include tests such as image guidance, port films and dosimetry.

** Excludes out-of-state patients and patients outside of the Applicant's service area.
Exhibit Y, pp. 7-8.

11. The Applicant's projected treatment utilization is shown on the table below:

TABLE 4
CURRENT AND PROJECTED TREATMENT* VOLUME

Machine / Location	Current FY2015**	Projected Volume			
		FY 2016	FY 2017	FY 2018	FY 2019
Varian (Middlesex)	5263	5,417	2,777	n/a	n/a
Novalis (Middlesex)	3326	3,423	5,146	5,887	6,061
Elekta (Proposed at Shoreline site)	n/a	n/a	1,685	3,513	3,609
Total	8,589	8,840	9,109	9,400	9,670

* Treatment volumes reflect only radiation therapy treatments and do not include tests such as image guidance, port films and dosimetry.

** Annualized based on Oct 2014 through March 2015 data
Exhibit N, p. 193.

12. Of the 125 breast cancer patients treated at the Hospital during FY2014, three (2%) were treated on the Novalis and 122 (98%) were treated on the Varian, which the Applicant proposes disposing of. Exhibit D, pp. 164-68.
13. The Applicant testified that the Varian was used to treat the majority of breast cancer patients primarily for "logistical concerns." Exhibit N, Responses to Letters Filed by Yale New Haven Health and Yale Medical Group, pp. 201, 203; Exhibit X, Transcript, Dr. Joseph Weissberg, Chairman of the Department of Radiation Oncology of Middlesex Hospital, pp. 83-86.

14. The Applicant represented that although in 2010 when it applied for CON approval to acquire the Novalis it could not be used as a stand-alone unit, its “knowledge of, and expertise with the use of IMRT and SRS/SBRT modalities has grown to the extent that the Novalis TX can now be used as a stand-alone unit. Exhibit D, p. 162.
15. The Applicant represented that no changes were made to the Novalis machine to enable it to treat Non-Hodgkin’s or Endometrial Cancers. Exhibit D, p. 162.
16. The Applicant represented in its CON application that patients with Non-Hodgkin’s Lymphoma and Endometrial Cancer could not be treated on the Novalis at Middlesex. However, later during public hearing testimony, Dr. Joseph Weissberg, Chairman of the Department of Radiation Oncology at Middlesex, testified that that was not accurate and such patients could receive treatment on the Novalis. Exhibit D, p. 163; Exhibit X, Transcript, Dr. Joseph Weissberg, pp. 83-85.
17. Dr. Peter Glazer, Chief of Radiation Oncology at YNHH, testified that the “Novalis has a smaller field size, which means the size of the radiation beam that can be emitted from the machine is smaller than most other LINACs, and this smaller field size necessarily means that there will be a subset of patients, who cannot be optimally treated on that equipment.”
Exhibit X, Transcript, Dr. Peter Glazer, p. 41.
18. Dr. Glazer explained the relevance of differences in field sizes, stating “the idea is to maximize the dose to the tumor and minimize the dose to the healthy tissues. So, with a field size limitation, the ability to achieve the best difference between healthy tissue and tumor tissue is reduced on the Novalis for some patients, in our experience, 15 to 25 percent.” He testified that although a treatment plan using the Novalis could be developed, it would not be as good as one without the limitation. He also testified that YNHH has multiple LINACs available and can treat patients for which the Novalis is not the ideal machine. Exhibit X, Transcript, Dr. Peter Glazer, pp. 42-3.
19. The Applicant’s CT-Simulator is located at its main campus in Middletown. All patients require at least one to two CT-Simulation visits, with some requiring more. Patients receiving treatment in Westbrook would be required to travel to Middletown for CT-Simulation. Exhibit N, p. 192
20. The Applicant acknowledged that other providers are exploring the potential of therapy plans that incorporate doing additional, possibly weekly, Simulations. The Applicant is not currently adopting this practice; however, it may routinely do three or four simulations in the future. Exhibit X, Transcript, Dr. Joseph Weissberg, Chairman of the Department of Radiation Oncology of Middlesex Hospital, pp.122-23.
21. CT-Simulation data from the radiation oncologists at Middlesex can be electronically transmitted to the treating physician at the Shoreline site. Exhibit X, Transcript, Dr. Joseph Weissberg, Chairman of the Department of Radiation Oncology of Middlesex Hospital, p. 121.
22. YNHH notes that by separating the site of simulation from the site of treatment, valuable interactions between the physician, simulation therapist, dosimetrist and treatment therapist are diminished. Dr. Peter Glazer testified that it is well-established that hand offs are a point in treatment when quality can be degraded and patient safety issues can arise. Exhibit X, Transcript, Dr. Peter Glazer, Chief of Radiation Oncology at Yale New Haven Hospital, pp. 38-39.

23. "Dislocation of a patient from an organized continuum of care for arbitrary geographical or institutional distribution of equipment should be resisted by both patient and physician. In the past, the use of ill-conceived formulas to geographically distribute facilities and radiation treatment units fostered mediocrity at the expense of programs successful because of high quality service." Inter-Society Council of Radiation Oncology, *Criteria for Utilization of Service*, Report Excerpt 111, 113 (1991). Exhibit Y, p. 18.
24. Shoreline patients needing stereotactic radiosurgery ("SRS") would be required to travel to Middletown. According to Dr. Weissberg, the Elekta would be used only for stereotactic body radiation therapy (SBRT) and patients requiring SRS treatment would be best treated on the Novalis, located at Middlesex. Exhibit X, Transcript, Dr. Joseph Weissberg, pp. 67-8.
25. The Applicant estimates that three patients annually, due to a brain tumor less than 3 centimeters, could not be treated on the Elekta and would need to travel to Middlesex for treatment on the Novalis. It also claims that only one patient per year would require a field size larger than that offered by the Novalis and would need to travel to Shoreline for treatment on the Elekta. Exhibit D, pp. 163-164; Exhibit N, p. 190.
26. YNHH's Senior Vice president of Operations testified that "in light of the fact that the linear accelerator which is to remain in Middletown [the Novalis] has limited, specialized capabilities, and the linear accelerator proposed to be moved to Westbrook cannot provide most SRS/SBRT treatments, the Applicant's estimates appear to be significantly understated." Exhibit P, Prefiled Testimony of Mr. Abe Lopman, Senior Vice President of Operations, Yale New Haven Hospital, p. 7.
27. Dr. Glazer testified that patients requiring a larger field size could be treated on the Novalis but sub-optimally, explaining that cervical and endometrial cancers often require a larger field size to encompass not just the directly impacted organs but the draining lymph nodes in the pelvis and abdomen as well. Likewise, for the treatment of non-Hodgkin's Lymphoma the lymph nodes in the neck, chest and the armpits must also be treated, requiring a large field size. Exhibit X, Transcript, Dr. Peter Glazer, Chief of Radiation Oncology, Yale New Haven Hospital, pp.41-42.
28. Dr. Glazer testified that he is not aware of any other facility in the country that uses a Novalis TX Radiosurgery as the only linear accelerator in its cancer center. Exhibit P, Pre-file Testimony, Dr. Peter Glazer, Chief of Radiation Oncology, Yale New Haven Hospital, p. 4.

29. There are three full-service existing providers of LINAC treatment in proximity to the Shoreline site.

**TABLE 5
EXISTING LINAC PROVIDERS IN THE AREA**

Provider	Address	Service	FY2013*	FY2013**	2014	Days of Operation	Number of LinAcs
Yale New Haven Hospital	111 Goose Lane, Guilford, CT	Radiation Therapy	46,200	38,351	37,256	Mon - Fri	8***
Lawrence & Memorial Hospital	230 Waterford Parkway South, Waterford CT	Radiation Therapy	9,439	8,251	9,666	Mon - Fri	2
Middlesex Hospital	536 Saybrook Road, Middletown	Radiation Therapy	12,571	8,914	8,211	Mon - Fri	2

* Based on data obtained from OHCA Report 450 (Linear Accelerator outpatient procedures)

** Based on data obtained from CHIME Data Patient Census Report (Outpatient Radiation Therapy)

*** Includes Saint Raphael, Yale-New Haven's York Street Campus and SMC

Exhibit B, p. 20, Exhibit P, Prefiled Testimony of Abe Lopman, p. 3.

30. YNHH's Shoreline Medical Center in Guilford, located 13 miles from the site of the proposal, provides radiation therapy including conventional radiotherapy, electron beam radiotherapy, three dimensional conformal radiotherapy, intensity modulated radiotherapy and stereotactic body radiotherapy in addition to a dedicated, on-site large bore CT-Simulator. Exhibit P, p. 3

31. Lawrence and Memorial Hospital, located 18 miles from the site of the proposal, operates two LINACs at its cancer center in Waterford and offers image guided radiation therapy, intensity modulated radiation therapy, stereotactic radiosurgery and stereotactic body radiotherapy and has a dedicated, on-site large bore CT-Simulator. Exhibit P, Prefiled Testimony of Abe Lopman, pp. 2- 3; Exhibit X, Tr. Testimony of Abe Lopman, p. 30.

32. There are 14 existing LINACs in a 28 mile radius from the Shoreline site. Exhibit P, Prefiled Testimony of Abe Lopman, p. 3.

33. YNHH states that based on its FY14 utilization, it has additional LINAC capacity at its Guilford location. Exhibit Z, p. 4.

34. The Applicant asserts that the proposal would promote a diversity of providers in the proposal's region. Exhibit X, Tr. Testimony of Mr. Vincent Capece, President and Chief Executive Officer, Middlesex Hospital, p. 14.

35. The Applicant claims that access to care for Medicaid patients who live closer to the Shoreline area may be improved by the proposal. Exhibit N, p. 192.

36. The Applicant does not project any changes in the payer mix of patients receiving LINAC treatment as a result of this proposal.

TABLE 6
APPLICANT'S CURRENT & PROJECTED LINAC PAYER MIX

Payer	FY 2014*		Projected					
			FY 2015*		FY 2016*		FY 2017*	
	Visits	%	Visits	%	Visits	%	Visits	%
Medicare	3,878	47%	3,994	47%	4,111	47%	4,236	47%
Medicaid	567	7%	610	7%	628	7%	647	7%
CHAMPUS & TriCare	-	-	-	-	-	-	-	-
Total Government	4,445	53.3%	4,604	54%	4,738	54%	4,882	65%
Commercial Insurers	3,869	46.4%	3,985	46%	4,102	44%	4,227	36%
Uninsured	25	.3%	-	-	-	-	-	-
Workers Compensation	0	0%	-	-	-	-	-	-
Total Non-Government	3,894	46.7%	3,985	46%	4,102	46%	4,227	36%
Total Payer Mix	8,339	100%	8,589	100%	8,840	100%	9,109	100%

*FY includes the period covered by FY October 1 through September 30; assumes no change in payer mix Exhibit B, p. 33; Exhibit Y, p. 11.

37. Based on FY2014 Connecticut hospital inpatient discharge data, 23% of patients originating from Middletown, which account for the largest percentage of the Applicant's LINAC patients, have Medicaid insurance.

**TABLE 7
MEDICAID INPATIENT DISCHARGES FROM APPLICANT'S SERVICE AREA**

	Middlesex Service Area	Total Discharges	Medicaid Discharges	% Medicaid
Shoreline Area	Chester	412	41	10%
	Clinton	1,315	263	20%
	Deep River	401	66	16%
	Essex	622	76	12%
	Haddam	716	59	8%
	Killingworth	518	38	7%
	Madison	1,582	139	9%
	Old Saybrook	1,257	119	9%
	Westbrook	758	129	17%
		Subtotal	7,581	930
Middletown Area	Colchester	1,494	195	13%
	Cromwell	1,685	214	13%
	Durham	616	42	7%
	East Haddam	726	108	15%
	East Hampton	1,235	208	17%
	Haddam	716	59	8%
	Marlborough	544	62	11%
	Middlefield	435	43	10%
	Middletown	5,867	1,377	23%
	Portland	994	126	13%
		Subtotal	14,312	2,434
Total Service Area		21,177	3,305	16%

Exhibit E, Letter from YNH to OHCA, p. 7.

38. Acquisition of the new LINAC will not require any changes in the existing price structure and no additional facility fees will be imposed as the result of this proposal. Exhibit B, p. 19.
39. The capital expenditures associated with the proposal would be offset by an estimated \$50,000 resale value of the Varian.

**TABLE 8
TOTAL PROPOSAL CAPITAL EXPENDITURE**

Purchase/Lease	Cost
Equipment (medical, non-medical imaging)	\$2,600,000
Construction/renovation	\$1,200,000
Total Capital Expenditure	\$3,800,000

Exhibit B, pp. 31, 35.

40. The proposal will have incremental losses in the first three full years of operation due to the acquisition costs (e.g., depreciation, interest) of the new LINAC.

TABLE 9
PROJECTED INCREMENTAL REVENUES AND EXPENSES

	FY 2016	FY 2017*	FY 2018	FY 2019
Revenue from Operations	\$0	\$209,000	\$295,000	\$430,000
Total Operating Expenses	\$0	\$420,000	\$737,000	\$750,000
Gain/Loss from Operations	\$0	(\$211,000)	(\$441,000)	(\$319,000)

* Proposed start of operations of LINAC services at Shoreline site
Exhibit B, p. 146.

41. OHCA is currently in the process of establishing its policies and standards as regulations. Therefore, OHCA has not made any findings as to this proposal's relationship to any regulations not yet adopted by OHCA. (Conn. Gen. Stat. § 19a-639(a)(1)).
42. This CON application is consistent with the overall goals of the Statewide Health Care Facilities and Service Plan. (Conn. Gen. Stat. § 19a-639(a)(2)).
43. The Applicant has not satisfactorily established that there is a clear public need for the proposal. (Conn. Gen. Stat. § 19a-639(a)(3)).
44. The Applicant has satisfactorily demonstrated that the proposal is financially feasible. (Conn. Gen. Stat. § 19a-639(a)(4)).
45. The Applicant has not satisfactorily demonstrated that the proposal will maintain quality, accessibility and cost effectiveness of health care delivery in the region. (Conn. Gen. Stat. § 19a-639(a)(5)).
46. The Applicant has not sufficiently shown that there would be no adverse change in the provision of health care services to the relevant populations and payer mix, including access to services by Medicaid recipients and indigent persons. (Conn. Gen. Stat. § 19a-639(a)(6)).
47. The Applicant has not satisfactorily identified the population to be affected by this proposal. (Conn. Gen. Stat. § 19a-639(a)(7)).
48. The Applicant's historical provision of radiation therapy services in the area does not support this proposal. (Conn. Gen. Stat. § 19a-639(a)(8)).
49. The Applicant has not satisfactorily demonstrated that this proposal would not result in an unnecessary duplication of existing services in the area. (Conn. Gen. Stat. § 19a-639(a)(9)).
50. The Applicant has not sufficiently demonstrated that there will be no reduction in access to services by Medicaid recipients or indigent persons. (Conn. Gen. Stat. § 19a-639(a)(10)).

51. The Applicant has satisfactorily demonstrated that the proposal will not have a negative impact on the diversity of health care providers in the area. (Conn. Gen. Stat. § 19a-639(a)(11)).
52. The proposal would not result in any consolidation that would affect health care costs or accessibility to care. (Conn. Gen. Stat. § 19a-639(a)(12)).

DISCUSSION

CON applications are decided on a case by case basis and do not lend themselves to general applicability due to the uniqueness of the facts in each case. In rendering its decision, OHCA considers the factors set forth in § 19a-639(a) of the Statutes. The Applicant bears the burden of proof in this matter by a preponderance of the evidence. *Jones v. Connecticut Medical Examining Board*, 309 Conn. 727 (2013).

Middlesex Hospital (the "Applicant" or "Hospital" or "Middlesex") is a not-for-profit, acute care hospital, located at 28 Crescent Street in Middletown, CT and is a subsidiary of Middlesex Health Systems, Inc. *FF1*. Shoreline Medical Center ("Shoreline site") is a satellite office of the Hospital located at 250 Flat Rock Place, Westbrook, CT that offers emergency care, women's services, imaging services, infusion therapy and chronic care management. *FF2*.

The Applicant offers oncology services at the Middlesex Hospital Cancer Center where it currently operates two linear accelerators ("LINACs"): a 2002 Varian 2100SCX ("Varian") and a Novalis TX ("Novalis"). *FF3*. The Applicant proposes selling its existing 13-year old Varian and purchasing a new Elekta Infinity LINAC ("Elekta"), with image-guided radiation that includes Volumetric Modulated Arc Therapy that enables a more targeted dose around a tumor. The Elekta would be installed at the Applicant's Shoreline site, and, after the removal of the Varian, only the Novalis would remain at Middlesex Hospital. *FF5*.

The Applicant has not shown the proposal would not result in an unnecessary duplication of services

There are other providers of LINAC services already established in the area of the Shoreline site. *FF29*. YNHH's Shoreline Medical Center in Guilford, located 13 miles from the site of the proposal, provides comprehensive radiation therapy including conventional radiotherapy, electron beam radiotherapy, three dimensional conformal radiotherapy, intensity modulated radiotherapy and stereotactic body radiotherapy in addition to a dedicated, on-site large bore CT-Simulator. *FF30*. YNHH has stated it has available capacity to treat additional patients at its Guilford location. *FF33*.

Additionally, Lawrence and Memorial Hospital, located 18 miles from the site of the proposal, operates two LINACs at its cancer center in Waterford and offers image guided radiation therapy, intensity modulated radiation therapy, stereotactic radiosurgery and stereotactic body radiotherapy and has a dedicated, on-site large bore CT-Simulator. *FF31*.

Due to the existence of other providers and available capacity in the proposal's area, the Applicant has failed to demonstrate that the project would not result in an unnecessary duplication of services. Additionally, the Applicant claims that the proposal will promote more options in terms of LINAC providers for patients in the area. *FF34*. While this may be true, Connecticut General Statute section 19a-639(a)(11) requires consideration of whether the proposal "will not negatively impact the diversity of health care providers and patient choice in the geographic region." Clearly, this particular criteria is intended to eliminate any negative impact on existing providers, not increase the diversity of providers. Consequently, the Applicant's argument is misplaced.

While the Applicant's historic LINAC utilization over the past three fiscal years may justify its continued use of two LINAC's, the Applicant has not satisfactorily demonstrated a clear public need to dispose of a LINAC from its cancer center at Middlesex to acquire and locate a LINAC at the Shoreline site. The

Shoreline site would not offer comprehensive care and still require patients to travel to Middlesex. Additionally, the Applicant has not demonstrated that doing so would maintain access to quality care.

Shoreline would not be a comprehensive care center, undermining claims of improved access and quality of care for Shoreline Area residents

It is undisputed that all LINAC patients require at least one CT-Simulation visit to plan LINAC treatments, but some require additional visits due to the radiation-targeted area's migration or the patient's body composition changing over the course of treatment. The Applicant's proposal lacks the inclusion of a CT-Simulator at its Shoreline site and requires patients from that area travel to Middlesex for CT-Simulation(s). *FF19*. The Applicant claims that patients at the Shoreline site would not be unduly burdened by travel to Middlesex to receive CT-Simulations and that its electronic record transmissions would allow for their uninterrupted treatment. *FF21*.

As stated in *Criteria for Utilization of Service*, submitted by the Applicant, "dislocation of a patient from an organized continuum of care for [reasons such as] an arbitrary geographical or institutional distribution of equipment should be resisted by both patient and physician. In the past, the use of ill-conceived formulas to geographically distribute facilities and radiation treatment units fostered mediocrity at the expense of programs successful because of high quality service." *FF22*. YNHH raises a similar concern of the proposed, bifurcated service. Dr. Peter Glazer, Chief of Radiation Oncology at Yale-New Haven Hospital, stated that, "by separating the site of simulation from the site of treatment, valuable interactions between the physician and the simulation therapist, dosimetrist and the treatment therapist are diminished" and that "in medicine, it's well-established that handoffs are a place where quality can be degraded and patient safety issues can arise." *FF23*.

The Applicant also acknowledged that other providers were exploring therapy plans that rely on more Simulations, with providers investigating doing simulations weekly for patients. *FF20*. Such additional CT-Simulations would require additional trips to Middlesex. The Shoreline site, as proposed, would not be a comprehensive care center due to the lack of a CT-Simulator and would disrupt communication between patients' physicians conducting CT-Simulations at Middlesex and those conducting LINAC treatments at the Shoreline site. The proposal's necessitating Shoreline Area patients travel to Middlesex for CT-Simulation undermines the Applicant's assertion that it improves access for those cancer patients.

Access is compromised by having only a single LINAC in Middlesex

Notably, leaving a single LINAC at Middlesex also implies that during periods when the Novalis requires maintenance or is inoperable, patients' treatment in the higher-volume area would be interrupted due to the lack of a back-up machine at Middlesex—the Applicant's primary cancer treatment center.

As such, the Applicant's claims that locating the new Elekta at its Shoreline site would improve access for its patients is unfounded as the majority of its patients are located in the Middletown area, as defined below, where services would likely be compromised by the proposal. *FF9*.

The Applicant has not demonstrated there is a clear public need to locate the Elekta in its Shoreline Region

The Applicant repeatedly claimed that locating the new Elekta LINAC at its Shoreline site would be more convenient for its patients located in that area. Mr. Vincent Capece, President and CEO of Middlesex Hospital, testified that the proposal would enable Middlesex to "better provide more convenient access to

its radiation therapy for a large number of shoreline cancer patients,” and that he “respect[s] the fact that there are differing estimates as to how many of [its] patients would find the linear accelerator in Westbrook more convenient” Mr. Capece elaborated that the proposal will enable the Applicant to maximize convenience for its Shoreline-area patients by reducing the number of trips to Middletown for their treatment. *FF6*. Although the proposal may reduce travel time for some Shoreline-area patients, convenience for a minority of patients is insufficient to demonstrate a clear public need for a LINAC in a given area.

In order to assess whether there is a clear public need for an additional LINAC in a given area it must, in part, be determined how many patients would receive treatment in that area. Based on historic utilization, patients originating from towns within the Applicant’s service area that are geographically closer to Middlesex (“Middletown Area”) would presumably seek LINAC treatment at Middlesex. Likewise, patients originating from towns closer to its Shoreline site (“Shoreline Area”) would presumably seek treatment there. *FF8*. During FY12 through FY14, the Applicant provided LINAC treatment to an average of 371 patients within its service area each year. *FF9*. Seventy-two percent of patients originated from the Middletown Area while only 28% originated from the Shoreline Area and, based on that, it can be expected that the great majority of future patients would seek treatment in Middletown. *FF9*.

The Applicant’s proposal includes locating the newer Elektra at the Shoreline site and disposing of a LINAC from its higher-volume main cancer center at Middlesex, leaving Middlesex with a single older machine to treat the great majority of its cancer patients.

The Applicant has not satisfactorily demonstrated how the proposal will improve the quality of health care delivery in the region

The two LINACs currently at the Hospital offer different field sizes and are capable of treating different tumor sizes and different types of cancers. The Applicant claims that the Novalis alone would be capable of treating virtually all types of cancers, despite its smaller field size. It also stated that the Elekta would be able to treat all patients presenting at its Shoreline site. *FF14*. However, the Applicant has been inconsistent in its position.

In 2010, OHCA approved the Applicant’s request to operate both the Novalis and the Varian at Middlesex. The Applicant requested authorization to employ both the Novalis and Varian based on its claim that “the Novalis . . . was not designed as a standalone unit. The maximum field size on the Novalis TX is 22 x 40 cm compared to the 40 x 40 cm on the Varian 2100 SCX. Accordingly, patients with very large treatment volumes, such as those with Hodgkin’s Lymphoma or ovarian or cervical cancer, cannot be treated on the Novalis TX.” *FF4*. Reversing its position, the Applicant now claims that, although it has made no changes to the machine, due to its increased knowledge of the technology, the Novalis can be used as a stand-alone unit. *FF15,16*.

Additionally, echoing statements made in its 2010 Modification Request, the Applicant stated in its application that patients diagnosed with Non-Hodgkin’s Lymphoma and endometrial cancer could not be treated with the Novalis. *FF4*. However, the Chairman of the Department of Radiation Oncology of Middlesex Hospital, Dr. Joseph Weissberg, testified during the hearing in this matter that the application was inaccurate and the Novalis was capable of treating those patients. *FF16*.

It is also unclear whether breast cancer patients would be able to receive the same quality of care on the Novalis. In 2014, only 2% of the Applicant’s 125 breast cancer patients were treated on the Novalis. The remaining 98% were treated on the Varian, which the Applicant proposes disposing of to purchase the

new Elekta. *FF12*. The Applicant states that the Varian was the machine used almost exclusively to treat breast cancer patients for “logistical concerns” and maintains that patients could be treated on either the Novalis or new Elekta. *FF13*. However, the Applicant did not adequately explain those logistical concerns.

Moreover, according to Dr. Weissberg, the Elekta would be used only for stereotactic body radiation therapy (“SBRT”) and patients requiring stereotactic radiosurgery (“SRS”) treatment would be best treated on the Novalis, located at Middlesex. *FF24*. Consequently, Shoreline patients needing SRS would be required to travel to Middletown.

The Applicant claims that, based on its historical treatment patterns, approximately one patient each year would, due to a larger tumor size, not be treatable on the Novalis at Middlesex. It also claims that only three patients each year, due to a brain tumor smaller than 3 centimeters, would not be treatable on the Elektra at Shoreline. It claims that only these patients would be required to travel to the alternate LINAC based on treatment limitations of the independent machines. *FF25*. YNHH contests this estimation, testifying that, “In light of the fact that the linear accelerator to remain in Middletown [the Novalis] has limited, specialized capabilities, and the linear accelerator proposed to be moved to Westbrook [the Elekta] cannot provide most SRS/SBRT treatments, the Applicant’s estimates appear to be significantly understated.” *FF26*.

YNHH does concur with the Applicant’s assessment that patients requiring a larger field size could be treated on the Novalis, however YNHH disputes that patients would receive the same quality of care. YNHH states treatment for some patients would be sub-optimal, explaining that Cervical and Endometrial cancers often require a larger field size to encompass not just the directly impacted organs but the draining lymph nodes in the pelvis and abdomen as well. Additionally, YNHH states that for the treatment of non-Hodgkin’s Lymphoma, the lymph nodes in the neck, chest and the armpits must also be treated and require a large field size. *FF27*. YNHH also notes that it is not aware of any other cancer center in the country that utilizes the Novalis as a standalone machine. *FF28*. Dr. Peter Glazer, Chief of Radiation Oncology at YNHH, explained, “the idea is to maximize the dose to the tumor and minimize the dose to the healthy tissues. So, with a field size limitation, the ability to achieve the best difference between healthy tissue and tumor tissue is reduced on the Novalis for some patients, in our experience, 15 to 25 percent. . .” He also stated that although a treatment plan could be developed using the Novalis, it would not be as good as one that was based on a machine with a larger field size. *FF18*.

As stated above, a large majority of the Applicant’s patients originate from the Middletown Area and would likely opt to be treated at Middlesex Hospital. The Applicant has not sufficiently demonstrated that the Novalis alone would be able to provide the same level of access to quality treatment at Middlesex that the Applicant is currently able to provide its patients via both the Novalis and the Varian machines.

The Applicant has not provided reliable evidence that the proposal would maintain the quality of care for patients seeking treatment for various types of cancer. Additionally, access to care would be jeopardized by the elimination of a machine from the main cancer treatment center at the hospital, particularly during periods when the single, remaining LINAC may be unavailable. For the above reasons, the Applicant has failed to demonstrate that there is a clear public need to acquire a LINAC for its Shoreline site.

The proposal would likely be financially feasible for the Applicant

Although the proposal would result in projected incremental losses for the Applicant from FY2016 through FY2019 due to depreciation attributable to its purchase of the Elekta, the Applicant projects overall gains. *FF40*. As such, overall, the proposal is likely financially feasible for the Applicant.

The Applicant has not adequately demonstrated that access to services for Medicaid patients would not be negatively impacted by the proposal

The Applicant claims that access to care for Medicaid patients in its Shoreline Area may be improved. *FF35*. However, the Applicant fails to take into consideration the proposal's impact on the town with the highest percentage of Medicaid patients in its service area. Of the towns from which patients originated, the highest percentage, 26%, was Middletown. *FF7*. As shown by FY14 Connecticut hospital inpatient discharge data, Middletown also comprises the highest percentage of Medicaid patients of the Applicant's service area towns. *FF37*. As stated above, the Middlesex LINAC would be responsible for treating more than 70% of all patients. The town from which most patients come is also the town with the highest concentration of Medicaid recipients. As a result, any effects of the proposal would likely have a greater impact on Medicaid patients. As discussed above, the Applicant would locate the older, single machine at Middlesex. If the older machine cannot perform certain functions, meet capacity demands or is temporarily non-operational, it would likely disproportionately impact the Middletown Area and, by extension, its Medicaid population.

Based on the aforementioned findings of fact and discussion originally contained in the Proposed Final Decision, the Applicant was found to have failed to meet its burden of proof in satisfying the statutory requirements of Conn. Gen. Stat. §§ 19a-639. However, subsequent to the Proposed Final Decision being issued, the Applicant modified its proposal to include, in part, the purchase of a device to expand the field size of the Novalis and the maintenance of a back-up LINAC at its cancer center in Middletown; the purchase of a CT-scanner with simulation capabilities for its Shoreline site; and the hiring of the American College of Radiology to conduct a consultative survey for Middlesex's radiation oncology program. Upon review and consideration of the Applicant's revised proposal, OHCA finds that the Applicant has met its burden of proof by a preponderance of the evidence and so orders approval of the application conditional upon the terms outlined in the following Order.

Order

NOW, THEREFORE, the Department of Public Health, Office of Health Care Access (“OHCA”) and Middlesex Hospital (“Applicant”), through their authorized representatives, hereby stipulate and agree to the following terms of settlement with respect to the Applicant’s request to acquire a non-hospital based linear accelerator (“LINAC”) at its Shoreline site:

1. Middlesex’s modified application is approved subject to the conditions and terms set herein.
2. Middlesex hereby modifies its request to acquire a non-hospital based linear accelerator for its Shoreline site to include the retention of its existing Varian LINAC, as a back-up unit only, at its cancer treatment center in Middletown (“Middletown site”). The Varian may be employed only during periods when the Novalis LINAC is inoperable due to maintenance, repair or other unavoidable interruptions in service or as needed to ensure the Varian maintains its functionality. Middlesex shall provide OHCA with written notification of its ceasing regularly scheduled operation of the Varian within thirty (30) days of such cessation.
3. Middlesex hereby modifies its request to locate a new Elekta LINAC at its non-hospital based Shoreline site, such that Middlesex shall, not more than 24 months after the effective date of this Agreement:
 - a. acquire an IMRT compensator device for its Middletown cancer center capable of increasing the Novalis LINAC’s field size to 40 x 40 cm,
 - b. acquire a dedicated CT-scanner with simulation capabilities at its Shoreline site,
 - c. establish immobilization device fabrication capabilities at its Shoreline site,
 - d. provide at its Shoreline site a complement of cancer-care services, including but not limited to medical oncology services, infusion, radiation oncology services, breast imaging, laboratory services, counselling and other related ancillary services, and
 - e. ensure an appropriate complement of physicians and medical professionals are available on-site at the Shoreline facility to deliver cancer treatment planning, implementation and follow-up services.

Middlesex shall provide OHCA with written notification that it has completed each of the actions listed in subsections (a) through (c) above not more than thirty (30) days of its completion of each.

4. Middlesex shall within one (1) year of full project implementation retain the American College of Radiology (“ACR”) to conduct a consultative survey for Middlesex’s radiation oncology program at both its Shoreline site and in Middletown and submit the resulting report to OHCA. For the purposes of this stipulation, “full project implementation” shall be defined as having executed all actions in Section 2 and Section 3 subsections (a), (b), (c) and (d). Furthermore, Middlesex shall thereafter seek full ACR radiation oncology accreditation for its Shoreline satellite site at the time it renews its accreditation for its main cancer center in Middletown.

5. Middlesex shall submit to OHCA:
 - a. proof of accreditation at its Shoreline site within thirty (30) days of receiving said accreditation
 - b. written notification of any loss of accreditation at its Shoreline site and/or Middletown site within thirty (30) days of receiving notice of said loss of accreditation.

6. Middlesex shall file semi-annual reports to OHCA for the information outlined in Sections 7, 8 and 9 below. The semi-annual periods shall be January 1 through June 30 and July 1 through December 31 for three (3) full years following commencement of radiation oncology services at the Shoreline site. The first report may be based on a partial reporting period depending on the date of activation of the new unit at the Shoreline site and should identify the partial reporting timeframe.

7. Middlesex shall report to OHCA, on the semi-annual basis outlined in Section 6 above, the number of treatments administered on each of Middlesex's three LINACs. Reported treatment volumes shall be based on the actual number of radiation oncology treatments, with one patient visit typically generating one billable unit. Reported treatment volumes shall exclude additional tests that may be performed on the LINAC but do not constitute "treatments" as generally defined by the medical community, such as image guidance, port films and dosimetry measurements. **Utilize the table format below using only incorporated town names¹:**

	# of treatments on Novalis (in Middletown)	# of treatments on Varian (in Middletown)	# of treatments on Elekta (at Shoreline site)
Town Name A			
Town Name B			
Town Name C			
Totals			

¹ List patients originating from hamlets, boroughs or villages as part of the encompassing incorporated town. A list of incorporated towns can be found at http://www.portal.ct.gov/cities_and_towns/.

8. Middlesex shall report to OHCA, on the semi-annual basis outlined in Section 6 above, information regarding the number of patients affected by either anticipated or unanticipated downtime on the Novalis LINAC . **Utilize the table format below (sample information provided for illustrative purposes only):**

Time period	Duration of downtime	Number of patients affected (either rescheduled or referred elsewhere)	Reason for downtime: unscheduled maintenance/repair, scheduled maintenance, unanticipated interruption (indicate reason)
#1 mm/dd/yyyy	2 days, 2 hours	5	Unanticipated interruption (back-up generator stopped working)
#2 mm/dd/yyyy	1 hour 45 minutes	0	Scheduled maintenance
#3 mm/dd/yyyy	1 day	1	Unscheduled maintenance/repair
Total/average	25.25 hours	2	

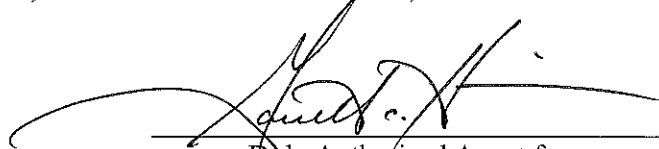
9. Middlesex shall report to OHCA, on the semi-annual basis outlined in Section 6 above, the number of patients receiving radiation oncology treatments at the Shoreline site and at the Middletown site by payor category. **Utilize the table format below:**

	Total	Medicare	Medicaid	CHAMPUS/ Tricare	Commercial	Uninsured	Worker's Comp.
Shoreline site							
Middletown site							
Total							


10. OHCA and Middlesex agree that this settlement represents a final agreement between OHCA and Middlesex with respect to OHCA Docket No. 15-31985-CON. The execution of this settlement resolves all objections, claims and disputes, which may or could have been raised by Middlesex with regard to OHCA Docket Number 15-31985-CON.
11. OHCA may enforce this settlement under the provisions of Conn. Gen. Stat. §§ 19a-642 and 19a-653 with all fees and costs of such enforcement to be governed by State Law.
12. This settlement shall be binding upon Middlesex and its successors and assigns.

Signed by Garrett C. Harican, Vice President, Strategic Planning & Ambulatory Operations
(Print name) (Title)

4/5/16
Date


Duly Authorized Agent for
Middlesex Hospital

The above Agreed Settlement is hereby accepted and so ordered by the Department of Public Health, Office of Health Care Access on April 20, 2016.


Janet M. Brancifort, MPH, BRT
Deputy Commissioner, Department of Public Health