

STATE OF CONNECTICUT

DEPARTMENT OF PUBLIC HEALTH Office of Health Care Access

July 27, 2015

IN THE MATTER OF:

An Application for a Certificate of Need filed Pursuant to Section 19a-638, C.G.S. by:

Northeast Regional Radiation Oncology Network, Inc. (NRRON)

Mr. Dennis P. McConville Chairman, NRRON ECHN 71 Haynes Street Manchester, CT 06040 Notice of Final Decision Office of Health Care Access Docket Number: 15-32001-CON

Acquisition of a Linear Accelerator ("LINAC")

Dear Mr. McConville:

This letter will serve as notice of the approved Certificate of Need Application in the above referenced matter. On July 27, 2015, the Final Decision, attached hereto, was adopted and issued as an Order by the Department of Public Health, Office of Health Care Access.

Kimberly R. Martone Director of Operations

Enclosure KRM:bc



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

Final Decision

Applicant:

Northeast Regional Radiation Oncology Network, Inc.

100 Haynes Street

Manchester, CT 06040

Docket Number:

15-32001-CON

Project Title:

Acquisition of a Linear Accelerator ("LINAC")

Project Description: Northeast Regional Radiation Oncology Network, Inc. d/b/a Community Cancer Care is proposing to acquire and operate a linear accelerator ("LINAC") at the Johnson Memorial Cancer Center at 142 Hazard Avenue, Enfield, with an associated capital cost of \$1,720,000.

Procedural History: The Applicant published notice of its intent to file a Certificate of Need ("CON") application in *The Journal Inquirer* (Manchester) on April 29, 30 and May 1, 2015. On May 27, 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 June 26, 2015. OHCA received no responses from the public concerning the proposal and no hearing requests were received from the public per Connecticut General Statutes ("Conn. Gen. Stat.") § 19a-639a(e). Deputy Commissioner Brancifort considered the entire record in this matter.

Docket Number: 15-32001-CON

Findings of Fact and Conclusions of Law

To the extent the findings of fact actually represent conclusions of law, they should be so considered, and vice versa. SAS Inst., Inc., v. S & H Computer Systems, Inc., 605 F. Supp. 816 (Md. Tenn. 1985).

- 1. Northeast Regional Radiation Oncology Network, Inc. ("NRRON" or "Applicant") is a non-profit joint venture consisting of three members: Johnson Memorial Hospital, Rockville General Hospital and Manchester Memorial Hospital. Ex. A, p. 9; Docket Number: 14-31960-MDF.
- 2. NRRON provides community-based radiation therapy services for cancer patients at two licensed outpatient clinics: the John DeQuattro Community Cancer Center in Manchester and the Johnson Memorial Cancer Center in Enfield ("Enfield"). Ex. A, p. 9.
- 3. NRRON proposes to acquire a linear accelerator ("LINAC") for the Enfield location. Ex. A, p. 8.
- 4. The existing Enfield LINAC, originally approved by OHCA on January 17, 1997 (Docket Number: 95-534), has been in operation since 1998 and is now aged past its useful life expectancy of eight to ten years. Ongoing age-related problems include increased frequency of downtime, lack of precision measurement, technological limitations and a high cost for repairs and replacement parts. Ex. A, pp. 8-9.
- 5. The existing LINAC will remain operational during the initial phase of renovations, but will be taken off-line and removed from service beginning October 1, 2015. Ex. A, p. 10.
- 6. The inconsistency of the LINAC's functionality has had a negative impact on patient care resulting in the rescheduling of exams, delays in cancer treatment, and in certain circumstances, unnecessary radiation exposure to update patient treatment plans. Ex. A, p. 9.
- 7. The new LINAC will be able to provide specific treatments that cannot be currently performed on the existing machine. These treatments include: electron beam therapy, used to treat the chest wall after mastectomy or the treatment of superficial tumors like skin cancer; high energy radiation, used for large patients with centrally located tumors (chest, abdomen, or pelvis); stereotactic body radiation therapy (SBRT), used in early stage lung cancer; and rapid arc intensity modulated radiation therapy (RA-IMRT), used to treat many tumor types including prostate cancer, cancers of the head and neck, lung and pelvic malignancies. Ex. A, pp. 8, 17; Ex. C, pp. 209-210.

Docket Number: 15-32001-CON

8. The majority (84%) of patients receiving radiation therapy at NRRON's Enfield location resided in Enfield and surrounding towns.

TABLE 1 SERVICE AREA TOWNS

Town	Patient Town of Origin				
Enfield	37%				
Stafford/Union	9%				
Windsor Locks	9%				
Somers	8%				
Suffield	6%				
East Windsor	6%				
Windsor	6%				
Ellington	3%				

Ex. A, pp. 33.

- 9. Using National Cancer Institute statistics (for all cancer types) as a basis for estimating the incidence and prevalence of cancer in the service area, there are approximately 6,800 patients that are currently living with cancer in the service area and approximately 700 new patients will be diagnosed with cancer each year. Ex. A, p. 15.
- 10. Historical volumes from FY 2012-2014 have averaged approximately 3,500 radiation therapy visits per year. FY 2015 volume is projected to increase based on year-to-date volumes from October 2014 through April 2015.

TABLE 2
ENFIELD SITE - HISTORICAL UTILIZATION BY SERVICE

	(Last	CFY Volume		
Service	FY 2012	FY 2013	FY 2014	FY 2015*
Radiation Therapy Visits	3,511	3,636	3,437	4,226
Total	3,511	3,636	3,437	4,226

^{*}Volume was annualized using 10/1/2014 through 04/30/2015 historical volumes.

Ex. A, p. 35.

Northeast Regional Radiation Oncology Network, Inc.

Docket Number: 15-32001-CON

11. Projected radiation therapy volume at the Enfield location is expected to remain stable from FY 2016 through FY 2019.

TABLE 3
ENFIELD SITE - PROJECTED UTILIZATION BY SERVICE

	Projected Volume						
Service	FY 2016*	FY 2017	FY 2018	FY 2019			
Radiation Therapy Visits	3,170	4,226	4,226	4,226			
Total	3,170	4,226	4,226	4,226			

^{*}FY 2016 projections assume that the Enfield site will be unavailable for three months to allow for the installation of the new LINAC.

Ex. A, p. 35.

12. The Applicant does not anticipate any changes in payer mix at its Enfield site as a result of this proposal.

TABLE 4
APPLICANT'S CURRENT & PROJECTED PAYER MIX

							Projec	cted				
Payer	FY 2014		FY 2015		FY 2016 ¹		FY 2017		FY 2018		FY 2019	
	Patients %		Patients	%	Patients	%	Patients	%	Patients	%	Patients	%
Medicare*	72	53%	89	53%	66	53%	89	53%	89	53%	89	53%
Medicaid*	9	7%	11	7%	8	7%	11	7%	11	7%	11	7%
CHAMPUS & TriCare	0	0%	0	0%	0	0%	О	0%	0	0%	0	0%
Total Government	0	60%	0	60%	0	60%	0	60%	0	60%	О	60%
Commercial Insurers	54	40%	66	40%	50	40%	66	40%	66	40%	66	40%
Uninsured	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
Workers Compensation	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
Total Non- Government	54	40%	66	40%	50	40%	66	40%	66	40%	66	40%
Total Payer Mix	135	100%	166	100%	125	100%	166	100%	166	100%	166	100%

*Includes managed care activity.

Ex. A, p. 27; Ex. C, p, 210.

13. 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. Ex. A, p. 19.

¹FY 2016 projections assume that the Enfield site will be unavailable for three months to allow for the installation of the new LINAC.

Northeast Regional Radiation Oncology Network, Inc.

Docket Number: 15-32001-CON

14. 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 and no additional revenue.

TABLE 5
PROJECTED INCREMENTAL REVENUES AND EXPENSES

	FY 2016 ¹	FY 2017	FY 2018	FY 2019
Revenue from Operations	\$1,116,790	\$1,512,673	\$1,537,373	\$1,562,815
Total Operating Expenses	\$1,208,514	\$1,581,191	\$1,208,514	\$1,595,499
Gain/Loss from Operations	(\$91,724)	(\$68,518)	(\$51,096)	(\$32,684)

FY 2016 projections assume that the Enfield site will be unavailable for three months to allow for the installation of the new LINAC.

Ex. A, p. 205.

15. Despite incremental losses, NRRON is projecting positive margins overall following the implementation of the proposal.

TABLE 6
PROJECTED REVENUES AND EXPENSES WITH CON

	FY 2016	FY 2017	FY 2018	FY 2019
Total Operating Revenue	\$6,534,161	\$6,665,993	\$6,774,822	\$6,886,917
Total Operating Expenses	\$6,431,931	\$6,649,349	\$6,721,700	\$6,794,778
Gain/Loss from Operations	\$102,230	\$16,644	\$53,122	\$92,139

Ex. A, p. 205.

- 16. 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))
- 17. 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))
- 18. The Applicant has established that there is a clear public need for the proposal. (Conn. Gen. Stat. § 19a-639(a)(3))
- 19. The Applicant has demonstrated that the proposal is financially feasible. (Conn. Gen. Stat. § 19a-639(a)(4))
- 20. The Applicant has 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))
- 21. The Applicant has 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))

Northeast Regional Radiation Oncology Network, Inc. Docket Number: 15-32001-CON

- 22. The Applicant has satisfactorily identified the population to be affected by this proposal. (Conn. Gen. Stat. § 19a-639(a)(7))
- 23. The Applicant's historical provision of radiation therapy services in the area supports this proposal. (Conn. Gen. Stat. § 19a-639(a)(8))
- 24. The Applicant has 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))
- 25. The Applicant has demonstrated that there will be no reduction in access to services by Medicaid recipients or indigent persons. (Conn. Gen. Stat. § 19a-639(a)(10))
- 26. 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))
- 27. The Applicant has satisfactorily demonstrated that the proposal will not result in any consolidation that would affect health care costs or accessibility to care. (Conn. Gen. Stat. § 19a-639(a)(12))

Docket Number: 15-32001-CON

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).

Northeast Regional Radiation Oncology Network, Inc. ("NRRON" or "Applicant") is a non-profit joint venture consisting of three members: Johnson Memorial Hospital, Rockville General Hospital and Manchester Memorial Hospital. *FF1* NRRON provides community-based radiation therapy services for cancer patients at two licensed outpatient clinics: the John DeQuattro Community Cancer Center in Manchester and the Johnson Memorial Cancer Center in Enfield ("Enfield"). *FF2* NRRON has operated a single LINAC at its Enfield location since 1998 and the machine has now surpassed it useful life expectancy of eight to ten years. Ongoing age-related problems include frequency of downtime, lack of precision measurement, technological limitations and high cost for repairs and replacement parts. *FF4* In addition, the LINAC's age-related functionality has had a negative impact on patient care, causing exams to be rescheduled, delayed treatments, and in certain circumstances, unnecessary radiation exposure to update patient treatment plans. *FF6* As a result, NRRON has requested approval to acquire a new LINAC. *FF3*

NRRON's Enfield location primarily serves patients in Enfield and surrounding towns. *FF8*. The service area is estimated to have 6,800 patients that are currently living with cancer and 700 new patients that will be diagnosed with cancer each year. *FF9* In serving this population, the Enfield location has averaged approximately 3,500 radiation therapy visits per year. *FF10* The new LINAC will provide patients in the area access to electron beam therapy, high energy radiation, stereotactic body radiation therapy (SBRT) and rapid arc intensity modulated radiation therapy (RA-IMRT) treatments that are not currently available at the Enfield location. *FF7*

Acquisition of the new LINAC will not result in any changes to the payer mix or the existing price structure and no additional facility fees will be imposed. *FF12-13* Although the Applicant is projecting incremental losses from operations as a result of the proposal, overall positive margins will still be achieved. *FF14-15* Thus, the Applicant has demonstrated that the proposal is financially feasible.

As a result of these combined factors, the Applicant has satisfactorily demonstrated that there is a clear public need for the proposal and that quality of care will improve through increased access to a greater array of radiation therapy treatments. Therefore, the Applicant has demonstrated that the proposal is consistent with the goals of the Statewide Health Care Facilities and Services Plan.

Order

Based upon the foregoing Findings and Discussion, the Certificate of Need application of Northeast Regional Radiation Oncology Network, Inc. d/b/a Community Cancer Care for the acquisition of a linear accelerator at its Enfield location is hereby APPROVED.

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

Jaly 27, 2015

Deputy Commissioner