

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

December 29, 2011

IN THE MATTER OF:

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

Notice of Final Decision
Office of Health Care Access
Docket Number: 11-31709-CON

Northeast Regional Radiation Oncology
Network, Inc. d/b/a Community CancerCare

**Acquisition of a Computed Tomography-
Simulator**

To: Kristoffer Popovitch
Northeast Regional Radiation Oncology
d/b/a Community CancerCare
100 Haynes Street
Manchester, CT 06040

Dear Mr. Popovitch:

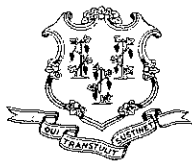
This letter will serve as notice of the Final Decision of the Office of Health Care Access in the above matter, as provided by Section 19a-638, C.G.S. On December 23, 2011, the Final Decision was rendered as the finding and order of the Office of Health Care Access. A copy of the Final Decision is attached hereto for your information.

Kimberly R. Martone
Director of Operations

Enclosure
KRM:swl

STATE OF CONNECTICUT

DEPARTMENT OF PUBLIC HEALTH



Jewel Mullen, M.D., M.P.H., M.P.A.
Commissioner

Dannel Malloy
Governor

Final Decision

Applicant: Northeast Regional Radiation Oncology Network, Inc.
d/b/a Community CancerCare

Docket Number: 11-31709-CON

Project Title: Acquisition of a Computed-Tomography Simulator

Project Description: Northeast Regional Radiation Oncology Network, Inc. ("NRRON") d/b/a Community CancerCare ("CancerCare") (herein referred to as "Applicant") proposes the acquisition of a Computed-Tomography Simulator ("CT-Simulator") to and to be located at the John A. DeQuattro Community Cancer Center ("JDCC") at 100 Haynes Street in Manchester. The total capital expenditure associated with this proposal is \$1,073,385.

Procedural History: On October 4, 2011, the Office of Health Care Access ("OHCA") received a Certificate of Need ("CON") application from the Applicant for the above-referenced project. The Applicant published notice of its intent to file the CON Application in *The Hartford Courant*, on June 9, 10 and 11, 2010. OHCA received no responses from the public concerning the Applicant's proposal and no hearing requests were received from the public per General Statutes § 19a-639a (e).

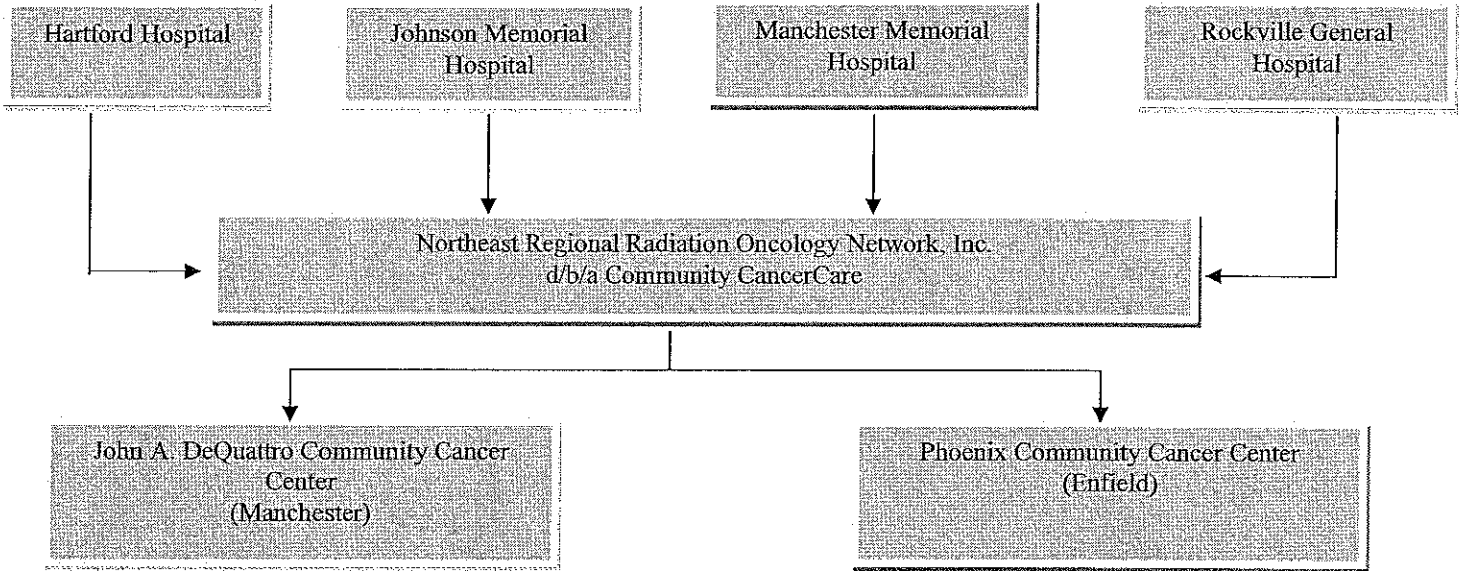
Findings of Fact

1. The Applicant is a regional not-for-profit joint venture between Hartford Hospital, Johnson Memorial Hospital, Rockville General Hospital and Manchester Memorial Hospital ("MMH"). Ex. A, p. 5.



2. NRRON's Chart of Organization is as follows: Ex. C, p. 124

**Northeast Radiation Oncology Network, Inc.
 d/b/a Community CancerCare**



3. The following towns are considered to be the Applicant's service area:

Table 1: Applicant's Service Area Towns

Andover	Bolton	Columbia
Coventry	East Hartford	Ellington
Glastonbury	Hebron	Manchester
Mansfield/Storrs	South Windsor	Stafford Springs
Tolland	Vernon/Rockville	Willimantic/Windham

Note: The towns identified include towns with more than 85% of patients treated at the JDCC during FY 2010. Ex. C, p. 118

4. The Applicant has two locations, the JDCC at 100 Haynes Street across from MMH and the Phoenix Community Cancer Center ("PCCC") at 142 Hazard Avenue in Enfield. Ex. A, p. 6.
5. The Applicant proposes to acquire a Phillips Brilliance Big Bore CT-Simulator, which will be located at the JDCC as part of the comprehensive cancer services provided at that location. Ex. A, p. 5.
6. The Applicant currently provides radiation oncology services and operates two (2) linear accelerators at the JDCC. Ex. C, p. 115.

7. The JDCC is licensed as an Outpatient Clinic by the Department of Public Health, accredited by the American College of Radiology and licensed by the Nuclear Regulatory Commission. Ex. C, p. 116.
8. The proposed CT Simulator will improve the quality of treatment planning capabilities necessary for the radiation therapy procedures provided at the JDCC. Ex. A, p. 5.
9. CT simulation is an essential precursor to radiation therapy, whereby immobilization devices are created and the simulation image is performed simultaneously on the CT simulator table designed for this purpose. Ex. A, p. 6.
10. In comparing the two methods of simulation, studies have shown that the target volumes and field sizes are smaller for virtual than conventional simulation in lung cancer with the associated reduction in irradiation of normal tissue. Smaller field sizes have also been reported for maxillary cancer with corresponding reduction in long-term side effects. Ex. A, p. 57.
11. Another perceived advantage of virtual simulation is the improved coverage of the gross tumor volume and the avoidance of organs at risk (OAR") as a result of better visualization of soft tissue structures on a CT scan compared with a simulator image. Ex. A, p. 57
12. The addition of cone beam CT to conventional simulators may add flexibility to departments with both a scanner and a simulator. However localization is achieved, it must be considered as part of the overall process that leads to treatment. The accuracy of the data acquisition and transfer is vital to this process and a comprehensive QA program is essential. Ex. A., p. 64.
13. Currently, CT simulations are performed at MMH on a diagnostic CT scanner not designed for radiation therapy simulations, making the process challenging and difficult for the Applicant's patients. Ex. A, p. 6.
14. The CT simulation exams are first planned as a virtual procedure where immobilization devices are fabricated specific to the patient's needs in a separate room away from the diagnostic CT scanner. Ex. A, p. 6.
15. Once the immobilization device is fabricated, the patient must travel to the diagnostic CT area of MMH and begin the treatment planning session. Ex. A., p. 6.
16. Upon completion of the treatment planning session, the patient and the fabricated immobilization device must travel from MMH CT area to the JDCC to complete the process. The patient is usually required to disrobe at each point of care. Ex. A, p. 6.

17. The quality of care is a concern with the current process. Since the patient's radiation treatment is planned in 3 locations, it increases the likelihood that the patient's position will vary, adding unnecessary uncertainty to the focused delivery of the radiation therapy treatment. Ex. A, p. 6.
18. A dedicated CT-Simulator at the JDCC will enable patients to undergo their radiation oncology care at one location, which will allow the highest quality of radiation treatment planning. Ex. A, p. 7.
19. Virtual simulations performed by the Radiation Oncologist and Medical Physicist would be performed directly on the table of the CT simulator at the JDCC. As soon as the necessary information has been collected, the actual CT scan would be performed without moving the patient between buildings. Ex. C, p. 117.
20. Additionally, the dedicated unit will allow greater scheduling flexibility not currently available from the mixed use CT scanner located at MMH. Ex. A, p. 7
21. CT simulation capabilities at the JDCC will also reduce the time burden placed upon patients undergoing a simulation for radiation therapy. The current process takes approximately 90 minutes to 2 hours to completed, whereas the entire procedure can be completed in approximately 1 hour with a dedicated CT simulator. Ex. C, p. 117.
22. NRRON will assume the billing process and decrease the confusion that is often caused by the patients receiving two bills from two separate facilities since two separate entities (NRRON & MMH) are currently providing services for the same treatment. Ex. A, p. 6
23. The patient population to be served by the proposed CT-Simulator includes patients diagnosed with cancer. According to data available from the Connecticut Tumor Registry, the prevalence of cancer cases originating from the Applicant's service area is approximately 800 patients each year since 2009.

Table 3: Cancer cases in Applicant's Service Area

	2008	2009	2010	2011 YTD	2011 Estimated
Cancer Cases	923	832	842	485	831

Source: Connecticut Tumor Registry

YTD: Preliminary cases available in Connecticut Tumor Registry (January-July 21, 2011)

All years based on Calendar Year

Ex. C, p. 117

24. The patient population at NRRON will not change as a result of this proposal. Ex. A, p. 7

25. The Applicant's historical CT Simulations are listed as follows:

Table 4: Historical CT Simulations

	2005	2006	2007	2008	2009	2010	2011	Growth 2005-2011
CT Simulations	346	341	371	440	404	349	420	3.3%

Ex. C, p. 121

26. The Applicant attributes the decline in simulation utilization between FY 2008- FY 2010 to the referral of radiation oncology patients who lived north of Manchester to the PCCC in Enfield as there was a single linear accelerator ("LinAc") at the JDCC's old location at 73 Haynes Street. During this time, the LinAc was utilized above maximum capacity by expanding the schedule to accommodate patients after hours and scheduling staff to work overtime to meet treatment demands, which resulted in patient volume in excess of what would have normally been expected with the operation of a single LinAc. Ex. C, p. 120.

27. Accordingly, as more and more demands were placed on the single LinAc and as the JDCC prepared to move to its current location at 100 Haynes Street in 2010, efforts to refer patients to the PCCC increased. This resulted in an inadvertent decline in simulation utilization between FY 2008 and 2010. Ex. C., p. 120.

28. There are no CT-Simulators currently being operated by another provider within the JDCC's service area. Ex. A, p. 8.

29. The proposal will have a minimal impact on the only existing provider (MMH) of CT simulations in the JDCC's service area, as the volume of simulations to be performed at the JDCC represents less than 2% of the total CT volume performed at the hospital (less than 2 patients per day). CT Simulations will only be performed on the JDCC's patients undergoing radiation therapy. Ex. C, p. 119.

30. The CT Simulator will not have a power injector to perform diagnostic CT scans, which encompasses the remaining 98% of MMH's volume. Ex. C, p.119.

31. The following table represents the projected CT Simulations for the next three fiscal years:

Table 5: Projected CT Simulations

	FY 2012	FY 2013	FY 2014
CT Simulations	433	446	460

Note: Projections based on actual historical utilization
 Ex. A, p. 8 & Ex. C, p. 121

32. Along with historical utilization, NRRON based its assumptions for the proposed CT Simulator on the growth index/percentage outlined by the United States census report and accessibility of the treatment schedule with the newly purchased LinAc. Ex. A, p. 10.
33. All referrals are from physicians at the JDCC. Ex. A, p. 9.
34. The proposed total capital expenditure associated with this proposal is as follows:

Table 6: Total Capital Expenditure

CT-Simulator	\$658,185
Medical Equipment Purchase	\$62,200
Construction/Renovation	\$353,000
Total Capital Expenditure	\$1,073,385

Ex. A, p. 12

35. The Applicant proposes to fund the proposed capital expenditure through NRRON's Operations. Ex. A, p. 12
36. The Applicant projects an incremental gain for FY 2012 of \$9,238 and incremental losses as result of this proposal of \$(64, 074) and \$(61,342) for FYs 2013 and 2014. Ex. C, p. 133.
37. The Applicant projects the following total revenues and expenditures with the proposal:

Table 7: Projected Overall Revenues and Expenditures With the Proposal

	FY 2012	FY 2013	FY 2014
Revenues From Operations	\$6,479,680	\$6,689,368	\$6,8484,072
Total Operation Expense	\$6,177,685	\$973,970	\$1,077,668
Overall Gain (Loss) from Operations	\$301,995	\$252,486	\$300,678

Ex. C, p. 133.

38. The Applicant's current and proposed patient payer mix does not change as a result of this proposal:

Table 8: Applicant's Current and Projected Payer Mix

Payer	Current	Projected
Medicare	49.0%	49.0%
Medicaid	1.0%	1.0%
CHAMPUS & TriCare	0.0%	0.0%
Total Government	50.0%	50.0%
Commercial Insurers	49.0%	49.0%
Uninsured	1.0%	1.0%
Workers Compensation	0.0%	0.0%
Total Non-Government	50.0%	50.0%
Total Payer Mix	100%	100%

Ex. D, p. 13.

39. The acquisition of this CT-Simulator will positively impact the financial strength of the health care system in the local area by enhancing the quality of care delivered and improving the efficiency of care delivery. The improved operational efficiencies attained will help reduce operating costs associated with the current process.

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 General Statutes §19a-639 (a) and the Applicant bears the burden of proof in this matter by a preponderance of the evidence. *Goldstar Medical Services, Inc., et al. v. Department of Social Services*, 288 Conn. 790 (2008); *Swiller v. Commissioner of Public Health*, No. CV 95-0705601 (Sup. Court, J.D. Hartford/New Britain at Hartford, October 10, 1995); *Bridgeport Ambulance Serv. v. Connecticut Dept. of Health Serv.*, No. CV 88-0349673-S (Sup. Court, J.D. Hartford/New Britain at Hartford, July 6, 1989); *Steadman v. SEC*, 450 U.S. 91, 101 S.Ct. 999, *reh'g den.*, 451 U.S. 933 (1981); *Bender v. Clark*, 744 F.2d 1424 (10th Cir. 1984); *Sea Island Broadcasting Corp. v. FCC*, 627 F.2d 240, 243 (D.C. Cir. 1980).

The Applicant is a not-for-profit joint venture between four hospitals, including MMH. FF1,4. The Applicant offers comprehensive cancer services at JDCC in Manchester and the PCCC in Enfield. FF4. The Applicant is proposing to acquire a CT-Simulator to be located at the JDCC in Manchester. FF5.

The JDCC is accredited by the American College of Radiology and licensed by the Nuclear Regulatory Commission. FF7. The Applicant currently provides radiation oncology services and operates two linear accelerators at the JDCC. FF6. CT simulation is an essential precursor to radiation therapy, whereby immobilization devices are created and the simulation image is performed all at once on the CT-Simulator table designed for this purpose. FF9. Another advantage of virtual simulation is improved

coverage of the gross tumor volume and the avoidance of OARs as a result of improved visualization of soft tissue structure on a CT scan compared with a simulator image, particularly if shielded by bone. FF11.

Currently, CT simulations are performed at MMH on a diagnostic CT scanner. FF13. CT simulation exams are first planned as a virtual procedure in a separate room away from the diagnostic CT unit where immobilization devices are fabricated specific to the patient's needs. FF14. Once the immobilization device is fabricated, the patient must then travel to the diagnostic CT area of MMH and begin the treatment planning session. FF15. Upon completion of the treatment planning session, the patient and the fabricated immobilization device must travel from MMH's CT area to the JDCC to complete the process. FF16. Additionally, the patient is usually required to disrobe at each point of care. FF16. A dedicated CT Simulator in one location will reduce the time burden placed upon patients and reduce the process time from approximately two hours to approximately one hour. FF21. Moreover, the quality of care will improve since radiation treatment can be planned and performed in one location. FF19.

The CT Simulator will only be used for radiation therapy treatment planning as it is not equipped with power injector to perform diagnostic CT scans. FF31. NRRON will assume the billing process and decrease the confusion that is often caused by the patients receiving two bills from two separate facilities since two separate entities (NRRON & MMH) are currently providing services for the same treatment. FF22. Finally, although NRRON will experience incremental losses, the financial statements demonstrate that NRRON will continue to have overall operating gains. FF37-38. The acquisition of this CT-Simulator will positively impact the financial strength of the health care system in the local area by enhancing the quality of care delivered and improving accessibility. Additionally, the improved operational efficiencies will reduce operating costs associated with the current process.

OHCA finds that the Applicant has demonstrated that the proposed acquisition of a CT Simulator will improve the accessibility and quality of health care for the Center's patients.

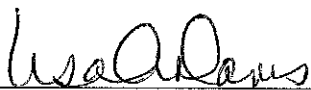
Order

Based upon the foregoing Findings and Discussion, the Certificate of Need application of Northeast Regional Radiation Oncology Network, Inc. d/b/a Community CancerCare for the acquisition of a Computed-Tomography Simulator to be located at the John A. DeQuattro Community Cancer Center at 100 Haynes Street, Manchester is hereby **approved**.

All of the foregoing constitutes the final order of the Office of Health Care Access in this matter.

By Order of

12/29/11
Date


Lisa A. Davis, MBA, BSN, RN
Deputy Commissioner, OHCA