



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

February 28, 2014

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: 13-31855-CON

New Milford Hospital

**Acquisition of a Computed
Tomography-Simulator at New Milford
Hospital**

To:

Sally F. Herlihy, MBA, FACHE
Vice President, Planning
Western Connecticut Health Network
24 Hospital Avenue
Danbury, CT 06810

Dear Ms. Herlihy:

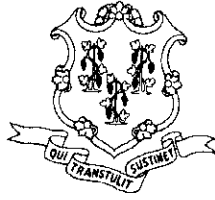
This letter will serve as notice of the Final Decision of the Office of Health Care Access in the above matter, as provided by Section 19a-638, C.G.S. On February 28, 2014, the Final Decision was rendered as the finding and order of the Office of Health Care Access. A copy of the Final Decision is attached hereto for your information.

Kimberly R. Martone
Director of Operations

Enclosure
KRM:swl

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(If you require aid/accommodation to participate fully and fairly, contact us either by phone, fax or email)
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**Department of Public Health
Office of Health Care Access
Certificate of Need Application**

Final Decision

Applicant: New Milford Hospital, Inc.
21 Elm Street, New Milford, Connecticut

Docket Number: 13-31855-CON

Project Title: Acquisition of a Computed-Tomography Simulator

Project Description: New Milford Hospital, Inc. (“Hospital” or “Applicant”), proposes to acquire a Computed-Tomography (“CT”) Simulator to be located at New Milford Hospital, 21 Elm Street, New Milford, Connecticut. The total capital expenditure associated with this proposal is \$1,100,000.

Procedural History: On July 29, 2013, the Office of Health Care Access (“OHCA”) received the initial Certificate of Need (“CON”) application from the Hospital for the above-referenced project. The Hospital published notice of its intent to file the CON Application in the *News Times* (Danbury) on April 26, 27 and 28, 2013. The application was deemed complete on November 29, 2013. OHCA received no responses from the public concerning the Hospital’s proposal and no hearing requests were received from the public per Connecticut General Statutes § 19a-639a(e). In rendering her decision, Deputy Commissioner Davis considered the entire record in this matter.

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).

Findings of Fact and Conclusions of Law

1. The Hospital is an acute care hospital located at 21 Elm Street, New Milford, Connecticut. Ex. A, p. 3.
2. The Hospital is proposing to acquire a new CT Simulator to replace its existing conventional Radiation Oncology Simulator. Ex. A, p. 6.
3. Western Connecticut Health Network, Inc. ("WCHN") is the parent corporation of New Milford Hospital and Danbury Hospital. Office of Health Care Access, Fiscal Year 2012 Annual Reporting.
4. The Hospital's primary service area consists of the following Connecticut towns: New Milford, Sherman, Washington, Kent, Roxbury, and Bridgewater. Ex. A, p. 10.
5. WCHN offers a full continuum of cancer care services, including risk assessment, prevention, screening, detection, diagnosis, treatment, support services, research, survivorship, and end-of-life care. Exhibit C, p. 53.
6. The Hospital's Diebold Family Cancer Center ("Center") is accredited in radiology, mammography and radiation oncology services by the American College of Radiology and the National Accreditation Program for Breast Centers. Ex. A, p. 6.
7. In December 2012, the Center was re-approved "with commendation" by the American College of Surgeons ("ACoS"), Commission on Cancer. The designation, offered by ACoS every three years, distinguishes exceptional hospital performance in ongoing improvement and public accountability for cancer treatment services. Ex. A, p. 6.
8. A Simulator is used as part of the treatment planning process for determining a patient's course of radiation therapy. The images generated by a Simulator assist physicians in determining the optimal treatment path. Ex. A, p. 6.
9. Currently, the Hospital's patients first visit the Radiation Oncology Department where immobilization devices are constructed. A patient, usually dressed in a hospital gown, must then be escorted down the hall to the Radiology Department to obtain CT imaging for planning. Since the CT bore is sized for diagnostic scans, the patient often has to be repositioned along with the treatment immobilization devices to fit the patient through the scanner, causing discomfort for the patient. Ex. A, pp. 6-7.
10. The Hospital's existing Simulator was acquired in 1998 and has been in operation for more than 15 years. The Simulator reached end-of-life in April 2013, with

technical support for the equipment discontinued and x-ray film used by the Simulator difficult to obtain. Ex. A, pp. 6, 9.

11. The proposed CT Simulator offers multiple clinical, operational and administrative advantages, all of which lead to enhanced cancer care delivery:
 - a) Treatment efficiencies;
 - b) Digitalization;
 - c) Comfort and convenience; and
 - d) Potential for expanded treatment options.Ex. A, p. 7.
12. The proposed CT Simulator will offer advanced imaging capabilities that will eliminate the need for patients to visit both the Radiation Oncology and Radiology Departments, thus consolidating treatment planning. Ex. A, p. 7.
13. The proposed CT Simulator will allow the Hospital's Radiation Oncology Department to become completely digitalized, eliminating the need for x-ray film, service contracts for film processors and silver reclaiming, as well as the need for fixer and developer. Additionally, the use of digital images will support the use of electronic medical records. Ex. A, p. 7.
14. With the proposed CT Simulator, patients will be able to have their entire planning procedure completed within the Radiation Oncology Department. The large bore CT Simulator provides for enhanced diversity in positioning and better accommodates immobilization devices and larger-sized patients. Ex. A, p. 7.
15. Additionally, "4-D CT capability," a radiation oncology-specific software package, will allow the Hospital to provide expanded stereotactic body radiation therapy ("SBRT"). SBRT treatment provides highly accurate, precise and focused radiation delivery to tumors while minimizing radiation to adjacent healthy tissue. SBRT patients experience fewer treatment visits and side effects than with conventional radiation therapy. Ex. A, p. 7.
16. The Center currently offers SBRT treatment only for brain lesions. The proposed CT Simulator will allow this treatment to be offered for other parts of the body as well. Ex. A, p. 7.
17. There is also the potential for expanded treatment options with 4D CT capability which will allow the Radiation Oncology Department to outline treatment volumes for areas of the body affected by breathing motion, in order to allow for more accurate imaging, treatment planning and delivery to these areas. Ex. A, p.16.
18. The proposed CT Simulator features a state-of-the-art CT scanner with a localization package, patient marking system and a virtual simulator capable of producing real-time digitally composited radiographs, thus offering high-

resolution imaging and short examination time for a full range of procedures including volumetric localizations, simulation and verification for conformal, high-precision and stereotactic radiotherapy planning. Ex. A, p.15.

19. The Hospital has experienced overall growth in CT Simulation volume since 2010:

Table 1: Historical CT Simulations

	2010	2011	2012	2013
CT Simulations*	86	123	121	152

*Conventional Simulator and CT Scan

Ex. A, p. 13 & Ex. E.

20. The volume increase is multifactorial, including the expanded technology available with the Hospital's Trilogy System, a linear accelerator system becoming operational in October 2010. The system enhanced the delivery of radiation oncology with image guidance, stereotactic capability and robotic couch positioning. The Hospital's affiliation with Danbury Hospital positively impacted patient volumes as well, through increased collaboration between the two institutions. Ex. A, pp. 14-15.

21. The Hospital is projecting stable utilization for FYs 2014-2016 based on historical volume:

Table 2: Projected CT Simulations

	FY 2014	FY 2015	FY 2016
CT Simulations	152	152	152

Ex. E.

22. The projected volume is also based partly on the assumption that approximately one half of all new cancer patients will receive radiation therapy. Each of those patients will require one CT simulation in order to formulate their individualized treatment plan. Ex. A, p. 15.
23. The proposed CT Simulator will not result in unnecessary duplication of service as it is replacing an existing piece of equipment. The only other provider in the service area is the Hospital's affiliate, Danbury Hospital. Ex. A, pp. 9, 12.
24. The proposed total capital expenditure associated with this proposal is as follows:

Table 3: Total Capital Expenditure

CT Simulator	\$900,000
Other Non-Construction	\$200,000
Total Capital Expenditure	\$1,100,000

Ex. A, p. 17.

25. This proposal is financially supported by a \$1,000,000 grant received from the Diebold Foundation. Ex. A, p. 17.
26. The Hospital will provide funding for the \$100,000 difference between Diebold Foundation funding and the actual total capital expenditure required for the purchase of the equipment. Ex. C, p. 52.
27. Although the Hospital is projecting annual losses for the next three years, only \$406,000 is attributed to this proposal, due to depreciation and a maintenance contract:

Table 4: Hospital Revenues with the Proposal

	FY 2014	FY 2015	FY 2016
Revenue from Operations	\$72,137,000	\$73,799,000	\$75,759,000
Total Operating Expenses*	\$(78,121,000)	\$(80,533,000)	\$(82,797,000)
Gain/(Loss) from Operations	\$(5,984,000)	\$(6,734,000)	\$(7,272,000)

Note: Projected incremental losses attributed to depreciation and maintenance contract are \$406,000 annually.

*Operating expenses include salaries/fringe benefits, professional/contracted services, supplies/drugs, bad debts, other operating expenses, depreciation/amortization, interest expense and lease expense.

Exhibit A, pp. 19, 48.

28. WCHN reported an actual Gain from Operations of \$42,512,453 for FY 2012. Office of Health Care Access, Fiscal Year 2012 Annual Reporting.
29. The acquisition of the proposed CT Simulator will reduce the Hospital's operating costs due to operational efficiencies. Ex. A, p. 17.
30. The Hospital's patient population mix will remain unchanged as a result of this proposal:

Table 5: Applicant's Projected Payer Mix

Payer	Actual FY2013	Year 1 FY 2014	Year 2 FY 2015	Year 3 FY 2016
Medicare	46.7%	46.7%	46.7%	46.7%
Medicaid	10.1%	10.1%	10.1%	10.1%
CHAMPUS & TriCare	0.2%	0.2%	0.2%	0.2%
Total Government	56.9%	56.9%	56.9%	56.9%
Commercial Insurers	39.9%	39.9%	39.9%	39.9%
Uninsured	1.9%	1.9%	1.9%	1.9%
Workers Compensation	1.4%	1.4%	1.4%	1.4%
Total Non-Government	43.1%	43.1%	43.1%	43.1%
Total Payer Mix	100.0%	100.0%	100.0%	100.0%

Ex. A, p. 18.

31. This proposal is cost effective as it replaces an outdated and end-of-life conventional simulator with a new state-of-the-art CT Simulator that will improve operational efficiencies. Ex. A, p. 19.
32. 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 adopted by OHCA. (Conn. Gen. Stat. § 19a-639(a)(1))
33. The application is consistent with the overall goals of the State Health Care Facilities and Services Plan. (Conn. Gen. Stat. § 19a-639(a)(2))
34. The Applicant has established that there is a clear public need for its proposal. (Conn. Gen. Stat. § 19a-639(a)(3))
35. The Applicant has satisfactorily demonstrated that its proposal is financially feasible. (Conn. Gen. Stat. § 19a-639(a)(4))
36. The Applicant has satisfactorily demonstrated that its proposal will maintain access and improve the quality of health care delivery in the region and it has satisfactorily demonstrated an improvement in cost effectiveness. (Conn. Gen. Stat. § 19a-639(a)(5))
37. The Applicant has shown that there will be an improvement in the provision of health care services to the relevant populations and payer mix. (Conn. Gen. Stat. § 19a-639(a)(6))
38. The Applicant has satisfactorily identified the population to be served and has satisfactorily demonstrated that this population has a need as proposed. (Conn. Gen. Stat. § 19a-639(a)(7))
39. The Applicant's historical provision of treatment in the service area supports this proposal. (Conn. Gen. Stat. § 19a-639(a)(8))
40. The Applicant has satisfactorily demonstrated that the proposal will not result in an unnecessary duplication of existing services in the area. (Conn. Gen. Stat. § 19a-639(a)(9))

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). 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).*

The Hospital, a subsidiary of WCHN, is seeking authorization to acquire a CT Simulator to replace its conventional Radiation Oncology Simulator. *FF1-3*. The existing Simulator, acquired in 1998, is past its useful life and the vendor no longer provides technical support. Additionally, x-ray film utilized by the current Simulator is difficult to obtain. *FF10*.

The Hospital operates the comprehensive, nationally accredited and certified Diebold Family Cancer Center, which utilizes a conventional Simulator as part of patients' treatment planning process for determining the course of radiation therapy. *FF6-8*. Currently, patients must undergo portions of their simulation planning in two different locations within the Hospital. Patients first visit the Radiation Oncology Department where immobilization devices are constructed. Patients then must be escorted to the Radiology Department to be scanned on a traditional CT scanner to obtain imaging for planning. Since the Radiation Department CT scanner is sized for diagnostic scanning, the patient has to be repositioned and treatment immobilization devices have to be fitted, causing discomfort for the patient. *FF9*.

The CT Simulator will consolidate treatment planning and eliminate the need for transferring/transporting patients between departments, as it allows for enhanced diversity in positioning and better accommodates immobilization devices and larger-sized patients. *FF12,14*. In addition to the aforementioned treatment efficiencies, the proposed CT Simulator offers operational, administrative and clinical advantages. *FF11*. It will allow the Hospital's Radiation Oncology Department to become completely digitalized, resulting in operational efficiencies and enhancing support for electronic medical records. *FF13*. Additionally, the acquisition of a CT Simulator and its radiation oncology-specific software will allow the Hospital to expand its Stereotactic Body Radiation Therapy beyond the brain, the only area of the body for which it is currently offered. This treatment provides highly accurate, precise and focused radiation delivery to tumors, resulting in the minimization of radiation to adjacent healthy tissue. As an added benefit, this treatment results in fewer treatment visits and side effects for patients. *FF15&16*. It will also allow the Hospital to more accurately plan treatment and delivery to areas of the body affected by breathing motion. *FF17*. It is clear that the advancement in technology provided by the proposed CT Simulator will provide a higher quality treatment option for the patient. Therefore, the Applicant has demonstrated that its proposal will maintain access while improving the quality of health care delivery in its service area.

Danbury Hospital, also owned by WCHN, is the only other provider with a CT Simulator in the Hospital's service area. Since the CT Simulator is replacing existing out-of-date equipment, there will be no impact on area providers, no duplication of service in the service area and no change in the patient payer mix. *FF3,23,31*. Therefore, the Applicant has satisfactorily demonstrated that its proposal will not result in an unnecessary duplication of existing CT Simulation services in its service area.

The Hospital has seen growth in simulations since FY2010 and is projecting stable utilization for the first three years of the proposal. *FF19,21*. Based on the actual historical utilization, the projections appear to be reasonable and achievable.

Although the capital expenditure associated with the acquisition of the CT Simulator is \$1,100,000, the proposal is financially supported by a \$1,000,000 grant from the Diebold Foundation. *FF24&25*. The Hospital will only be responsible for contributing \$100,000 toward the cost of the CT Simulator. *FF26*. Due to the equipment depreciation and cost of the annual maintenance contract, the Hospital is projecting incremental losses. *FF27*. However, considering WCHN reported an actual gain from operations of \$42,512,453 for FY 2012; the Applicant has demonstrated that its proposal is financially feasible. *FF28*.

The Applicant has demonstrated clear public need for the acquisition of the CT Simulator due to the overall superior care it delivers. Replacing the conventional Simulator with a CT Simulator will improve the quality of care provided to cancer patients at the Hospital and in the service area by providing the standard of care associated with modern treatment planning and delivery. The Applicant has satisfactorily shown that access to care will be maintained, quality of care will be improved and a potential improvement in cost effectiveness may be achieved through operational efficiencies.

Order


Based upon the foregoing Findings of Fact and Discussion, the Certificate of Need application of The New Milford Hospital, Inc. for the acquisition of a Computed Tomography Simulator to be located at 21 Elm Street, New Milford, Connecticut 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
Office of Health Care Access

Date

2/28/14



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