



## Office of Health Care Access Certificate of Need Application

### Final Decision

**Applicants:** The Norwalk Hospital Association d/b/a Norwalk Hospital and Norwalk Radiology and Mammography Center

**Docket Number:** 06-30827-CON

**Project Title:** Acquire and Operate an Additional Outpatient 1.5 T High Field Magnetic Resonance Imaging Scanner

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

**Filing Date:** February 6, 2007

**Decision Date:** July 20, 2007

**Default Date:** August 15, 2007

**Staff Assigned:** Paolo Fiducia

**Project Description:** The Norwalk Hospital Association d/b/a/ Norwalk Hospital and Norwalk Radiology and Mammography Center (“Applicants”) propose to acquire and operate an additional 1.5 T High Field magnetic resonance imaging (“MRI”) scanner, at an associated capital expenditure of \$2,263,399.

**Nature of Proceedings:** On February 6, 2007, the Office of Health Care Access (“OHCA”) received a Certificate of Need (“CON”) application from the Applicants proposing to acquire and operate an additional 1.5 T High Field magnetic resonance imaging (“MRI”) scanner, at an associated capital expenditure of \$2,263,399. The Applicants are health care facilities or institutions as defined by Section 19a-630 of the Connecticut General Statutes (“C.G.S.”).

A notice to the public concerning OHCA's receipt of the Applicants' Letter of Intent was published on September 24, 2006, in *The Hour* (Norwalk). Pursuant to 19a-639 (C)(3), three individuals or an individual representing an entity with five or more people had until February 27, 2007, the twenty-first calendar day following the filing of the Applicants' CON Application, to request that OHCA hold a public hearing on the Applicant's proposal. OHCA received no hearing requests from public by February 27, 2007.

OHCA's authority to review and approve, modify or deny the CON application is established by Section 19a-639, C.G.S. The provisions of this section, as well as the principles and guidelines set forth in Section 19a-637, C.G.S., were fully considered by OHCA in its review.

## Findings of Fact

### Clear Public Need

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

1. Norwalk Radiology and Mammography Center ("NRMC") is a joint venture between NRC Equipment Associates and the Southwest Connecticut Corporation ("SWC"). SWC is a for-profit subsidiary of Norwalk Health Services Corporation ("NHSC"). NHSC is the parent corporation of Norwalk Hospital Association d/b/a Norwalk Hospital ("Hospital"). (*February 6, 2007, Initial CON Application, page 6*)
2. The Applicants currently operate (3) MRI scanners: a high field 1.5 T MRI scanner located on the Hospital's campus, and an open MRI scanner and a high field short bore MRI scanner located at NRMC. (*February 6, 2007, Initial CON Application, pages 6-7*)
3. The Hospital is the entity that will purchase the proposed MRI scanner and bill for all MRI services rendered. (*February 6, 2007, Initial CON Application, pages 6-7*)
4. NRMC and the Hospital ("Applicants") propose to acquire and operate an additional 1.5 Tesla High Field MRI scanner to be physically located at the NRMC facility at 148 East Avenue in Norwalk, Connecticut. (*February 6, 2007, Initial CON Application, page 6*)
5. The Hospital provides a full range of inpatient, emergency, and outpatient imaging services on its hospital campus. In addition, NRMC provides a full range of outpatient imaging services including digital mammography, CT scanning, ultrasound, plain x-rays, osteoporosis scanning, fluoroscopy, and MRI. (*February 6, 2007, Initial CON Application, page 7*)

6. The Applicants are seeking authorization to acquire and operate a General Electric Gold Seal 1.5 Tesla Excite II Echospeed 8 channel short bore. *(February 6, 2007, Initial CON Application, page 116)*
7. The Applicants' primary service area ("PSA") includes the towns of Norwalk, Westport, Wilton, New Canaan, and Weston. *(February 6, 2007, Initial CON Application, page 19)*
8. According to the Applicants, in FY 06, residents from these towns were responsible for 74.5% of the MRI scans performed at NRMC and 70% of the outpatient MRI scans performed on the Norwalk Hospital campus. *(February 6, 2007, Initial CON Application, page 19)*
9. The Applicants' secondary service area ("SSA") includes the towns of Fairfield, Darien and Stamford. *(February 6, 2007, Initial CON Application, page 19)*
10. The Applicants claimed the need for the proposed acquisition of an additional 1.5T high field MRI scanner is based on the following:
  - a. There is expected continued demand for growth in MRI services due to increased utilization, new applications, projected service area population growth, and in general, the aging of the population;
  - b. The acquisition and operation of an additional high field MRI scanner will improve both access and quality of care for patients in need of breast imaging MRI services;
  - c. The historical increases in demand for breast MRI applications are expected to continue;
  - d. There is an increasingly constrained ability to respond to the current and future needs and expectations of the patients of Norwalk Hospital and NRMC that require MRI services due to the following:
    - Scheduling delays.
    - Inability to further expand scheduled hours operation.
    - Equipment operating close to total capacity.*(February 6, 2007, Initial CON Application, page 10)*
11. The Applicants state that NRMC currently has the only MRI in the five town primary service area with breast imaging technology and capability. The proposed additional magnet will have the same breast imaging capabilities. While the scanner located on Norwalk Hospital's campus is a high field 1.5T unit, it is an older scanner and is not capable of doing MRI breast imaging or MRI guided biopsies. *(February 6, 2007, Initial CON Application, page 13)*
12. The Applicants state that in the past year, breast MRI scans performed at NRMC have increased 38.6%, while mammography procedures have increased 1.8%. NRMC services over 14,000 mammography patients per year. As the volume of mammography studies increase, there are more abnormalities detected where MRI studies are indicated. In January 2005, NRMC performed .03 breast MRIs for each mammogram. This ratio has increased to .07 in December 2006, more than double.

**Table 1: NRMC's FY 2005-2006 Breast MRI Scans and Mammography Procedures**

Year	Breast MRI Scans	Mammography Procedures
FY 05	603	13,869
FY 06	836	14,113
<b>Increase form FY 05</b>	<b>38.6%</b>	<b>1.8%</b>

(February 6, 2007, Initial CON Application, page 14)

13. The Applicants state that each MRI unit located at NRMC is operational an average of 70.25 hours per week. Scans are performed until 9:00 p.m. on Monday through Thursday, until 5:00 p.m. on Friday and from 7:30 a.m. to 1:00 p.m. on Saturday. The MRI unit located at Norwalk Hospital is available until 11:00 p.m. on weekdays and until 3:00 p.m. on weekends. The ability to expand hours of operation is limited due to the following: (February 6, 2007, Initial CON Application, page 17)

- Lack of availability of clinical staff;
- Operation of the NRMC facility is limited (i.e. building is not available on Sunday);
- Patients have not been receptive to further expansion of hours.

14. The Applicants used a targeted utilization rate of 85% to recognize routine maintenance, staff training, and equipment repair. The table below demonstrates that the FY 07 scan volume equaled 94.2% and 105.5% of total capacity for the equipment located at NRMC and 69.5% for the Hospital's scanner. (July 13, 2007, Additional Information, page 3)

**Table 2: Comparison of FY 07 Scan Volume to Equipment Capacity**

<b>NRMC LOCATION: High Field MRI Scanner</b>	
a. Number of MRI Scanners	1
b. Average Hours Per Week Units are Operational	70.25
c. Weeks per Year	51
d. Targeted utilization as % of Capacity	85%
e. Annual Total Capacity For Procedures in Hours (a*b*c*d)	3,045
f. MRI: Average Scan Time in Hours	0.6
g. Annual Capacity MRI Scans per Equipment (e divided by f)	5,076
h. FY 06 MRI Scans	4,782
i. FY 06 Scans as % of Total Capacity of Equipment (h divided by g)	<b>94.2%</b>
<b>NRMC LOCATION: Open MRI Scanner</b>	
a. Number of MRI Scanners	1
b. Average Hours Per Week Units are Operational	70.25
c. Weeks per Year	51
d. Targeted utilization as % of Capacity	85%
e. Annual Total Capacity For Procedures in Hours (a*b*c*d)	3,045
f. MRI: Average Scan Time in Hours	0.95
g. Annual Capacity MRI Scans per Equipment (e divided by f)	3,206
h. FY 06 MRI Scans	3,382
i. FY 06 Scans as % of Total Capacity of Equipment (h divided by g)	<b>105.5%</b>

<b>NORWALK HOSPITAL CAMPUS LOCATION</b>	
a. Number of MRI Scanners	1
b. Average Hours Per Week Units are Operational	96
c. Weeks per Year	51
d. Targeted utilization as % of Capacity	85%
e. Annual Total Capacity For Procedures in Hours (a*b*c*d)	4,162
f. MRI: Average Scan Time in Hours	0.75
g. Annual Capacity MRI Scans per Equipment (e divided by f)	5,549
h. FY 06 MRI Scans	3,857
i. FY 06 Scans as % of Total Capacity of Equipment (h divided by g)	<b>69.5%</b>

15. The volume of MRI scans by service area town for FY 2004 through annualized (actual scan volume through 6/30/07) FY 2007 for the two scanners located at NRMC and the one scanner located on the Hospital campus are displayed in the next two tables:

**Table 3: NRMC: MRI Scan Volume by Service Area Town**

<b>NRMC: MRI Scans</b>	<b>FY 2004</b>	<b>FY 2005</b>	<b>FY 2006</b>	<b>FY 2007</b>
Norwalk	1,176	1,957	2,951	3,144
Westport	378	702	1,058	1,075
Wilton	227	512	772	753
New Canaan	160	306	462	637
Weston	121	245	370	457
Fairfield	84	207	313	325
Darien	103	202	305	286
Stamford	100	186	280	245
All Other Towns	357	677	1,019	1,242
<b>Total</b>	<b>2,706</b>	<b>4,994</b>	<b>7,530</b>	<b>8,164</b>

**Table 4: Norwalk Hospital: MRI Scan Volume by Service Area Town**

<b>NRMC: MRI Scans</b>	<b>FY 2004</b>	<b>FY 2005</b>	<b>FY 2006</b>	<b>FY 2007</b>
Norwalk	2,676	2,382	1,878	1,845
Westport	886	633	439	366
Wilton	744	567	399	330
New Canaan	562	438	264	252
Weston	342	259	182	155
Fairfield	234	169	131	138
Darien	246	164	117	94
Stamford	209	162	122	73
All Other Towns	1,440	1,184	1,016	604
<b>Total</b>	<b>7,339</b>	<b>5,958</b>	<b>4,548</b>	<b>3,857</b>

(February 6, 2007, Initial CON Application, page 20, May 17, 2007, Completeness Questions, page 2 and July 13, 2007, Additional Information, page 5)

16. The following providers of imaging services in the Applicants' PSA:

**Table 5: Imaging Services Providers in the Applicants' PSA**

Name	Address	Equipment	Hours of Operation
East Avenue Radiology Dr. Russo	111 East Avenue, Norwalk, CT	Picker 0.2T Open	M-F 8am-5pm Sat. 8am-noon

(February 6, 2007, Initial CON Application, page 25)

17. The following providers of imaging services in the Applicants' SSA:

**Table 6: Imaging Services Providers in the Applicants' SSA**

Name	Address	Equipment	Hours of Operation
Diagnostic Imaging Center of Darien	6 Thornal Circle, Darien, CT	Open MRI	M-F 8am-4pm
Connecticut Open MRI	1055 Post Road, Fairfield, CT	High Field Open MRI	M-F 7am-11pm Sat.&Sun.7am- 7pm
Advanced Radiology Consultants	1315 Washington Boulevard, Stamford, CT	Open MRI	M-F 7:30am- 5:30pm Sat. 7:30am-2:30pm
Tully Health Center	32 Strawberry Hill Court Stamford, CT	MRI	M-F 8am-8pm Sat. & Sun. 8am-4pm
Stamford Hospital	20 Shelburne Road, Stamford, CT	High Field MRI	7 days per week 24 hours per day

(February 6, 2007, Initial CON Application, page 25)

18. The following table shows the volume of Norwalk Hospital MRI scans by inpatient, emergency department, and outpatient for FYs 2004-2007:

**Table 7: Norwalk Hospital MRI scans**

MRI scans	FY 2004	FY 2005	FY 2006	FY 2007 Annualized
Inpatient	1,311	1,251	1,403	1,372
ED	20	26	32	56
Outpatient	6,008	4,681	3,113	2,429
<b>Total</b>	<b>7,339</b>	<b>5,958</b>	<b>4,548</b>	<b>3,857</b>

Note: The Applicant stated that the continued decrease in volume of scans performed at the Hospital is due to the inability to perform scans on patients in need of Breast MRI imaging or MRI guided breast biopsies. In addition, the decline in outpatient scan volume is due to the continued patient and physician preference for a community based outpatient center.

(May 17, 2007, Completeness Questions, page 3 and July, 13, 2007, Additional information, page 4)

19. The following table shows the historical and projected volume by scanner:

**Table 8: Historical and Projected Volume by Scanner**

	<b>High Field MRI: Hospital's Campus</b>	<b>Open MRI: NRMC</b>	<b>High Field MRI: NRMC</b>	<b>Proposed High Field MRI: NRMC</b>	<b>Total</b>	<b>% Increase</b>
FY 05	5,958	825	4,169	0	10,952	9.0%
FY 06	4,548	3,105	4,425	0	12,078	10.3%
FY 07*	3,857	3,382	4,782	0	12,021	(0.5%)
FY 08	4,000	3,241	4,619	1,539	13,399	10.9%
FY 09	4,000	3,241	4,619	2,745	14,605	9.0%
FY 10	4,000	3,241	4,619	4,059	15,919	9.0%

\* FY 2007 Annualized

(February 6, 2007, Initial CON Application, page 25 and July 13, 2007, Additional Information, page 4)

20. The Applicants based the MRI volume projections on the following factors:

*Year 1: Fiscal Year 2008*

- The proposed new high field MRI unit would be operational as of 10/1/07.
- Total MRI scans would increase by 9% (1,087 scans) over FY 06 actual volume (12,078 scans).
- An additional 234 scans would be performed on the proposed new unit.
- The volume performed on the high field MRI scanner, located on the Hospital's campus, would decrease to 4,000 scans. It was assumed that the 548 scan reduction from FY 06 volume would transfer to the new MRI unit located at NRMC. This anticipated loss reflects increased appointment availability within the system for procedures at NRMC and improved access to a freestanding imaging center for elective outpatient imaging procedures.
- The existing two scanners located at NRMC (high field and open) would perform a combined total volume of 7,860 scans.
- All remaining MRI scan volume would be performed on the proposed unit.

*Year 2 and 3: Fiscal Years 2009 and 2010*

- Total MRI scans would increase by 9% over the prior year.
- The high field MRI scanner located on the Hospital's campus would remain at 4,000 scans.
- The existing two scanners located at NRMC would remain at a combined total volume of 7,860 scans.
- All remaining MRI scan volume would be performed on the proposed unit.

(February 6, 2007, Initial CON Application, page 24 and May 17, 2007, Completeness Questions, page 4)

21. The Applicants state that any transfer of outpatient activity to the proposed MRI scanner would be offset by growth in inpatient and emergency department MRI scans.

(May 17, 2007, Completeness Questions, page 4)

22. The following table shows the projected number of breast MRI scans for the first three years of operation at NRMC:

**Table 9: Projected Breast MRI scans**

<b>FY</b>	<b>Mammograms</b>	<b>% Increase</b>	<b>Breast MRI scans</b>	<b>Ratio of Breast MRI to Mammograms</b>
2007	14,680	4.0%	1,028	0.07
2008	15,267	4.0%	1,069	0.07
2009	15,877	4.0%	1,111	0.07
2010	16,513	4.0%	1,156	0.07

*(April 2, 2007, Completeness Questions, page 4)*

23. The hours of service for the proposed MRI scanner will be Monday through Friday from 8:00 a.m. to 5:00 p.m. *(February 6, 2007, Initial CON Application, page 21)*

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

24. The proposed total capital expenditure associated with this proposal is as follows:

**Table 10: Proposed Total Capital Expenditure**

Major Medical Equipment (Purchase)	\$1,353,099
Medical Equipment (Purchase)	12,000
Construction/Renovation	898,300
<b>Total Capital Expenditure</b>	<b>\$2,263,399</b>

*(February 6, 2007, Initial CON Application, page 33)*

25. The proposed high field MRI unit will be located in +/- 1,500 square feet space between the existing two MRIs. This will result in efficient patient flow and improved patient service, and efficiencies related to technologist and radiologist staffing. *(February 6, 2007, Initial CON Application, page 34)*
26. The proposed project will be financed entirely through operating funds. *(February 6, 2007, Initial CON Application, page 37)*
27. The Applicants project incremental gains from operations with implementation of the project of \$292,000, \$990,000 and \$1,801,000 for FY 2008, FY 2009 and FY 2010, respectively. *(February 6, 2007, Initial CON Application, page 121)*



28. The Applicants existing payer mix is not expected to change as a result of this project. The current and projected payer mix for the first three years of operating the proposed MRI scanner is as follows:

**Table 11: The Applicants Current & Projected Payer Mix**

<b>Payer</b>	<b>Current Payer Mix</b>	<b>Year 1 Projected Payer Mix</b>	<b>Year 2 Projected Payer Mix</b>	<b>Year 3 Projected Payer Mix</b>
Medicare	27.81%	27.81%	27.81%	27.81%
Medicaid	0.97%	0.97%	0.97%	0.97%
CHAMPUS & TriCare				
<b>Total Govnt. Payers</b>	<b>28.78%</b>	<b>28.78%</b>	<b>28.78%</b>	<b>28.78%</b>
Commercial Insurers	68.85%	68.85%	68.85%	68.85%
Uninsured	0.97%	0.97%	0.97%	0.97%
Workers Compensation	1.40%	1.40%	1.40%	1.40%
<b>Total Non-Govnt. Payers</b>	<b>71.22%</b>	<b>71.22%</b>	<b>71.22%</b>	<b>71.22%</b>
<b>Payer Mix</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>

*(February 6, 2007, Initial CON Application, page 39)*

29. There is no State Health Plan in existence at this time. *(February 6, 2007, Initial CON Application, page 8)*
30. The proposal is consistent with the Applicants' long-range plan. *(February 6, 2007, Initial CON Application, page 8)*
31. The Applicants' proposal will not change the Applicants' teaching or research responsibilities. *(February 6, 2007, Initial CON Application, page 31)*
32. All radiologists who read MRIs are Fellowship trained and American Board of Radiology certified. *(February 6, 2007, Initial CON Application, page 31)*
33. This proposal will aid the Applicants in improved productivity and cost containment through application of technology and reengineering of operations. *(February 6, 2007, Initial CON Application, page 30)*
34. The Applicants have sufficient technical and managerial competence to provide efficient and adequate service to the public. *(February 6, 2007, Initial CON Application, page 28)*

## Rationale

The Office of Health Care Access (“OHCA”) approaches community and regional need for the proposed service on a case by case basis. Certificate of Need (“CON”) applications do not lend themselves to general applicability due to a variety of factors, which may affect any given proposal; *e.g.* the characteristics of the population to be served, the nature of the existing services, the specific types of services proposed to be offered, the current utilization of services and the financial feasibility of the proposed services.

Norwalk Radiology and Mammography Center (“NRMC”) is a joint venture between NRC Equipment Associates and the Southwest Connecticut Corporation (“SWC”). SWC is a for-profit subsidiary of Norwalk Health Services Corporation, the parent corporation of Norwalk Hospital Association d/b/a Norwalk Hospital (“Hospital”). NRMC and the Hospital propose to acquire and operate a 1.5 Tesla High Field MRI scanner to be physically located at the NRMC facility at 148 East Avenue in Norwalk, Connecticut. The Applicants currently operate (3) MRI scanners, a high field 1.5T MRI scanner located on the Hospital’s campus, and an open MRI scanner and a high field short bore MRI scanner located at NRMC. The Hospital is the entity that will purchase the proposed MRI scanner and bill for all MRI services rendered.

The Applicant based the need of the project on the expected continued demand for growth in MRI services due to increased utilization, new applications, projected service area population growth, and the aging of the population. Specifically, the demand for breast MRI applications has increased and is projected to continue to increase for the existing referral base at NRMC and the Hospital. The existing MRI scanner located at the Hospital is an older scanner and is not capable of doing MRI breast imaging or MRI guided biopsies. Therefore, the acquisition and operation of an additional high field MRI scanner will improve both access and quality of care for patients in need of breast imaging MRI services. The Applicants have demonstrated that the existing MRI scanners at NRMC are at or exceed equipment capacity. The existing high field MRI scanner at NRMC is currently operating at 94.2%, and the open MRI scanner is operating at 105.5% scan volume capacity. The Applicants are unable to expand hours of operation of the existing scanners due to lack of availability of clinical staff and available operating days at NRMC.

The Applicants anticipate a transfer of outpatient scan volume from Norwalk Hospital to NRMC due to increased appointment availability within the system for procedures at NRMC and improved accessibility to a community based outpatient imaging center for elective outpatient imaging procedures. The Applicants state that any transfer of outpatient activity to the proposed MRI scanner would be offset by growth in inpatient and emergency department MRI scans. Based on the foregoing reasons, OHCA finds that the Applicants have provided sufficient evidence to substantiate the need for the proposed additional MRI scanner acquisition and that the proposal will improve the quality and accessibility of MRI services in the greater Norwalk area.

The associated capital expenditure with the proposal is \$2,263,399. The Applicants will finance the proposed project through available operating funds. The Hospital projects incremental gains from operations with implementation of the project of \$292,000, \$990,000 and \$1,801,000 for FYs 2008-2010. Although OHCA can not draw any conclusions, the Hospital's volume and financial projections upon which they are based appear to be reasonable.

## Order

Based upon the foregoing Findings and Rationale, the Certificate of Need application of The Norwalk Hospital Association d/b/a Norwalk Hospital and Norwalk Radiology and Mammography Center (“Applicants”) to acquire and operate an additional outpatient 1.5 Tesla High Field MRI, at a total capital expenditure of \$2,263,399, is hereby GRANTED, subject to conditions:

1. This authorization shall expire on July 20, 2008. Should the Applicants MRI scanning project not be completed by that date, the Applicants must seek further approval from OHCA to complete the project beyond that date.
2. The Applicants shall not exceed the approved total capital expenditure of \$2,263,399. In the event that the Applicants learn of potential cost increases or expects that final project costs will exceed those approved, the Applicants shall notify OHCA immediately.
3. The Applicants shall notify OHCA in writing of the initial date of the operation of the 1.5 tesla high field MRI scanner by no later than one month after the new scanner becomes operational.

Should the Applicants fail to comply with any of the aforementioned conditions, OHCA reserves the right to take additional action as authorized by law.

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

July 20, 2007

Signed by Cristine A. Vogel  
Commissioner

CAV:pf