

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

August 1, 2013

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: 12-31810-CON

Yale-New Haven Hospital

Acquisition of a 3.0 Tesla Magnetic
Resonance Imaging Scanner for the
Yale-New Haven Children's Hospital

To: Ms. Nancy Rosenthal
Senior Vice President, Health Systems Development
Department of Planning & Business Development
Yale-New Haven Hospital
2 Howe Street
New Haven, CT 06511

Dear Ms. Rosenthal:

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 August 1, 2013, 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.

A handwritten signature in black ink, appearing to read "Kimberly R. Martone", written over a horizontal line.

Kimberly R. Martone
Director of Operations

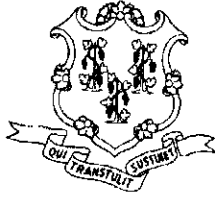
Enclosure

KRM:lkg

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Office of Health Care Access Certificate of Need Application

Final Decision

Applicant: Yale-New Haven Hospital
20 York Street, New Haven, CT 06504

Docket Number: 12-31810-CON

Project Title: Acquisition of a Dedicated 3.0 Tesla Magnetic Resonance
Imaging Scanner for the Yale-New Haven Children's Hospital

Project Description: Yale-New Haven Hospital ("Applicant" or "YNHH") is proposing the acquisition of a 3.0 Tesla Magnetic Resonance Imaging ("MRI") Scanner dedicated for use at the Yale-New Haven Children's Hospital.

Nature of Proceedings: The Applicant published notice of its intent to file the Certificate of Need ("CON") application in *The New Haven Register* on November 14, 15 and 16, 2012. On December 14, 2012, the Office of Health Care Access ("OHCA") received the CON application from the Applicant for the above-referenced project. On March 15, 2013, OHCA deemed the CON application complete.

On March 22, 2013, the Applicant was notified of the date, time and place of the hearing. On March 23, 2013, a notice to the public announcing the hearing was published in *The New Haven Register*. Thereafter, pursuant to Connecticut General Statutes ("Conn. Gen. Stat.") § 19a-639a, a public hearing regarding the CON application was held on April 10, 2013.

Commissioner Jewel Mullen designated Attorney Kevin T. Hansted as the hearing officer in this matter. The hearing was conducted as a contested case in accordance with the provisions of the Uniform Administrative Procedure Act (Chapter 54 of the General Statutes) and Conn. Gen. Stat. § 19a-639a(f). The public hearing record was closed on April 26, 2013.

Findings of Fact

1. YNHH is a not-for-profit 1,470-bed acute care general hospital located at 20 York Street, New Haven, Connecticut and a health care facility or institution as defined by Conn. Gen. Stat. § 19a-639. Ex. A, p. 273
2. YNHH is proposing the acquisition of a 3.0 Tesla Siemens Magnetom Skyra MRI Scanner, to be dedicated for use in the Children's Hospital located in the West Pavilion of its New Haven campus, with the following special features:
 - Undockable table, which in the event of an adverse reaction to anesthesia or other emergency during the scan, the staff can detach and remove the patient quickly, enhancing patient safety;
 - Short, wide bore design to reduce episodes of claustrophobia;
 - Advanced cardiac software for pediatrics which allows imaging of children with congenital cardiac disease;
 - Tim® 4G and DOT Engine Technology¹ for high resolution imaging and faster acquisition and exam time and patient personalization for the patient's condition or clinical questions, which ensures more consistent imaging on follow-up exams that monitor the progression of disease or growth of pathology;
 - Spectroscopy package to examine metabolic changes in the brain; and
 - Patient supervision package with special video camera for monitoring patients during an exam.

Ex. A, pp. 2, 75, 276; Ex. C, p. 306; Ex. I, p. 368, Prefiled Testimony of Dr. Thomas Robin Goodman, Interim Chair/Chief of Diagnostic Radiology at YNHH and the Chief of Pediatric Radiology at Yale University School of Medicine.
3. YNHH will centralize its pediatric MRI exams into a single location specifically designed for children; using dedicated staff and child life support; and with no exposure to adult patients.

Ex. A, p. 15; Ex. I, p. 368, Prefiled Testimony of Dr. Goodman.
4. YNHH proposes operating the dedicated pediatric MRI scanner 7 a.m. to 9 p.m. Monday through Friday and 7 a.m. to 5 p.m. on Saturday. Children are not scanned any later than 9 p.m. Ex. C, p. 302

¹ Total imaging matrix ("Tim®") and Day optimizing throughput ("DOT").

5. YNHH currently operates eleven (11) MRI Scanners at the following locations:

Table 1: YNHH's Existing MRI Scanners by Location

Name and Location	Location and Scanner No.	Type and Tesla Strength	Purpose
MRI Center New Haven Campus 20 York St., New Haven	MRI Center 1	Closed 3.0T	Orthopedic, large patients, brain & prostate imaging
	MRI Center 2	Closed 1.5T	Bariatric & routine imaging
	MRI Center 3	Closed 1.5T	Cardiac & liver transplant program imaging
Smilow Cancer Center New Haven Campus 20 York St., New Haven	MRI Smilow 1	Closed 3.0T	Breast imaging only
	MRI Smilow 2	Closed 3.0T	Inpatient, outpatient & emergency department
	MRI Smilow 3	Closed 1.5T	Inpatient, outpatient & emergency department
	MRI Smilow 4	Closed 3.0T	Inpatient, outpatient & emergency department
	Operating Room	Intraoperative MRI *	Operating room only
Temple Radiology Shoreline Medical Center 111 Goose La., Guilford		Closed 1.5T	Outpatient and satellite emergency department
Temple Radiology 60 Temple St. New Haven		Closed 1.5T **	Physician offices patients
North Haven Medical Center 6 Devine St. North Haven		3.0T ***	Outpatients, patients with multiple sclerosis and patients of Smilow's satellite cancer center

* 3.0 T MRI for operating room use only was authorized under CON Application 08-31289-CON.

** Until July 2012, a second scanner, a stand-up 0.6T, was also operating at this location. The scanner was replaced with a temporary mobile MRI and located in Hamden.

***The scanner became operational on March 18, 2013, replacing the mobile scanner operating in Hamden.

Ex. A, pp. 15, 16; Ex. C, pp. 294-299; Ex. L, p. 413

6. In addition to the MRI Scanners listed in Table 1, YNHH is a joint venture partner in the Saint Raphael Magnetic Resonance Center² which operates a 1.5T and a 3.0T scanner on the Saint Raphael Campus at 330 Orchard St., New Haven. The two scanners are not appropriate for pediatric use as there are no pediatric anesthesiology services on the Saint Raphael Campus. Ex. A, pp. 16,19

² YNHH submitted a CON application to OHCA on January 25, 2013, requesting authorization from OHCA to end the joint venture and become the sole owner of the Saint Raphael Magnetic Resonance Center.

7. In Fiscal Year (“FY”) 2012, 97% of inpatients discharged from YNHH originated from Connecticut.³ Three-quarters of these inpatient discharges were from the following Connecticut towns: New Haven, West Haven, Hamden, East Haven, Branford, Bridgeport, Milford, North Haven, Guilford, Wallingford, Madison, North Branford, Waterbury, Meriden, Cheshire, Groton, Stratford, Clinton, Shelton, and Orange (“Service Area”).
CT DPH, Office of Health Care Access Acute Care Discharge Database

8. A dedicated MRI Scanner for the Children’s Hospital will enable pediatric MRI service centralization; create a pediatric friendly environment; and increase the efficiency of staff since:
 - a. MRI is the preferred imaging modality for children because it does not involve exposure to radiation;
 - b. Pediatric patients are currently served on various MRI Scanners located in multiple buildings designed for and primarily serving adult inpatients, outpatients, emergency department and trauma patients, exposing the children to a variety of ill adults and potentially increasing their anxiety about the procedure;
 - c. It will eliminate having to continuously move specialized pediatric staff to the different MRI locations to provide sedation and anesthesia for children that need it to receive their scans.Ex. A, pp. 4-6; Ex. C. pp. 302-306

9. The current MRI procedure requires that children receiving an MRI scan be:
 - Transported to an adult area away from other pediatric services;
 - Exposed to ill adults, including oncology, trauma and surgical patients; and
 - Required to use physical facilities that do not offer any child-sized furniture or equipment or child-oriented décor which help to reduce fear and anxiety.Ex. A, pp. 20, 22

10. Dr. Thomas Robert Goodman, Interim Chair/Chief of Diagnostic Radiology at YNHH and the Chief of Pediatric Radiology at Yale University School of Medicine, testified that “The majority of pediatric MRI scans are performed on the MRI Scanners in the Smilow Cancer Hospital.” Ex. A, p. 18; Ex. I, pp. 367-368, Prefiled Testimony of Dr. Goodman

11. The proposed MRI Scanner, to be operated in a child-friendly and clinically appropriate environment, will:
 - Accommodate the growth of MRI scanning as a preferred imaging modality for children;
 - Improve the delivery of pediatric MRI services; and
 - “provide a much improved environment for pediatric patients undergoing an MRI exam.”Ex. A, pp. 14, 16; Ex. I, p. 368, Prefiled Testimony of Dr. Goodman

³ The remaining 3% were from other states and countries.

12. Pediatric MRI scanning at YNHH grew 24% between 2009 and 2012. The following table reports the actual volumes by fiscal year and type of patient.

Table 2: Actual Pediatric MRI Scan Volume by Fiscal Year and Type

Type	2009	2010	2011	2012
Inpatient	760	1,034	939	1,077
Outpatient	2,937	3,246	3,388	3,370
Emergency	47	57	130	194
Total	3,744	4,337	4,457	4,641
Year to Year Increase	-	15.8%	2.8%	4.1%
Increase from 2009-2012				24%

Ex. A, p. 26

13. MRI scans are increasingly being preferred over computed tomography as an imaging modality for children since they do not involve exposure to radiation. In addressing the increased risks to children, Dr. Goodman stated, "Specifically, their bodies and tissues are more sensitive and too much radiation can increase the risk of developing a radiation-related cancer." Ex. A, pp. 14, 48; Ex. I, p. 368, Prefiled Testimony of Dr. Goodman
14. Recent developments in MRI technology, such as specialized pediatric coils and monitors, rapid pulse sequences, functional and metabolic imaging and novel contrast agents have led to an increase in MRI scanning of the body, brain, spine and bones. MRI is used by YNHH to assess pediatric heart function, metastatic screening, multifocal osteomyelitis, avascular necrosis and vascular anomalies. MRI also precludes expensive invasive procedures in pediatric patients, such as liver biopsies. Ex. I, pp. 370, 371, Prefiled Testimony of Dr. Goodman
15. YNHH's Y Access Transfer Line, which coordinates the transfer and admission of acutely ill patients to the hospital from referring physicians, is leading to significant increases in the number of acutely ill children transferred to the children's hospital, driving up the demand for pediatric MRI services, particularly those requiring anesthesia. Pediatric MRI transfers from non-YNHH physicians grew from 431 in FY 2010 to 1,018 in FY 2012, a 136 % increase. Ex. A, pp. 7-8; Ex. C, p. 307
16. Many children receiving an MRI scan frequently require sedation or general anesthesia since it is difficult for them to remain still during an hour-long scan. Therefore, pediatric MRI scans must be performed where pediatric anesthesia and sedation services can be provided. The percentage of children requiring anesthesia or sedation grew from 9% to 28% of annual pediatric MRI scan volumes between FY 2009 and FY 2012. Ex. A, pp. 14, 15; Ex. C. p. 409
17. Pediatric MRI scans that require anesthesia or sedation must have a pediatric anesthesiologist or nurse anesthetist present. "The Smilow Cancer Hospital is currently the only area where anesthesia or sedation services can be safely administered for pediatric patients." Ex. I, p. 369, Prefiled Testimony of Dr. Goodman

18. According to YNHH, none of the providers in its Service Area provide pediatric anesthesiology and pediatric MRI services. Ex. A, p. 25
19. As there are a limited number of facilities in the state that provide pediatric anesthesiology and MRI services, most pediatric MRI cases are referred to YNHH and Connecticut Children's Medical Center. Referral patterns are not expected to change as a result of the acquisition of the proposed MRI Scanner. Ex. A, p. 17
20. The proposed MRI Scanner, scan room and support spaces will facilitate the administration of sedation or anesthesia, reduce patient anxiety and improve the throughput of pediatric MRI patients. "Centralizing efforts into one area has added advantages, as well, in that [YNHH] is able to perform sedation and anesthesia far more easily and, therefore reduce the waiting time for children to have these types of examination." Ex. A, p. 33, Tr. Testimony of Dr. Goodman, p.7
21. Dr. Goodman testified that:
- A children's hospital without a pediatric MRI scanner is extremely unusual;
 - MRI is a vital component for pediatric imaging with an ever-growing list of indications for pediatric MRI use, including bowel pediatric enterography, urography, and cardiac work;
 - Children are susceptible to the carcinogenic effects of ionizing radiation that can damage a child's cells;
 - A dedicated pediatric MRI environment includes staff trained to deal with children, including nurses, child life specialists, pediatric anesthesiologists, and the pediatric radiologists;
 - Provision of pediatric MRI services on a dedicated scanner becomes easier for sedation and anesthesia cases and reduces the waiting time for children in general; and
 - Moving children out of adult scanners into a dedicated pediatric scanner provides space for other adult indications for MRI.
- Tr. Testimony of Dr. Goodman, pp.6-8
22. YNHH expects to initiate the use of the pediatric MRI Scanner at the start of FY 2014. The projected utilization of the pediatric MRI Scanner for inpatients and outpatients is reported in the following table, and reflects a projected 1% annual increase.

Table 3: Projected Utilization of the Proposed Pediatric MRI Scanner

	FY 2014	FY 2015	FY 2016
Projected Pediatric MRI Scans	4,261	4,304	4,346

Ex. A, pp. 18, 31; Ex. C, p. 313

23. YNHH assumes that 10% of the pediatric volume, mostly older children who do not require sedation, will receive their MRI scans on one of the scanners at the MRI Center. Ex. A, p 26; Ex. C, pp. 294, 296, 297
24. The total estimated capital expenditure for the acquisition of the MRI Scanner is \$5,875,828, including the imaging equipment purchase for \$2,392,690 and \$3,483,138 for

the required construction and renovations. YNHH will finance the project with operating funds (20%) and funded depreciation (80%). Ex. A, pp. 20-21

25. YNHH projects the following incremental gain from operations for the project:

Table 4: YNHH Incremental Gain from Operations Description

	FY 2014	FY 2015	FY 2016
Incremental Revenue from Operations	\$3,655,000	\$3,803,000	\$3,956,000
Incremental Operating Expense*	1,627,000	2,021,000	2,060,000
Incremental Gain from Operations	\$2,028,000	\$1,782,000	\$1,896,000

* Includes salaries, fringe benefits, professional and contracted services, supplies and drugs and depreciation.
Ex. A, p. 285

26. The minimum number of MRI scans required to show an incremental gain from operations for each of the next three fiscal years is between 803 and 969 scans.

Table 5: YNHH Minimum Number Required to Show Incremental Gain

Description	FY 2014	FY 2015	FY 2017
Total Incremental Operating Expenses	\$1,627,123	\$2,020,902	\$2,060,199
Average Revenue per Scan	\$2,025	\$2,086	\$2,149
Scans Needed to Show Incremental Gain from Operations	803	969	959

Ex. A, p. 33

27. YNHH expects the payer mix with the proposal to remain constant at FY 2013 distribution since the project will serve YNHH's existing patient population which is 36% government and 64% non-government:

Table 6: Current and Projected Patient Population Payer Mix

Primary Payer	Current FY 2013	Year 1 FY 2014	Year 2 FY 2015	Year 3 FY 2016
Medicare	0%	0%	0%	0%
Medicaid	35%	35%	35%	35%
CHAMPUS/TriCare	1%	1%	1%	1%
Total Government	36%	36%	36%	36%
Commercial	61%	61%	61%	61%
Uninsured	2%	2%	2%	2%
Workers Compensation	0%	0%	0%	0%
Total Non-Government	64%	64%	64%	64%
Total Payer Mix	100%	100%	100%	100%

Ex. A, pp. 21-22.

28. 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))
29. This CON application is consistent with the overall goals of the Statewide Health Care Facilities and Services Plan. (Conn. Gen. Stat. § 19a-639(a)(2))
30. YNHH has established that there is a clear public need for its proposal. (Conn. Gen. Stat. § 19a-639(a)(3))
31. YNHH has satisfactorily demonstrated that its proposal is financially feasible. (Conn. Gen. Stat. § 19a-639(a)(4))
32. YNHH has satisfactorily demonstrated that its proposal would improve the accessibility of health care delivery in the region and it has satisfactorily demonstrated a potential improvement in quality and cost effectiveness. (Conn. Gen. Stat. § 19a-639(a)(5))
33. YNHH has shown that there would be no change to the provision of health care services to the relevant populations and payer mix. (Conn. Gen. Stat. § 19a-639(a)(6))
34. YNHH has satisfactorily identified the population to be served by its proposal and has satisfactorily demonstrated that this population has a need as proposed. (Conn. Gen. Stat. § 19a-639(a)(7))
35. YNHH's historical MRI scanner utilization in the service area supports this proposal. (Conn. Gen. Stat. § 19a-639(a)(8))
36. YNHH has satisfactorily demonstrated that its proposal would not result in an unnecessary duplication of existing MRI scanning 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 § 19a-639(a) of the Statutes. 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).

Yale New Haven Hospital (“YNHH” or “Applicant”) is a not-for-profit 1,470-bed acute care general hospital located at 20 York Street, New Haven, Connecticut. Finding of Fact (“FF”) 1 YNHH is proposing the acquisition of a 3.0 Tesla Magnetic Resonance (“MRI”) Scanner to be dedicated for use in the Children’s Hospital located in the West Pavilion of its New Haven campus. YNHH will centralize its pediatric MRI exams into the single location specifically designed for children; using dedicated staff and child life support; ensuring pediatric patients have no exposure to adult patients. The proposed MRI Scanner will be designed for the safety of the children; include an undockable table; a short, wide bore design to reduce episodes of claustrophobia; and patient supervision package to monitor patients during scanning. The proposed MRI Scanner will also have advanced cardiac software; spectroscopy package; and technology for patient personalization. *FF 2&3.*

YNHH currently operates eleven MRI Scanners. On the main campus in New Haven there are three scanners in the MRI Center and five in the Smilow Cancer Center, including an intraoperative MRI Scanner that is used solely for patients having surgery. The Shoreline Medical Center in Guilford, Temple Radiology in New Haven, and the North Haven Medical Center each has one scanner. *FF 5.* There are two additional scanners on YNHH’s Saint Raphael campus that are not appropriate for pediatric use since there are no pediatric anesthesiology services available. *FF 6.*

MRI scans are increasingly being preferred over computed tomography as an imaging modality for children, as children are susceptible to the carcinogenic effects of ionizing radiation that can damage a child’s cells. *FF 13.* Moreover, there is an ever-growing list of indications for pediatric MRI use, including bowel pediatric enterography, urography, and cardiac work. *FF 14&21.* Additionally, the number of acutely ill pediatric patients transferred and admitted to YNHH through its Y Access Transfer Line is driving up the demand for pediatric MRI services. *FF 15.* Between 2009 and 2012, YNHH’s volume of pediatric MRI scans has grown 24%. *FF 12.*

As many as 28% of the children receiving MRI scans require sedation or general anesthesia since it is difficult for them to remain still during an hour-long scan. Currently, the Smilow Cancer Hospital is the only area where anesthesia or sedation services can be safely administered to pediatric patients, but transporting them to Smilow exposes them to oncology, trauma and surgical patients, which may induce fear and anxiety. A dedicated pediatric MRI Scanner in the children’s hospital will eliminate the need to move specialized pediatric staff to different MRI locations to administer sedation and anesthesia to children. *FF 8, 10, 16, 17 & 20.*

Based on the anticipated increase in the use of pediatric MRI scans; the proposed MRI Scanner's advanced imaging capabilities; and the unique environment in which the proposed MRI Scanner will be located, OHCA concludes that YNHH has demonstrated a clear public need for its proposal. Additionally, none of the other MRI scan providers in YNHH's Service Area provide pediatric anesthesiology and pediatric MRI services. *FF 18*. Therefore, OHCA concludes that there will not be an unnecessary duplication of existing MRI scanning services.

The total estimated capital expenditure for the acquisition of the proposed MRI Scanner and the construction and renovations needed to accommodate the MRI Scanner is \$5,875,828, to be financed through YNHH's funded depreciation and operating funds. *FF 24*. YNHH projects incremental gains from operations associated with the proposal for the first three full fiscal years of operation. *FF 25*. Therefore, OHCA concludes that the proposal is financially feasible.

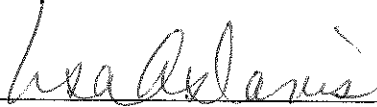
Order

Based upon the foregoing Findings of Fact and Discussion, the Certificate of Need application of Yale-New Haven Hospital for the acquisition of a 3.0 Tesla Magnetic Resonance Imaging Scanner to be located at 20 York St., New Haven, Connecticut, and dedicated to pediatrics, is hereby **APPROVED**.

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

Date

8/1/13


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